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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to _____
Commission file number: 001-38079

UROGEN PHARMA LTD.

(Exact name of registrant as specified in its charter)

Israel	**98-1460746**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
400 Alexander Park, Princeton, NJ	**08540**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code:
(646) 768-9780
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Ordinary Shares, par value NIS 0.01 per share	URGN	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☑	Smaller reporting company	☑
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the ordinary shares held by non-affiliates of the registrant as of June 30, 2023 totaled approximately $190.4 million based on the closing price for the registrant's ordinary shares on that day as reported by the Nasdaq Stock Market LLC. Such value excludes ordinary shares held by executive officers, directors and certain entities affiliated with directors as of June 30, 2023.

As of March 7, 2024, there were 34,122,087 of the registrant's ordinary shares outstanding.

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PART I

INTRODUCTION

Unless otherwise indicated, “UroGen Pharma,” "UroGen," “the Company,” “our Company,” “we,” “us” and “our” refer to UroGen Pharma Ltd. and its subsidiary, UroGen Pharma, Inc.

UroGen *RTGel* and *Jelmyto* are trademarks of ours that we use in this Annual Report on Form 10-K (this "Annual Report"). This Annual Report also includes trademarks, tradenames, and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this Annual Report appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to our trademark and tradenames. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We maintain our books and records in U.S. dollars, and prepare our financial statements in accordance with accounting principles generally accepted in the United States ("GAAP"), as issued by the Financial Accounting Standards Board.

The terms “shekel,” “Israeli shekel” and “NIS” refer to New Israeli Shekels, the lawful currency of the State of Israel, and the terms “dollar,” “U.S. dollar” or “$” refer to United States dollars, the lawful currency of the United States. All references to “shares” in this Annual Report refer to ordinary shares of UroGen Pharma Ltd., par value NIS 0.01 per share.

We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the “safe harbor” created by those sections. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part I, Item 1A, “Risk Factors” in this Annual Report.

We may, in some cases, use words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements and are based upon our current expectations, beliefs, estimates and projections, and various assumptions, many of which, by their nature, are inherently uncertain and beyond our control. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the timing and conduct of our clinical trials of UGN-102 and our other product candidates, including statements regarding the timing, progress and results of current and future nonclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of UGN-102 and our other product candidates;
- our expectations regarding timing for application for and receipt of a regulatory review decision for any of our product candidates;
- our ongoing and planned development of product candidates including UGN-103, UGN-104, UGN-201 and UGN-301, and our discovery of new product candidates;
- our expectations regarding future growth, including our ability to develop, and obtain regulatory approval for, new product candidates;

- our ability to obtain additional financing to support our operations;
- our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
- our ability to maintain our existing collaboration and licensing arrangements and enter into and maintain other collaborations, licensing arrangements or in-license or acquire rights to other products, product candidates or technologies;
- our plans to develop and commercialize our in-line and investigational product candidates;
- our estimates regarding the commercial potential and market opportunity for our product pipeline and investigational products;
- our estimates regarding expenses, future revenues, capital requirements and the need for additional financing;
- the impact of our research and development expenses as we continue developing investigational product candidates;
- the future nonclinical and clinical development of licensed products, including UGN-103, UGN-104, UGN-201 and UGN-301, and their commercial opportunity; and
- the impact of government laws and regulations.

We caution you that the risks, uncertainties and other factors referenced above may not contain all of the risks, uncertainties and other factors that are important to you. In addition, we cannot guarantee future results, level of activity, performance or achievements. You should refer to the section of this Annual Report under Part I, Item 1A, “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

If our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. Any forward-looking statement made by us in this Annual Report speaks only as of the date of this Annual Report or as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This Annual Report may contain market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this Annual Report is generally reliable, such information is inherently imprecise.

RISK FACTOR SUMMARY

Below is a summary of the material factors that make an investment in our ordinary shares speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors," and should be carefully considered, together with other information in this Annual Report and our other filings with the U.S. Securities and Exchange Commission ("SEC") before making investment decisions regarding our ordinary shares.

- We will require additional financing to fund our operations and achieve our goals, and a failure to obtain this capital when needed and on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.
- We are highly dependent on the successful commercialization of our only approved product, *Jelmyto*.
- We have limited experience as an organization in marketing and distributing products and are therefore subject to certain risks in relation to the commercialization of *Jelmyto* and any of our product candidates that receive regulatory approval.
- The market opportunities for *Jelmyto* and our product candidates may be smaller than we anticipate or limited to those patients who are ineligible for established therapies or for whom prior therapies have failed and may be small.
- *Jelmyto* and any of our product candidates that receive regulatory approval may fail to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success.
- *Jelmyto* and our product candidates, if approved, will face significant competition with competing technologies and our failure to compete effectively may prevent us from achieving significant market penetration.
- In addition to *Jelmyto*, we are dependent on the success of our lead product candidate, UGN-102, and our other product candidates, including obtaining regulatory approval to market our product candidates in the United States.
- UGN-102 may not meet its secondary endpoint in the ongoing Phase 3 ENVISION trial.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.
- We have entered into collaboration and licensing agreements and in the future may enter into collaboration and licensing arrangements with other third parties for the development or commercialization of our product candidates. If our collaboration and licensing arrangements are not successful, we may not be able to capitalize on the market potential of these product candidates.
- We currently contract with third-party subcontractors and single-source suppliers for certain raw materials, compounds and components necessary to produce *Jelmyto* for commercial use, and to produce UGN-102, UGN-103, UGN-104, UGN-201, and UGN-301 for nonclinical studies and clinical trials, and expect to continue to do so to support commercial scale production of UGN-102, UGN-103, UGN-104 and UGN-201, if approved, as well as UGN-301 if approved as a monotherapy or for any approved product that includes UGN-301. There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers, including single-source suppliers. Furthermore, our existing third-party subcontractors and single-source suppliers may not be able to meet the increased need for certain raw materials, compounds and components that may result from our commercialization efforts. This increases the risk that we will not have sufficient quantities of *Jelmyto*, UGN-102, UGN-103, UGN-104, UGN-201 or UGN-301 or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any of our other products we develop.
- If we fail to attract and keep senior management and key personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize any of the products we develop.
- We have a limited operating history and have incurred significant losses and negative cash flows since our inception, and we anticipate that we will continue to incur significant losses and negative cash flows for the foreseeable future, which makes it difficult to assess our future viability.
- Our indebtedness resulting from our Loan Agreement could adversely affect our financial condition or restrict our future operations.
- If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our product candidates and technologies are not adequate, we may not be able to compete effectively, and we otherwise may be harmed.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights or the patents of our licensors, which could be expensive and time consuming.
- If the FDA does not conclude that UGN-102 satisfies the requirements under 505(b)(2), or if the requirements for our product candidates are not as we expect, the approval pathway for these product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.
- We expect current and future legislation affecting the healthcare industry, including healthcare reform, to impact our business generally and to increase limitations on reimbursement, rebates and other payments, which could adversely affect third-party coverage of our products, our operations, and/or how much or under what circumstances healthcare providers will prescribe or administer our products, if approved.
- *Jelmyto* and any of our product candidates that receive regulatory approval will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses, limit or withdraw regulatory approval and subject us to penalties if we fail to comply with applicable regulatory requirements.
- It may be difficult for us to profitably sell our product candidates if coverage and reimbursement for these products is limited by government authorities and/or third-party payor policies.
- Our research and development and other significant operations are located in Israel and, therefore, our results may be adversely affected by

political, economic and military instability in Israel.

Item 1. Business

Overview

We are a biotechnology company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers. We have developed *RTGel*® reverse-thermal hydrogel, a proprietary sustained release, hydrogel-based technology that has the potential to improve therapeutic profiles of existing drugs. Our technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. Our approved product *Jelmyto*® (mitomycin) for pyelocalyceal solution, and our investigational candidate, UGN-102 (mitomycin) for intravesical solution, are designed to ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer ("low-grade UTUC") and low-grade intermediate risk non-muscle invasive bladder cancer ("low-grade intermediate risk NMIBC"), respectively. In addition, our immuno-uro-oncology pipeline includes UGN-301 (zalifrelimab), an anti-CTLA-4 antibody, which we intend to study as both monotherapy and combination therapy.

***RTGel*: Our Reverse Thermal Hydrogel Technology**

RTGel is a novel proprietary polymeric biocompatible, reverse thermal gelation hydrogel technology, which, unlike the general characteristics of most forms of matter, is liquid at lower temperatures and converts into gel form when warmed to body temperature. We believe that these characteristics promote ease of delivery into and retention of drugs in body cavities, including the bladder and the upper urinary tract, forming a transient reservoir of drug that dissolves over time while preventing rapid excretion, providing for increased dwell time. *RTGel* leverages the physiologic flow of urine to provide a natural exit from the body.

RTGel's components are polymer-based and are inactive ingredients that are used in U.S. Food and Drug Administration ("FDA") approved *Jelmyto*. We formulate *RTGel* with an active drug: mitomycin in the case of *Jelmyto* and UGN-102. The resulting formulations are instilled intravesically in liquid form directly into the upper urinary tract or bladder using standard instillation methodologies via catheters or nephrostomy tube, and thereafter convert into gel form at body temperature. Subsequently, upon contact with urine, *RTGel* gradually dissolves and releases the active drug over a period of several hours and is less affected by urine creation and voiding cycles as compared to water formulations.

We believe that *RTGel*, when formulated with an active drug, may allow for the improved efficacy of treatment of various types of urothelial and specialty cancers and urologic diseases without compromising the safety of the patient or interfering with the natural flow of fluids in the urinary tract. *RTGel* achieves this by:

- increasing the exposure of active drugs in the bladder and upper urinary tract by significantly extending the dwell time of the active drug while conforming to the anatomy of the bladder and the upper urinary tract, which allows for enhanced drug tissue coverage. For example, the average dwell time of the standard aqueous mitomycin formulation, currently used as adjuvant treatment, in the upper urinary tract is approximately five minutes, compared to approximately six hours when mitomycin is formulated with *RTGel*;
- administering higher doses of an active drug than would otherwise be possible using standard water-based formulations. For instance, it is only possible to dissolve 0.5 mg of mitomycin in 1 mL of water while it is possible to formulate up to 8 mg of mitomycin with 1 mL of *RTGel*; and
- maintaining the active drug's molecular structure and mode of action.

These characteristics of *RTGel* enable sustained release of mitomycin in the urinary tract for both *Jelmyto* and UGN-102. Further, *RTGel* may be particularly effective in the bladder and upper urinary tract where tumor visibility and access are challenging, and where there exists a significant amount of urine flow and voiding. We believe that these characteristics of *RTGel* may prove useful for the local delivery of active drugs to other bodily cavities in addition to the bladder and upper urinary tract.

Mitomycin—Our Target Active Drug for the Treatment of Low-Grade UTUC and Low-Grade Intermediate Risk NMIBC

Mitomycin is a generic drug currently utilized off-label as an adjuvant chemotherapy for the treatment of low-grade NMIBC after trans-urethral resection of bladder tumor ("TURBT"). Off-label means that while the FDA has not approved mitomycin as adjuvant treatment in the post-TURBT setting for low-grade intermediate risk NMIBC patients, physicians are permitted to utilize it as standard of care for this indication as part of medical practice. Mitomycin is administered using a water-based solution, which has a relatively short dwell time in the bladder limited to first voiding. Mitomycin often causes temporary irritation of the urinary tract, including the need to urinate frequently and urgently. In the upper urinary tract, the dwell time of aqueous mitomycin is limited to approximately five minutes as urine flows continuously and no active retention by the patient is feasible. Numerous *in vitro* models, *in vivo* studies and computer simulations have shown that increased dwell time of mitomycin in the bladder results in increased time to recurrence of urothelial cancer. In one such study, it was shown that mitomycin activity increased with exposure time. Specifically, the MIC90, or mean inhibitory concentration that causes 90% inhibition in cell growth, was 11-fold lower when exposure time was increased from 30 minutes to eight hours.

Mitomycin's mechanism of action is on the cancer cell's DNA and has been demonstrated to be most effective when the cancer cell is in its S-phase, or synthesis phase, during which the DNA is replicated. Each cancer cell goes through various phases during the cell cycle. However, the cell cycle is not synchronized in all cancer cells, which means that at any given point in time only a portion of the cancer cells are at their S-phase, or susceptible to the instilled mitomycin in the bladder. Increased dwell time, facilitated by our *RTGel* preparations *Jelmyto* and UGN-102, is designed to increase cell killing in vitro when compared to aqueous solutions of mitomycin.

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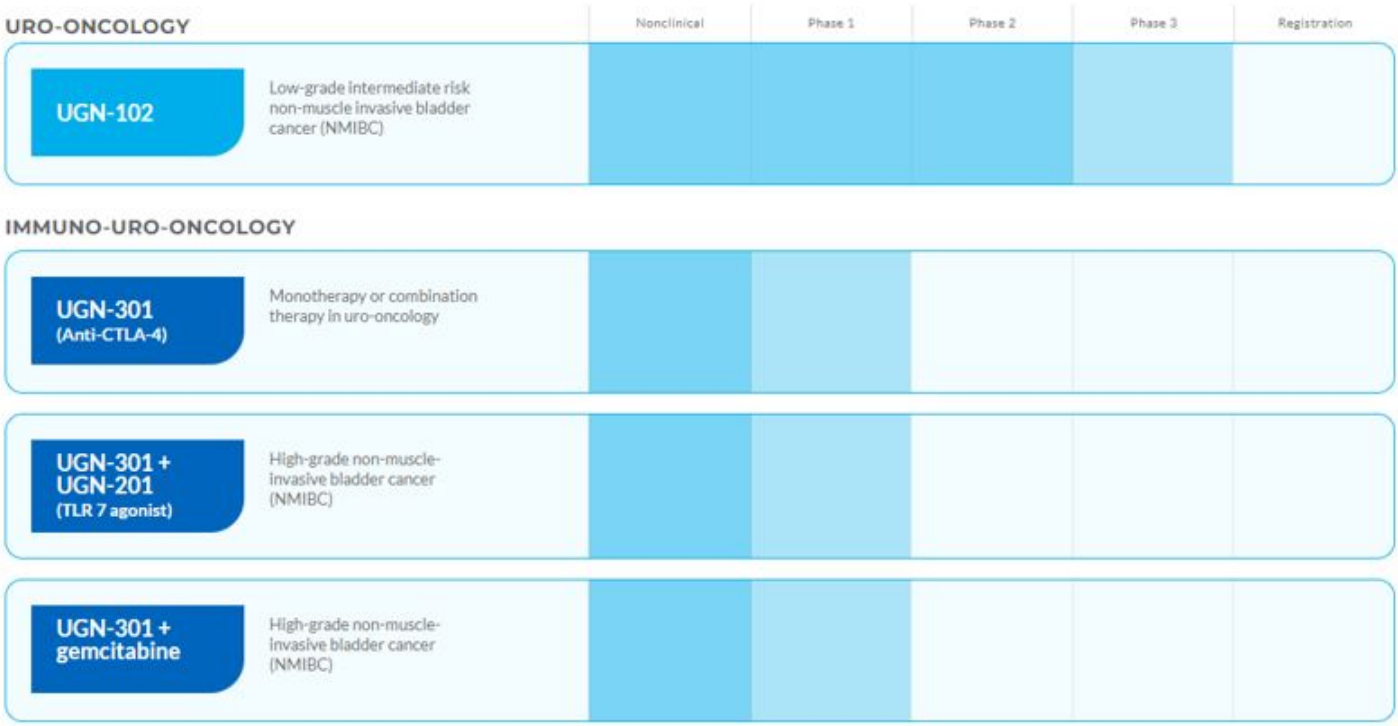
Our Pipeline

The following chart summarizes the current status of our pipeline:



Jelmyto

Jelmyto is our novel sustained-release *RTGel*-based formulation of mitomycin that we have developed for the treatment of low-grade UTUC. *RTGel* is liquid at lower temperatures and converts into gel form at body temperature. This temperature-dependent viscosity characteristic allows for instillation of the chilled *Jelmyto* in its liquid form to the upper urinary tract via standard urinary procedures utilizing a catheter or nephrostomy tube. Once instilled, *Jelmyto* converts into gel form at body temperature. Subsequently, upon contact with urine, *Jelmyto* gradually dissolves and releases the active drug, mitomycin, over a period of several hours versus several minutes for mitomycin in its water-based formulation. We believe that this substantial increase in dwell time of mitomycin positions *Jelmyto* as a chemoablation treatment for low-grade UTUC, potentially sparing patients from repeated tumor resection procedures and potentially reducing the need for upper urinary tract surgeries, including kidney removal.

Upper Tract Urothelial Carcinoma ("UTUC")

UTUC refers to malignant changes of the urothelium (the epithelial lining) of the upper urinary tract of the calyces, renal pelvis and ureter. Low-grade UTUC managed with endoscopic resection typically exhibits a high rate of local recurrence. High-grade UTUC is associated with renal parenchymal invasion and the development of metastases. UTUC accounts for approximately 5% to 10% of all new cases of urothelial cancer, which together with recurrent cases, results in an estimated annual incidence in the United States of up to 7,000 cases. UTUC is nearly three times more common in men than women and is typically diagnosed in patients in their 60s and 70s. Tumor grade is the key prognostic factor at the time of diagnosis of UTUC and is assigned based upon microscopic examination of tumor tissue. Approximately 40% of the patients diagnosed annually with UTUC in the United States have low-grade UTUC.

Limitations of Other Treatments for Low-Grade Upper Tract Urothelial Carcinoma

Before the approval of *Jelmyto* in April 2020, there were no drugs approved by the FDA for the treatment of low-grade UTUC, representing a significant unmet medical need. The current standard of care for the treatment of low-grade UTUC is radical nephroureterectomy ("RNU"), which is complete kidney and upper urinary tract removal. Recent advances in resection instrument technology have allowed physicians to treat patients with low-grade UTUC using endoscopic tumor resection, a kidney-sparing treatment, rather than nephroureterectomy followed by adjuvant chemotherapy, typically mitomycin, treatment. However, the specific anatomy and physiology of the upper urinary tract make the performance of organ-sparing endoscopic tumor resection and instillation of adjuvant chemotherapy challenging, leading to high recurrence rates. Patients often undergo multiple endoscopic resection procedures, which increases the probability of potential complications of resection, including perforation and ureteral stricture, or a narrowing of the ureter. Endoscopic tumor resection, which aims to be a kidney sparing surgical procedure, is conducted only in patients with low-grade disease and with limited tumor burden (unifocal tumor, low grade histology, less than 2 cm in greatest dimension). Ultimately, 70% to 80% of patients with low-grade UTUC undergo an RNU. Treatment is further complicated by the fact that low-grade UTUC is most commonly diagnosed in patients over 70 years of age, who may already have compromised kidney function and other comorbidities such as cardiovascular disease, diabetes and pulmonary disease and may suffer further complications as a result of a major surgery.

Our Solution: Jelmyto (mitomycin) for pyelocalyceal solution

On April 15, 2020, the FDA approved our new drug application (“NDA”) for *Jelmyto* (mitomycin) for pyelocalyceal solution, formerly known as UGN-101, for the treatment of adult patients with low-grade UTUC. *Jelmyto* consists of mitomycin, an established chemotherapy, and sterile hydrogel, using our proprietary sustained release *RTGel* technology. It has been designed to prolong exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. New product exclusivity for *Jelmyto* expired on April 15, 2023; however, Orphan Drug exclusivity extends until April 15, 2027. Additionally, the main patents that protect *Jelmyto* in the United States are set to expire in January 2031. These patents were listed in the FDA's Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

The FDA evaluated the *Jelmyto* NDA under Priority Review, which is reserved for medicines that may represent significant improvements in safety or efficacy in treating serious conditions. *Jelmyto* was also granted Breakthrough Therapy Designation by the FDA, which was created to expedite the development and review of drugs developed for serious or life-threatening conditions with high unmet need.

The FDA approval was based on results from our Phase 3 OLYMPUS trial showing *Jelmyto* achieved clinically significant disease eradication in adults with low-grade UTUC. Findings from the final study results include:

- Complete response ("CR") (primary endpoint) of 58% (41/71) in the intent-to-treat population and in the sub-population of patients who were deemed not capable of surgical removal at diagnosis.
- At the 12-month time point for assessment of durability, 23 patients remained in CR of a total of 41 patients, eight had experienced recurrence of disease and 10 patients were unable to be evaluated.
- Durability of response was estimated to be 81.8% at 12 months by Kaplan-Meier analysis. The median duration of response was not reached.
- The most commonly reported adverse events (≥ 20%) were ureteric obstruction, flank pain, urinary tract infection, hematuria, abdominal pain, fatigue, renal dysfunction, nausea, dysuria and vomiting. Most adverse events were mild to moderate and manageable. No treatment-related deaths occurred.

In December 2022, we presented new data from a follow up study to the OLYMPUS trial designed to obtain long-term data on *Jelmyto*. Based on data available for 16 of the 23 patients who had remained in CR at the end of the OLYMPUS study, the median duration of response in that subset of patients was 28.9 months. Thirteen patients remained in CR, two patients had recurrence of low grade-UTUC on the same side as treated in OLYMPUS, and one patient underwent RNU due to ureteral stricture without evidence of UTUC at the time of surgery. No patient had progressed to high-grade disease.

In June 2020, we initiated our commercial launch of *Jelmyto* in the United States. We have staffed, trained and prepared a customer-facing team that includes territory business managers with deep experience in both urology and oncology. These territory business manager positions are led by seven regional business director positions, who are in turn supported by seven regional operations manager positions. Each region is additionally supported by one to two clinical nurse educators to provide education and training around instillation, as well as a field reimbursement manager to help ensure access and reimbursement for appropriate patients and key account directors who engage with C-suite individuals to introduce a *Jelmyto* service line. In addition, our organization currently includes several medical science liaisons who appropriately engage with physicians interested in learning more about UroGen, *Jelmyto* and our technology, both in person and virtually. In total, our customer-facing team comprises approximately 80 representatives.

We are committed to helping patients access *Jelmyto*. Our market access teams have laid the foundation for coverage and reimbursement, meeting multiple times with payors. Medicare patients with supplemental coverage are covered and the vast majority of commercial plans have policies in place, in whole covering over 150 million lives. In addition to reimbursement and access, we have also been focused on ensuring seamless integration into physician practices. We have implemented processes to help make *Jelmyto* preparation and administration seamless for practitioners and patients, including entering into agreements with various national, regional and local specialty pharmacies under which the pharmacy, following receipt of a patient prescription, prepares and dispenses the *Jelmyto* admixture on our behalf. In September 2022, the FDA authorized an extension of the in-use period for the *Jelmyto* admixture from eight hours to 96 hours (four days) following reconstitution of the product, adding convenience and flexibility in managing patient care.

In October 2020, a Medicare C-Code was issued for *Jelmyto*. The Centers for Medicare & Medicaid Services ("CMS") established a permanent and product-specific J-code for *Jelmyto* that took effect on January 1, 2021 and replaced the C-Code. CMS has granted *Jelmyto* a New Technology APC (Ambulatory Payment Classification), effective from October 1, 2023. We have also launched a registry to capture data and evaluate real world outcomes in patients with low-grade UTUC that have been or will be treated with *Jelmyto*. The purpose of the registry is to study the use of *Jelmyto* in clinical practice in the United States and address specific clinical questions.

Uro-Oncological Indications Targeted by Our Product Candidates

UGN-102 (mitomycin) for intravesical solution

UGN-102 is our sustained-release formulation of mitomycin that we are developing for the treatment of low-grade intermediate risk NMIBC. It is administered locally using standard urinary procedures utilizing a catheter inserted into the bladder, and is designed to persist in the bladder despite urine flow and bladder movement. Once instilled, UGN-102 converts into a semisolid gel form at body temperature. Subsequently, upon contact with urine, UGN-102 gradually dissolves and releases the active drug, mitomycin, over a period of several hours. In contrast, mitomycin in its current water-based formulation, is released at the time of first voiding, which is often less than an hour. We believe that the resulting significantly increased dwell time of mitomycin in the bladder prolongs exposure of mitomycin to the tumor tissue and therefore has the potential to chemoablate both visible and undetectable tumors. With regard to UGN-102, we own three issued U.S. patents and two issued patents in Europe. These issued patents are expected to expire in 2031. Medac has intellectual property protection for its proprietary mitomycin formulation technology expected through June 2035.
We also own three pending U.S. applications and any patents that issue from these applications is expected to expire between 2031 and 2043.

Bladder Cancer

The bladder is a hollow organ in the pelvis with flexible muscular walls. Its main function is to store urine before it leaves the body. Urine is produced by the kidneys and is then carried to the bladder through the upper urinary tract tubes, called ureters. The bladder wall has four main layers. The innermost lining is comprised of cells called urothelial or transitional cells, and this inner layer is called the urothelium or transitional epithelium. Beneath the urothelium, there is a layer called the lamina propria. Next is a thick layer of muscle called the muscularis propria followed by a layer of perivesical fat.

Bladder cancer accounts for approximately 90% to 95% of all new cases of urothelial cancer in the United States (estimated new cases in 2023 of 82,290). Bladder cancer is nearly three to four times more common in men than women, and, is most commonly diagnosed in their 70s. Bladder cancers are described as non-muscle invasive or muscle-invasive based on how far into the wall of the bladder they have invaded. Non-muscle invasive bladder cancer ("NMIBC") can then be characterized as low, intermediate, or high risk and can also be characterized as low- or high-grade. Patients with low-grade intermediate risk NMIBC have frequent recurrences of disease that can be difficult to control using contemporary standards of care.

Low Grade Intermediate Risk ***Non-Muscle Invasive Bladder Cancer***

NMIBC can be characterized as low, intermediate, or high risk, which is determined based on tumor grade and stage. Tumors are graded as low or high (approximately 70% of NMIBC patients have a tumor that is classified as low-grade). Low-grade intermediate risk NMIBC is defined as having one or two of following characteristics: tumor larger than 3 cm, multiple tumors in the bladder and a recurrence in less than one year from the prior tumor.

The standard of care for treating low-grade intermediate risk NMIBC patients is TURBT. TURBT is a surgical procedure for tumor removal usually conducted under general anesthesia in a hospital setting and may require an overnight stay. There are known risks associated with the surgical procedure itself, including bleeding, hospitalization and an increased risk of death in patients in their 60s and 70s. Moreover, TURBT's success is tied to the physician's ability to overcome challenges in properly identifying, reaching and resecting all tumors. No drugs have been approved by the FDA for the primary treatment of low-grade intermediate risk NMIBC. Efficacy of drug treatments has historically been limited due to challenges presented by bladder physiology, specifically the fact that urine is produced and voided frequently, thus diluting the concentration of the drug almost immediately and causing the excretion of the drug from the bladder at first urine voiding. A subset of low-grade intermediate risk NMIBC patients is at risk for frequent local recurrences.

Due to lack of treatment options to reduce recurrences in these patients, they are managed with repeat TURBT for each subsequent recurrence. We estimate, based upon a review of peer-reviewed and publicly available data, an addressable population of low-grade intermediate risk NMIBC patients of approximately 80,000 in the U.S. annually.

Limitations of Current Therapies for Low-Grade Non-Muscle Invasive Bladder Cancer

Recurrence, which occurs in approximately 80% of patients, is the primary threat for patients with low-grade NMIBC. Multiplicity, or number of tumors, tumor size and prior recurrence rate are the most important variables in determining the likelihood and potential severity of recurrence. The current standard of care for low-grade NMIBC is TURBT. The most common complications, risks and limitations of TURBT include:

- bleeding at the time of surgery that requires clot irrigation;
- infection of the bladder;
- injury to the urethra and bladder perforation with potential intra-abdominal leakage;
- reimplantation and cell migration;
- repeat TURBT procedures, which are necessary for approximately 10% of patients within three months;
- complete removal of tumor tissue often not being feasible;
- potential recurrence of up to 25% of the tumors at the original treatment site; and
- some tumors not being detectable.

Post-operative adjuvant treatments for low-grade NMIBC, which are given to prevent reimplantation of the cancerous cells, consist primarily of chemotherapy in the case of low-grade tumors and immunotherapy in the case of high-grade tumors, and are administered intravesically via catheter. Adjuvant intravesical chemotherapy is used in low-grade tumors following TURBT in order to try to delay tumor recurrence but is not used as a chemoablation agent. The rationale is to expose tumors to high local drug concentrations while minimizing the systemic exposure, thereby enhancing the treatment effect and reducing the drug toxicity. In practice, in the U.S., adjuvant chemotherapy in this setting is only used in 0-30% of the eligible population.

No drugs have been approved by the FDA for the primary treatment of low-grade NMIBC. Mitomycin is the drug used most often for intravesical chemotherapy in this patient population. It is used off-label as an adjuvant treatment in the post-operative setting for low-grade tumors with high risk of recurrence. Other drugs that have been used off-label include docetaxel and gemcitabine.

Our Solution: UGN-102 (mitomycin) for intravesical solution

We are evaluating the safety and efficacy of UGN-102, our novel sustained-release formulation of mitomycin for the treatment of low-grade intermediate risk NMIBC.

UGN-102 is administered locally using the standard practice of intravesical instillation directly into the bladder via a catheter. The instillation into the bladder is expected to take place in a physician's office as a non-operative outpatient treatment, in comparison with TURBT or similar surgical procedures, which are operations often conducted under general anesthesia and may require an overnight stay. Complete surgical tumor removal often has limited success due to the inability to properly identify, reach and resect all tumors. We believe that an effective chemoablation agent can potentially provide better eradication of tumors irrespective of the detectability and location of the tumors. In addition, by reducing the need for surgery, patients may avoid potential complications associated with surgery and anesthesia.

In October 2021, we reported final data from the Phase 2b OPTIMA II trial. The single-arm, open label trial completed enrollment of 63 patients at clinical sites across the United States and Israel in September 2019. Patients were treated with six weekly instillations of UGN-102 and underwent assessment of CR (the primary endpoint) four to six weeks following the last instillation; 65%, or 41 out of 63 patients, treated with UGN-102 achieved a CR three months after the start of therapy. In this subset of patients, 39 (95%), 30 (73%), and 25 (61%) remained disease-free at six, nine, and 12 months after treatment initiation, respectively. The probability of durable response nine months after CR (12 months after treatment initiation) was estimated to be 72.5% by Kaplan-Meier analysis. Thirteen patients had documented recurrences. Fifty-seven of 63 (90%) patients completed all six instillations of UGN-102 according to the study protocol. Median duration of response was not reached. The most common adverse events, greater than 10%, were most often reported as mild to moderate in severity and include dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection. The final data was published online in The Journal of Urology in October 2021 and was included in the January 2022 print edition.

In December 2022 we presented new data from a follow up study to the OPTIMA II study designed to obtain long-term data on UGN-102 that shows median duration of response of 24.4 months based on available data for 15 out of 25 patients who achieved a CR in OPTIMA II. Seven patients remained in CR, six patients had recurrence of low-grade disease, one patient had progression to high-grade disease and one patient withdrew consent but remained in CR at the last evaluation prior to discontinuation. All patients were alive at the last contact, and five patients were known to have had post-study treatment with TURBT or fulguration.

We initiated our Phase 3 ATLAS trial in December 2020 and until November 2021, were enrolling patients in this trial comparing UGN-102 with or without TURBT to standard of care, TURBT. In parallel, we continued to engage in discussions with the FDA and, based on this dialogue, we designed a trial in order to demonstrate the efficacy and safety of UGN-102. This Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy in patients with low-grade intermediate risk NMIBC. The design of the Phase 3 ENVISION trial is similar to our Phase 2 OPTIMA II trial in that the patient population has similar clinical characteristics, receives the same investigational treatment regimen and undergoes similar efficacy and safety assessments and qualitative follow-up. Study participants receive six once-weekly intravesical instillations of UGN-102. The primary endpoint is CR rate at three months after the first instillation, and the key secondary endpoint is durability of response in patients who achieve CR at the three-month assessment.

In February 2022, we announced the initiation of the Phase 3 ENVISION trial, targeting enrollment of 220 patients across 90 sites. In December 2022 we completed our target enrollment of the Phase 3 ENVISION trial. As a result of the FDA's acceptance of a single arm approach, we stopped enrollment of the Phase 3 ATLAS trial. However, at the time enrollment was stopped, patients who had signed an informed consent were able to complete screening, and if eligible were randomized into the trial.

On July 27, 2023, we announced topline data from our Phase 3 trials, ATLAS and ENVISION. In the ATLAS trial, UGN-102 met its primary endpoint of disease-free survival, reducing risk of recurrence, progression, or death by 55%. Results of the ATLAS trial also showed a 64.8% CR rate at three months for patients who only received UGN-102, compared to a 63.6% CR rate at three months for patients who only received a TURBT. The ENVISION trial met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.2% rate of CR at three months following the initial treatment. Additional data evaluating the secondary endpoint of duration of response from ENVISION is anticipated in 2024. In both trials, the safety profile of UGN-102 was acceptable, with a safety profile comparable to that observed in previous clinical trials of UGN-102.

We also initiated a Phase 3b study with the objective of demonstrating whether UGN-102 can be administered at home by a qualified home health professional, avoiding the need for repeated visits to a healthcare setting for instillation. As per the study design, patients in this study received six once-weekly intravesical instillations of UGN-102 with the initial treatment visit occurring at the investigative site and instillation performed by a qualified physician. Treatment visits two to six took place at the patient's home and instillations were performed by a properly trained and qualified home health professional. The primary endpoints of the study include safety and tolerability, discontinuations from at home study treatment and feedback from patients, home health professionals and investigators via standardized questionnaires. The study completed enrollment with a total of eight patients across four centers and all study visits for these enrolled patients have been completed. Preliminary results were reported through a press release in February 2023, finding that UGN-102 was suitable to administer at home by a visiting nurse under the supervision of a treating physician and resulted in 75% of patients achieving a CR, defined as no detectable disease three months after starting treatment. Patients, nurses and investigators also completed home instillation feasibility questionnaires. These standardized feasibility questionnaires highlighted that all eight patients preferred at-home to in-office treatment, and five of six patients recommended UGN-102 home instillation instead of TURBT. Home instillation was reported as feasible for visiting nurses, and three of four investigators considered at-home treatment "not different" than in-office treatment.

In October 2023 we announced our agreement with the FDA on plans for submission of an NDA for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of CR at 12 months from the pivotal ENVISION trial, will support submission of an NDA for the treatment of low-grade intermediate risk NMIBC. The FDA indicated that it may seek the advice of the Oncology Drug Advisory Committee as part of the NDA review process. The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls ("CMC") sections of the NDA, which we submitted in January 2024. Based on our agreement with the FDA, we expect to complete the submission of the rolling NDA for UGN-102 in September 2024.

In January 2024 we entered into a licensing and supply agreement with medac Gesellschaft für klinische Spezialpräparate m.b.H. (“medac”) to develop UGN-103 and UGN-104 which are intended to be next-generation formulations of UGN-102 and *Jelmyto*, respectively, that combine medac’s proprietary mitomycin formulation technology with our *RTGel* technology, which we believe will provide advantages related to production, cost, supply and product convenience. We plan to initiate a Phase 3 study in 2024 to explore the safety and efficacy of UGN-103 in low-grade intermediate risk NMIBC. We also plan to initiate a Phase 3 study in 2024 to explore the safety and efficacy of UGN-104 in low-grade UTUC.

UGN-301 (zalifrelimab) intravesical solution

Our immuno-uro-oncology pipeline includes UGN-301 (zalifrelimab), an anti-CTLA-4 antibody, which we intend to study as a standalone agent and as a combination therapy. The first combination we are investigating clinically involves the sequential use of UGN-201 (imiquimod), a toll-like receptor-7 ("TLR 7") agonist, and UGN-301 in high-grade non-muscle invasive bladder cancer ("high-grade NMIBC"). The second combination we are investigating clinically involves the sequential administration of gemcitabine and UGN-301 to the bladder in high-grade NMIBC. UGN-301 is delivered using our proprietary *RTGel* technology, which has been designed to significantly improve the effectiveness of certain intravesical therapies.

High-Grade Non-Muscle Invasive Bladder Cancer

High-grade NMIBC is a highly aggressive form of bladder cancer. TURBT followed by adjuvant intravesical immunotherapy with Bacillus of Calmette and Guerin ("BCG") is the current standard of care therapy for high-grade NMIBC. However, the high rates of recurrence and significant risk of progression to muscle-invasive tumors are particularly dangerous. Radical cystectomy, or bladder removal is strongly advocated in patients with BCG-unresponsive NMIBC (i.e., patients with BCG-refractory and BCG-relapsing tumors in whom further BCG therapy is not recommended) or for patients who cannot tolerate BCG. We estimate based upon a review of peer-reviewed and publicly available data that there are approximately 18,700 BCG-unresponsive patients in the U.S. annually.

Limitations of Current Therapies for High-Grade NMIBC

Only five drugs have been approved for high-grade NMIBC, all used as adjuvant treatment: Thiotepa, which was approved in 1959, and is no longer used in practice; BCG, which was approved in 1989; Valstar® (valrubicin), which was approved in 1998; Keytruda® (pembrolizumab), which was approved by the FDA in 2020; and Adstiladrin® (nadofaragene firadenovec-vncg), which was approved by the FDA in 2022 for BCG unresponsive CIS.

BCG, an immunotherapy-based drug, is used as an adjuvant treatment for patients with high-grade NMIBC. Upon recurrence, which occurs in approximately 70% of patients, the patients undergo another round of BCG therapy with a response rate of approximately 30%. Radical cystectomy, or surgical removal of the bladder, is also a common treatment option for patients who fail multiple intravesical BCG therapies. However, treatment with BCG is associated with undesirable side effects (including local irritation, systemic symptoms of immune activation and a small but serious risk of systemic absorption leading to mycobacterial sepsis and death), as evidenced by a boxed warning on the label, which is a warning placed on a prescription drug's label by the FDA and is designed to call attention to serious or life-threatening risks.

Our Solution: UGN-301 (zalifrelimab) intravesical solution

We are exploring the use of immunotherapy for the treatment of high-grade NMIBC, and have pursued a series of nonclinical studies to determine whether our proprietary *RTGel* technology might provide a method for delivering highly potent immunomodulators directly to the bladder surface thereby avoiding toxicity associated with systemic administration. Our immuno-uro-oncology pipeline includes UGN-301, an anti-CTLA-4 antibody, which we intend to study as a single agent and as a combination therapy. CTLA-4 antibodies are seen as potentially potent and comprehensively acting immunomodulators due to the ability to stimulate cytotoxic T cells, while simultaneously inhibiting suppressive T-regulatory cells. When administered systemically, they have led to improved outcomes in patients suffering from advanced cancers.

The completion of non-human primate toxicity studies supported the initiation of a multi-arm Phase 1 study of UGN-301 in combination with other agents. We believe that this approach leverages our unique drug delivery technology and provides an opportunity to evaluate intravesical delivery of UGN-301 in combination with other immuno-modulators, chemotherapies, gene therapy and innate immune stimulators.

The first combination we are investigating clinically involves the sequential use of UGN-201 (imiquimod), a TLR 7 agonist, and UGN-301 in high-grade NMIBC. Toll-like receptors are pattern recognition receptors whose importance in stimulating innate and adaptive immunity has been established by recent studies. Toll-like receptors are able to sense microbial components as well as host-derived endogenous molecules released by injured tissues and play a critical role in defending against invading pathogens. Imiquimod, in its topical formulation, is FDA approved for several indications, including superficial basal cell carcinoma. UGN-201 is a liquid formulation of imiquimod for intravesical administration that has been optimized for delivery in the urinary tract. We acquired UGN-201 from Telormedix SA, a private Swiss-based biotechnology company, in the fourth quarter of 2015. Telormedix conducted all of the previous studies related to UGN-201, including the Phase 1 and Phase 1b studies. We have obtained Orphan Drug Designation for UGN-201 for the treatment of CIS in the bladder. We have an active Investigational New Drug Application ("IND") for UGN-201, which has been effective since 2013.

The second combination we are investigating clinically involves the sequential administration of gemcitabine and UGN-301 to the bladder in high-grade NMIBC. Gemcitabine is a chemotherapy that is used intravesically to treat high grade NMIBC where it is administered as a liquid formulation.

We believe these two combinations could elicit both an innate and adaptive immune response, which may translate into a long-lasting acquired immune response, and potentially represent a valid post-TURBT adjuvant treatment of high-grade NMIBC. UGN-301 is delivered using our proprietary *RTGel* technology, which has been designed to significantly improve the effectiveness of certain intravesical therapy. We believe that these combinations make local therapy a potentially more effective treatment option while minimizing systemic exposure and its potential side effects.

In March 2022, we announced FDA clearance of our IND to begin a novel Phase 1 clinical study of UGN-301 in patients with recurrent NMIBC. The novel study design utilizes a Master Protocol that we believe is a more efficient and streamlined approach to development. It will provide more flexibility to add study arms as the trial progresses and is expected to increase efficiency and potentially reduce costs. We expect the Master Protocol will allow us to more quickly evaluate safety, tolerability and dosing of UGN-301 in combination with additional immunomodulators and chemotherapies, with the goal of developing optimized treatment regimens for patients. The multi-arm Phase 1 study, which is expected to support the development of UGN-301 in high-grade NMIBC, was initiated in April 2022 and is actively enrolling. We expect safety and tolerability data from this Phase 1 study in mid-2024.

Research and Development and License Agreements

Agenus Agreement

In November 2019, we entered into a license agreement with Agenus Inc. ("Agenus"), pursuant to which Agenus granted us an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary monoclonal antibody of Agenus known as AGEN1884 (zalifrelimab), an anti-CTLA-4 antagonist, for the treatment of cancers of the urinary tract via intravesical delivery. UGN-301 is a formulation of zalifrelimab administered using *RTGel* technology that is in Phase 1 clinical development for high-grade NMIBC.

MD Anderson Agreement

In January 2021, we announced that we had entered into a three-year strategic research collaboration agreement with MD Anderson focusing on the sequential use of UGN-201 and UGN-301 as an investigational treatment for high-grade NMIBC. Pursuant to the agreement, we have made bi-annual payments totaling $2.0 million to MD Anderson to fund the collaboration, recognized evenly over the associated period through research and development expenses. In July 2022, we determined that we had achieved the objectives that we established when the agreement was initiated, and notified MD Anderson that we were exercising our right to conclude the collaboration in 2022 as we did not foresee initiating further development activities as part of the collaboration, although we will continue to collaborate on existing joint projects. As a result of this notification, we were not responsible for any further fixed bi-annual funding payments in 2023, although we are responsible for costs related to existing joint projects to the extent they exceed the payments already made to MD Anderson.

Our Competitive Strengths

We believe our approved product and lead product candidates for uro-oncology, which are being developed by leveraging our expertise in drug development and our proprietary formulation technology, have the ability to replace the repetitive, costly, sub-optimal and burdensome tumor resection procedures that represent the current standards of care. Furthermore, we believe our proprietary formulation technology has broad applications and may allow us to develop additional product candidates for indications within and beyond the urinary tract.

***Potential ability to develop additional minimally invasive, drug therapies for uro-oncology*.** Leveraging our innovative formulation technology, we developed *Jelmyto*, our first commercial product and UGN-102, our lead product candidate, as potential replacements to treatment for low-grade UTUC and low-grade intermediate risk NMIBC, respectively. *Jelmyto* is a chemoablation agent designed to overcome the challenges posed by the anatomy of the urinary tract by increasing the dwell time and enhancing the tissue coverage of mitomycin. UGN-102 is also being developed as a chemoablative therapy that may provide a non-invasive durable treatment option for patients. Clinical data generated to date supports our belief that our approved product and lead product candidate may provide new therapeutic options to the current surgical procedures, providing chemoablation treatment that has the potential to better eradicate tumors irrespective of their detectability and location within the urinary tract.

Expertise in developing proprietary formulations of drugs for clinical benefit. We focus on developing proprietary *RTGel* formulations of previously approved drugs and novel therapeutics which we are investigating, whose efficacy for a particular indication is limited by current formulations or routes of administration. Our expertise has enabled us to develop proprietary *RTGel*-based formulations for previously approved drugs and drugs in clinical development, including clinical stage proprietary formulations of mitomycin and zalifrelimab. Our formulations are designed to significantly increase the dwell time and exposure of the drugs to the target sites and limit the need for urine retention, potentially providing enhanced clinical activity, reduced patient burden and increased patient compliance over existing formulations and modes of administration. We have a strong research and development team to advance our product candidates.

Streamlined development risks and efficiencies for our pipeline product candidates. *Jelmyto* was approved with the FDA's 505(b)(2) regulatory pathway, which provides a streamlined, capital efficient pathway when compared to traditional drug development. We also expect to use the 505(b)(2) regulatory pathway for UGN-102, UGN-103 and UGN-104. Furthermore, *Jelmyto* and UGN-201 have received Orphan Drug Designation from the FDA for the treatment of low-grade UTUC and CIS, respectively, which provides seven years of regulatory exclusivity following FDA approval.

Leverageable proprietary formulation technology. We believe that *RTGel* has multiple potential applications beyond urology. Our formulation know-how may enable us to develop different drug formulations to facilitate the delivery, retention and sustained release of active drugs to a variety of targeted body cavities. We believe that our proprietary formulation technology can improve the efficacy of locally administered drugs in body cavities that present anatomical and physiological challenges related to frequent wash out, rapid excretion and bodily secretions.

Strong intellectual property position. We have a robust intellectual property portfolio that includes 43 granted patents worldwide and more than 45 pending patent applications filed in the US, Europe, Israel, Japan, Canada, China, Mexico and Australia. In the United States, we currently have 19 granted patents that are directed to protect our approved product, *Jelmyto* and our lead product candidate, UGN-102, a proprietary *RTGel* technology, various local compositions comprising different active ingredients, inter alia compositions comprising a Botulinum Toxin, UGN-201, UGN-302 (the sequential use of UGN-201 and UGN-301) and our future product candidates that are under company research. These patents claim methods, combination products and novel compositions for treating different diseases, especially cancer in internal cavities, in particular urinary tract cancer. Our issued patents are set to expire between 2024 and 2037.

Experienced and accomplished leadership team with proven track record. We have an experienced management team, with each member possessing deep experience in the biotechnology and related industries. Our President and Chief Executive Officer, Liz Barrett was CEO of Novartis Oncology and a member of the Executive Committee of Novartis. She previously served as Global President of Oncology at Pfizer Inc. At Pfizer, she held numerous leadership positions, including President of Global Innovative Pharma for Europe, President of the Specialty Care Business Unit for North America, and President of United States Oncology. Prior to Pfizer, she was Vice President and General Manager of the Oncology Business Unit at Cephalon Inc. Ms. Barrett also worked at Johnson & Johnson. In addition, our Chairman, Arie Belldegrun, M.D., is a seasoned biotech executive and was the founder, Chairman, Chief Executive Officer and President of Kite Pharma, Inc., which was sold to Gilead Sciences, Inc. Dr. Belldegrun is also a urologist by training. We believe that our leadership team is well-positioned to lead us through clinical development, regulatory approval and commercialization for our product candidates.

Our Growth Strategy

We are a biotechnology company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers. Some key growth drivers are as follows:

Establish our approved product, Jelmyto, as standard of care in low-grade UTUC.

We secured FDA approval of *Jelmyto* in April 2020 and launched in June 2020. Our current priority is to continue our efforts to ensure the successful commercialization of *Jelmyto* and to establish *Jelmyto* as standard of care in low-grade UTUC.

Advance our product candidate UGN-102 and establish it as the first primary non-surgical chemoablative therapy in its target indication following regulatory approval.

We submitted an IND for UGN-102 in June 2018. On July 27, 2023, we announced topline data from our Phase 3 trials, ATLAS and ENVISION, and additional data evaluating the secondary endpoint of duration of response from ENVISION is anticipated in 2024. We believe that UGN-102 has the potential to be a new therapeutic option for the treatment of low-grade intermediate risk NMIBC patients, if approved.

Expand our uro-oncology product pipeline.

We believe that UGN-301 in combination with other potential agents could represent an option for the post-TURBT adjuvant treatment of high-grade NMIBC. In April 2022 we initiated a multi-arm Phase 1 study, which is expected to support the development of UGN-301 in high-grade NMIBC. We believe that the combination treatments make local therapy a potentially more effective treatment option while minimizing systemic exposure and its potential side effects. We also plan to initiate a Phase 3 study in 2024 to explore the safety and efficacy of UGN-103 in low-grade, intermediate risk NMIBC. We also plan to initiate a Phase 3 study in 2024 to explore the safety and efficacy of UGN-104 in low-grade UTUC. UGN-103 and UGN-104 combine medac's proprietary mitomycin formulation technology with our RTGel technology, which we believe will provide advantages related to production, cost, supply and product convenience.

Utilize our proprietary technology to expand our pipeline to other body cavities and indications.

We believe that *RTGel* may be suitable for multiple additional applications. Our know-how may enable us to develop different drug formulations to facilitate the delivery, retention, increased dwell time and sustained release of active drugs to a variety of targeted body cavities. In the future, we may also choose to develop our *RTGel* technology in combination with other drugs to treat cancer and other indications endemic to such body cavities.

Evaluate and selectively pursue potential collaborations in specialty oncology, uro-oncology and urology as well as to develop improved formulations and RTGel product life-cycle management strategies.

We are focused on driving growth through business development and geographic footprint expansion focusing on sustained nearer-term revenue growth, innovation, high unmet need and cost-effective value creation. We are seeking potential partnerships with leading academic institutions as well as other biotechnology and pharmaceutical companies. Such collaborations may allow us to obtain financial support and to capitalize on the expertise and resources of our potential partners, which could allow for new and improved versions of approved or clinical stage drugs and could accelerate the development and commercialization of additional product candidates.

Intellectual Property

Our patent estate includes patents and patent applications with claims directed to our approved product, *Jelmyto* and our lead product candidate, UGN-102, a proprietary *RTGel* technology, various local compositions comprising different active ingredients, inter alia compositions comprising a Botulinum Toxin, UGN-201, UGN-302 (the sequential use of UGN-201 and UGN-301) and our future product candidates that are under company research.

In the United States, we currently have 19 granted patents that are directed to protect our approved product, *Jelmyto* and our lead product candidate, UGN-102, a proprietary *RTGel* technology, various local compositions comprising different active ingredients, inter alia compositions comprising a Botulinum Toxin, UGN-201 and our future product candidates that are under company research. These patents claim methods, combination products and novel compositions for treating different diseases, especially cancer in internal cavities, in particular urinary tract cancer. These issued patents are set to expire between 2024 and 2037. In total, our IP portfolio includes 43 granted patents worldwide, and more than 45 pending patent applications filed in the US, Europe, Israel, Japan, Canada, China, Mexico and Australia that are directed to cover various methods, systems and compositions for treating cancer locally, by intravesical means, utilize various active ingredients and the combinations thereof. These patent applications, if issued, are set to expire between 2031 and 2043.

As noted earlier, companies are required as part of the NDA submission process to list patents with the FDA whose claims cover the applicant's product. Accordingly, we have listed two patents for *Jelmyto* in the FDA's Orange Book upon approval of *Jelmyto* for commercial sale, as part of the NDA process.

Our worldwide intellectual property portfolio includes patents and patent applications filed in many jurisdictions such as the US, Europe, Israel, Japan, Canada, China and Australia of which are expected to remain in effect until 2043, if allowed:

- Hydrogel-based pharmaceutical compositions for optimal delivery of various therapeutic agents to internal cavities such as the bladder and/or urinary tract.
- The method for treating bladder cancer, upper urinary tract cancer and urothelial cancer using hydrogel-based compositions.
- Proprietary mitomycin formulation for treating bladder cancer, upper urinary tract cancer and urothelial cancer.
- The method for treating overactive bladder and interstitial cystitis topically without a need for injections in the bladder wall.
- Special catheters and in-dwelling ureter-catheter systems for optimal delivery of a drug into the renal cavity.
- Pharmaceutical compositions comprising an imidazoquinolin-amine (specifically imiquimod) for treating bladder cancer diseases.
- Composition comprising immunomodulators such as anti-PD1 and/or anti-CTLA4 for topical/intravesical administration as a monotherapy or a combo-therapy.
- Novel phospholipid drug analogs (new chemical entities) for treating cancer or infections.
- Hydrogel for removal ureteral and renal stones.

In addition to patents, we have filed applications for trademark registration with the United States Patent and Trademark Office (the "USPTO"), as well as certain other international jurisdictions for *Jelmyto* ®, *RTGel* ®, UroGen ® and Cystoject™ and for certain other tradenames and logos. In addition, we have a registered trademark in the U.S. covering a stylized design of our UroGen Pharmaceutical logo.

Furthermore, we rely upon trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. Preparing and filing patent applications is a joint endeavor of our research and development team and our in-house and external patent attorneys. Our patent attorneys conduct patent prior-art searches and then analyze the data in order to provide our research and development team with recommendations on a routine basis. This results in:

- protecting our product candidates that are under development;
- encouraging pharmaceutical companies to negotiate development agreements with us; and
- preventing competitors from attempting to design-around our inventions.

Competition

We are developing products for patients with low-grade UTUC, low-grade NMIBC and high-grade NMIBC.

Prior to *Jelmyto*, there were no approved drugs used to treat the low-grade UTUC. Tumor resection surgeries are conducted in some cases of low-grade UTUC; however, complete kidney and upper urinary tract removal is the standard of care for recurring UTUC. We are aware of a company called Steba Biotech with an IND granted in December 2020 who has initiated a Phase 3 study of padeliporfin for the treatment of adult patients with low-grade and unifocal high-grade UTUC.

We do not know whether other competitors in the NMIBC space are already developing, or plan to develop, UTUC treatments. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, easier to administer or less costly than our product candidates.

The standard of care for treating low-grade NMIBC is repeated TURBT procedures. While effective, patients with low-grade intermediate risk NMIBC experience frequent recurrences and repeated surgical procedures. Mitomycin is sometimes used off-label as adjuvant treatment in the post-TURBT setting for low-grade NMIBC patients. However, off-label usage as a standard of care does not change the FDA's approval criteria and does not suggest that FDA approval is more likely than for other investigational drugs. Companies such as Janssen and Lipac are conducting, or have recently conducted clinical trials for product candidates for the treatment of low-grade intermediate risk NMIBC.

The standard of care for treating high-grade NMIBC patients is the TURBT procedure for papillary tumor resection, followed by post-operative adjuvant BCG. In the case of high-grade disease without papillary tumor (CIS), BCG is used alone as primary therapy. BCG was approved by the FDA in 1989, since its approval, only three other drugs were approved for high-grade NMIBC: Valstar, approved by the FDA in 1998; Keytruda, approved by the FDA in 2020; and Adstiladrin, approved by the FDA in 2022 for BCG unresponsive CIS. Valstar is indicated for patients with CIS that do not respond to BCG treatment and is rarely used. Keytruda was approved for CIS with or without papillary involvement for patients who do not respond to BCG treatment.

It remains to be seen whether the broader urology community will adopt a systemic infused immunotherapy into their clinical management of BCG unresponsive NMIBC. In addition to these approved options, off-label intravesical chemotherapy can be used (such as gemcitabine and cisplatin). If the disease can no longer be controlled, patients will typically proceed to cystectomy, or surgical removal of the bladder, to prevent progression to muscle invasive and metastatic disease. There are several products in the development pipeline, most of which are treatments targeted for high-grade NMIBC patients who have failed BCG treatment and are facing cystectomy.

We are aware of several pharmaceutical companies that are developing drugs in the fields of urology and uro-oncology, such as AADi, LLC, Biocancell Ltd., Bristol Myers Squibb, CG Oncology Inc., enGene Holdings, Ferring Pharmaceuticals, FKD Therapies Oy, GSK, ImmunityBio, Janssen, Merck Sharp & Dohme Corp, Pfizer, Prokarium, Protara Therapeutics, Roche, Samyang Biopharma, Steba Biotech Ltd., SURGE Therapeutics, Viralytics Limited and Vyriad. In addition, we face competition from existing standards of treatment, surgical tumor resection procedures. If we are not able to demonstrate that our product candidates are at least as safe and effective as such courses of treatment, medical professionals may not adopt our product candidates in replacement of the existing standard of care.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our potential competitors include large and experienced companies that enjoy significant competitive advantages over us, such as greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition, and more experience and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities. These companies may develop new drugs to treat the indications that we target or seek to have existing drugs approved for use for the treatment of the indications that we target.

These potential competitors may therefore introduce competing products without our prior knowledge and without our ability to take preemptive measures in anticipation of their commercial launch. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or exclusively licensing products that are more effective, easier to administer or less costly than our product candidates.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of our products.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests that must be conducted in accordance with good laboratory practices ("GLPs");
- submission of an IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board ("IRB"), for each clinical site or centrally before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended use, performed in accordance with good clinical practices ("GCPs");
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with current good manufacturing practices ("cGMP") and GCPs; and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

The testing and approval process requires substantial time, effort and financial resources. Nonclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a product candidate, we must submit the results of the nonclinical tests and nonclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some nonclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each study site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans. Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, if the drug has been associated with unexpected serious harm to subjects, or based on evolving business objectives or competitive climate. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise us to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—Studies are initially conducted to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.
- Phase 2—Controlled studies are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—These clinical trials are undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. Evidence is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations so long as the global sites are also representative of the U.S. population and the conduct of the study at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which includes the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the study by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Information about some clinical trials, including a description of the trial and trial results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the Federal Food, Drug and Cosmetic Act ("FDCA"). Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events ("SAEs") occur.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

505(b)(2) Regulatory Approval Process

Section 505(b)(2) of the FDCA ("505(b)(2)"), provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The applicant may rely upon the FDA's prior findings of safety and efficacy for an approved product that acts as the reference listed drug for purposes of a 505(b)(2) NDA. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support any changes from the reference listed drug. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy, but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an abbreviated new drug application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include nonclinical and clinical data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo* or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and under Part D, can often be substituted by pharmacists under prescriptions written for the reference listed drug.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list patents with the FDA which claims cover the applicant's product. The patents chosen as part of this submission do not reflect the entire patent estate or set of product protections associated with this product, which may provide various protections beyond the patents submitted in the NDA application. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Any applicant who submits an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a Paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the competitor has provided a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner regularly takes action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. The applicant may also elect to submit a statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. On February 25, 2024, we received a Paragraph IV Certification Notice Letter from Teva Pharmaceuticals, Inc. ("Teva"), providing notification that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of *Jelmyto*. In the Notice Letter, Teva alleges that two of the patents listed in the FDA Orange Book for *Jelmyto*, U.S. Patent Numbers 9,040,074 and 9,950,069 each of which expires in January 2031, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission.

Exclusivity

The FDA provides periods of regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to New Chemical Entities ("NCEs"). An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, was essential to the approval of the application and was conducted or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

The Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan Drug Designation must be requested before submitting an NDA. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA Orphan Drug Designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and a waiver of the NDA application user fee.

Expedited Development and Review Programs

The FDA is required to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment, and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the submission of the IND for the product candidate. The FDA must determine if the product candidate qualifies for Fast Track and Breakthrough Therapy designations within 60 days after receipt of the sponsor's request.

For Fast Track and Breakthrough Therapy products, the sponsor may have more frequent interactions with the FDA and the FDA may initiate review of sections of a Fast Track or Breakthrough Therapy product's NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a Fast Track or Breakthrough Therapy application does not begin until the last section of the NDA is submitted. In addition, the Fast Track and Breakthrough Therapy designations may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process. A Fast Track and Breakthrough Therapy designated product candidate would ordinarily meet the FDA's criteria for priority review.

Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and nonclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA may refer applications for drugs that contain active ingredients that have not previously been approved by the FDA or drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The FDA's NDA review times may differ based on whether the application is a standard review or priority review application. The FDA may give a priority review designation to drugs that are intended to treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA has set the review goal of 10 months from the 60-day filing date to complete its initial review of a standard NDA for a New Molecular Entity ("NME") and make a decision on the application. For non-NME standard applications, the FDA has set the review goal of 10 months from the submission date to complete its initial review and to make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date and non-NME applications within six months of the submission date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding the submission.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter ("CRL"), or approval letter. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or nonclinical testing, or other information or analyses in order for the FDA to reconsider the application. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a risk evaluation and mitigation strategy ("REMS"), as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product, or impose additional post-marketing requirements, based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, which has resulted in a boxed warning. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies.

Post-approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacturing, periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing annual program user fee requirements for any approved products, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA. Physicians, in their independent professional medical judgement, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. We, however, are prohibited from marketing or promoting drugs for uses outside of the approved labeling but may share truthful and not misleading information that is otherwise consistent with the product's approved labeling.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act also imposes obligations on manufacturers of pharmaceutical products related to product tracking and tracing.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. Any of these sanctions could result in adverse publicity, among other adverse consequences.

Other Healthcare Regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services ("HHS"), and its various divisions, including the CMS, and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense and state and local governments. Our business activities must comply with numerous federal, state, and foreign healthcare laws and regulations, including those described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable, in whole or in part, by Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value, including unlawful financial inducements paid to prescribers and beneficiaries, as well as impermissible promotional practices. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the "ACA"), amended the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it, to have violated the statute. The ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or for approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

As a condition of receiving Medicaid coverage for prescription drugs, the Medicaid Drug Rebate Program requires manufacturers to calculate and report to CMS their Average Manufacturer Price ("AMP"), which is used to determine rebate payments shared between the states and the federal government and, for some multiple source drugs, Medicaid payment rates for the drug, and for drugs paid under Medicare Part B, to also calculate and report their average sales price, which is used to determine the Medicare Part B payment rate for the drug. In January 2016, CMS issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the AMP is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the ACA. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's AMP for single source and innovator multiple source drugs beginning January 1, 2024. Drugs that are approved under a biologics license application ("BLA"), or an NDA, including a 505(b)(2) NDA, are subject to an additional requirement to calculate and report the manufacturer's best price for the drug and inflation penalties which can substantially increase rebate payments. For BLA and NDA drugs, the Veterans Health Care Act requires manufacturers to calculate and report to the Department of Veterans Affairs a different price called the Non-Federal AMP, offer the drugs for sale on the Federal Supply Schedule, and charge the government no more than a statutory price referred to as the Federal Ceiling Price, which includes an inflation penalty. A separate law requires manufacturers to pay rebates on these drugs when paid by the Department of Defense under its TRICARE Retail Pharmacy Program. Knowingly submitting false pricing information to the government could result in significant penalties and creates potential federal civil False Claims Act liability.

The Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created additional federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including public and private payors, or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. The ACA amended the federal health care fraud criminal statute implemented under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have violated the statute.

Additionally, the federal Open Payments program pursuant to the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, such professionals and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on HIPAA covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates as well as their covered subcontractors, including mandatory contractual terms and the implementation of certain safeguards of such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways, may not have the same effect and may not be preempted by HIPAA, thus complicating compliance efforts.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any payor, including commercial insurers. In addition, we may be subject to certain analogous foreign healthcare laws. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to marketing expenditures or payments and other transfers of value to physicians and other healthcare providers, and drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives.

Enforcement actions can be brought by federal or state governments or, in some cases, as "qui tam" actions brought by individual whistleblowers in the name of the government. Depending on the circumstances, failure to comply with these laws can result in significant penalties, including criminal, civil and administrative penalties, damages, fines, disgorgement, debarment from government contracts, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from government programs, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our business.

Coverage and Reimbursement

Our ability to commercialize any products successfully, including *Jelmyto*, UGN-102 and our other product candidates, if approved, also will depend in part on the extent to which coverage and adequate reimbursement for our products, once approved, and related treatments will be available from third-party payors, such as government health administration authorities, private health insurers and managed care organizations. Third-party payors determine which medications they will cover and separately establish reimbursement levels. Even if we obtain coverage for a given product by a third-party payor, the third-party payor's reimbursement rates may not be adequate to make the product affordable to patients or profitable to us, or the third-party payors may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Additionally, reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining and maintaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor.

Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In the United States, decisions about reimbursement for new medicines under Medicare are made by CMS, as the administrator for the Medicare program. Private third-party payors often use CMS as a model for their coverage and reimbursement decisions, but also have their own methods and approval process apart from CMS's determinations. Our experience to date has demonstrated coverage with CMS and commercial payors for *Jelmyto*, and we have established written policies with certain commercial providers. For example, in October 2020, a Medicare C-Code was issued for *Jelmyto*. CMS has established a permanent and product-specific J-code for *Jelmyto* that took effect on January 1, 2021. CMS granted *Jelmyto* a New Technology APC (Ambulatory Payment Classification), effective from October 1, 2023. A service is separately for paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. This generally occurs within two to three years from the time a new HCPCS code becomes effective. However, if CMS are able to collect sufficient claims data in less than two years, CMS may consider reassigning the service to an appropriate APC, or, if CMS does not have sufficient data at the end of three years upon which to base its reassignment to an appropriate clinical APC, CMS may keep the service in a New Technology APC until adequate data become available. Loss of our New Technology APC may result in Medicare beneficiaries losing access to *Jelmyto* in the hospital outpatient setting and *Jelmyto* becoming packaged into a comprehensive ambulatory payment classification.

Additionally, coverage policies and reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for any of our products or product candidates that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for medical products. Further, no uniform policy for determining coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available, or if reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Healthcare Reform Measures

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, in March 2010, the ACA was passed, which has changed health care financing by both governmental and private insurers and significantly affected the U.S. pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an additional rebate similar to an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate Program to Medicaid managed care organizations, expanded the 340B program, which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research.

There have been judicial and Congressional challenges, as well as efforts by the Trump Administration to repeal or replace certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute will remain in effect until 2032 unless additional U.S. Congressional action is taken. In addition, in January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several U.S. Presidential executive orders. Congressional inquiries and proposed and enacted legislation at the federal and state levels designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, on November 15, 2021, President Biden signed into law the Infrastructure Investment and Jobs Act. Beginning on January 1, 2023, manufacturers will be required to pay quarterly refunds to CMS for discarded amounts of certain single-dose container and single-use package drugs payable under part B of the Medicare program. Refunds are based on the discarded volume above 10% of the total allowed amount. However, in unique circumstances, CMS will increase the applicable threshold to 35%. At this time, CMS has determined that *Jelmyto* fits within this unique circumstance classification. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Additional health reform measures may continue and affect our business in unknown ways.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Manufacturing, Supply and Production

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturers for all of our required raw materials, active ingredients and finished products for our nonclinical research and clinical trials. We have signed commercial supply agreements for *Jelmyto* with third-party vendors. We may negotiate additional commercial supply agreements for our product candidates UGN-102, UGN-103, UGN-104, UGN-201 and UGN-301, or other back-up supply agreements with other third-party manufacturers for the commercial production of any approved products.

Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors. The relevant manufacturers of our drug products for our current nonclinical and clinical trials have advised us that they are compliant with both current good laboratory practice ("cGLP"), and cGMP.

Our future product candidates, if approved, may not be producible in sufficient commercial quantities, in compliance with regulatory requirements or at an acceptable cost. We and our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP and cGLP for drugs on an ongoing basis, as mandated by the FDA and foreign regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

Marketing, Sales and Distribution

Our U.S. subsidiary, UroGen Pharma, Inc., was formed to support our U.S. development and potential commercialization efforts. Our commercial management team is comprised of experienced professionals in sales, sales operations, market access, marketing and medical affairs. In addition, we have established a customer-facing team that includes territory business managers with deep experience in both urology and oncology. These territory business manager positions are led by seven regional business director positions, who are in turn supported by three regional operations manager positions. Each region is additionally supported by one to two clinical nurse educators to provide education and training around instillation, as well as a field reimbursement manager to help ensure access and reimbursement for appropriate patients and key account directors who engage with C-suite individuals to introduce a *Jelmyto* service line. In addition, our organization currently includes several medical science liaisons who appropriately engage with physicians interested in learning more about UroGen, *Jelmyto* and our technology, both in person and virtually. In total, our customer-facing team comprises approximately 80 representatives.

Our sales force is focused on promoting *Jelmyto,* and educating potential prescribers to identify patients, activate accounts and gain formulary access, as applicable. In the event that we receive regulatory approvals for our products in markets outside of the United States, we intend, where appropriate, to pursue commercialization relationships, including strategic alliances and licensing, with pharmaceutical companies and other strategic partners, which are equipped to market or sell our products through their well-developed sales, marketing and distribution organizations in such countries.

In addition, we may out-license some or all of our worldwide patent rights to more than one party to achieve the fullest development, marketing and distribution of any products we develop.

Employees

As of January 31, 2024, we had 201 employees worldwide, 161 in the United States and 40 in Israel, many of whom hold advanced degrees. Of the 161 employees in the United States one was a part-time employee, and of the 40 employees in Israel, two were part-time. None of our employees are subject to a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our relationships with our employees are good.

Israeli labor laws govern the length of the workday and workweek, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination, payments to the National Insurance Institute, and other conditions of employment and include equal opportunity and anti-discrimination laws. While none of our employees is party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees in Israel by order of the Israeli Ministry of Economy and Industry. These provisions primarily concern pension fund benefits for all employees, insurance for work-related accidents, recuperation pay and travel expenses. We generally provide our employees with benefits and working conditions beyond the required minimums.

Corporate Information

Our legal and commercial name is UroGen Pharma Ltd, with registered offices at 9 Ha'Ta'asiya St., Ra'anana 4365007, Israel. We are a company organized under the laws of State of Israel. We were formed in 2004 with an indefinite duration. We are registered with the Israeli Registrar of Companies. Our principal executive offices are located at 400 Alexander Park Drive, 4th Floor, Princeton, NJ 08540. Our telephone number is (646)768-9780. Investors should contact us for any inquiries through the address and telephone number of our principal executive office. We maintain a web site at http://www.urogen.com. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our website is not incorporated into this Annual Report.

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other information with the SEC. Our filings with the SEC are available free of charge on the SEC's website at *www.sec.gov* and on our website under the "Investors & Media" tab as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors

RISK FACTORS

An investment in our ordinary shares involves a high degree of risk. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the SEC, including the following risk factors which we face. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this Annual Report. See "Special Note Regarding Forward-Looking Statements" above.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

We have a limited operating history and have incurred significant losses and negative cash flows since our inception, and we anticipate that we will continue to incur significant losses and negative cash flows for the foreseeable future, which makes it difficult to assess our future viability.

We are a biotechnology company with a limited operating history upon which you can evaluate our business and prospects. We are not profitable and have incurred net losses in each period since we commenced operations in 2004, including net losses of $102.2 million and $109.8 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $679.3 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our ability to ultimately achieve recurring revenues and profitability is dependent upon our ability to successfully complete the development of our product candidates and obtain necessary regulatory approvals for and successfully manufacture, market and commercialize our products.

We believe that we will continue to expend substantial resources in the foreseeable future for the clinical development of our current product candidates or any additional product candidates and indications that we may choose to pursue in the future. These expenditures will include costs associated with research and development, conducting nonclinical studies and clinical trials, and payments for third-party manufacturing and supply, as well as sales and marketing of any of our product candidates that are approved for sale by regulatory agencies. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our clinical stage and nonclinical drug candidates and any other drug candidates that we may develop in the future. Other unanticipated costs may also arise.

Our future capital requirements depend on many factors, including:

- the timing of, and the costs involved in, clinical development and obtaining regulatory approvals for our product candidates;
- changes in regulatory requirements during the development phase that can delay or force us to stop our activities related to any of our product candidates;
- the cost of commercialization activities for *Jelmyto* and any other products approved for sale, including marketing, sales and distribution costs;
- our degree of success in commercializing *Jelmyto*;
- the cost of third-party manufacturing of our products candidates and any approved products;
- the number and characteristics of any other product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements, and the terms and timing of such arrangements;
- the extent and rate of market acceptance of any approved products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent and other intellectual property claims, including potential litigation costs, and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any;
- the repayment of outstanding debt;
- any product liability or other lawsuits related to our products or business arrangements;
- scientific breakthroughs in the field of urothelial cancer treatment and diagnosis that could significantly diminish the demand for our product candidates or make them obsolete; and
- changes in reimbursement or other laws, regulations or policies that could have a negative impact on our future revenue stream.

In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have not obtained regulatory approval for or commercialized any product except *Jelmyto*.

We will require additional financing to fund our operations and achieve our goals, and a failure to obtain this capital when needed and on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

We are not profitable and have had negative cash flow from operations since our inception. Since our inception, almost all our resources have been dedicated to the nonclinical and clinical development of our first commercial product, *Jelmyto*, and our lead product candidate UGN-102. As of December 31, 2023, we had cash and cash equivalents and marketable securities of $141.5 million. To fund our operations and develop our product candidates and commercialize *Jelmyto*, we have relied primarily on equity and debt financings and, following the launch of *Jelmyto* in June 2020, revenue generated from sales of *Jelmyto*.

In December 2019, we entered into a sales agreement (the "ATM Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which we may from time to time offer and sell our ordinary shares having an aggregate offering price of up to $100.0 million. The remaining capacity under the ATM Sales Agreement was approximately $83.4 million as of December 31, 2023, and subsequent to December 31, 2023, we sold approximately $26.6 million of our ordinary shares pursuant to the ATM Sales Agreement. As of February 29, 2024, $56.8 million remains available for sale under the ATM Sales Agreement.

In March 2021, we announced a transaction with RTW Investments ("RTW") totaling $75 million in funding for our company, which was received in May 2021, to support the launch of *Jelmyto* and the development of UGN-102 (the "RTW Transaction"). In return for the upfront cash payment, RTW is entitled to receive tiered future payments based on global annual net product sales of *Jelmyto* and UGN-102, if approved.

On March 7, 2022, UroGen Pharma Ltd., UroGen Pharma, Inc., as the borrower (the "Borrower"), and certain direct and indirect subsidiaries of the Company party thereto from time to time, as guarantors ("Guarantors" and, collectively with UroGen Pharma Ltd. and Borrower, "Credit Parties"), entered into a loan agreement (the "Loan Agreement") with funds managed by Pharmakon Advisors, L.P., including BPCR Limited Partnership (as a "Lender"), BioPharma Credit Investments V (Master) LP (as a "Lender"), and BioPharma Credit PLC, as collateral agent for the Lenders (in such capacity, "Collateral Agent"), pursuant to which the Lenders agreed to make term loans to the Borrower in an aggregate principal amount of up to $100.0 million (the "Term Loans") to be funded in two tranches. The first tranche of $75.0 million ($72.6 million of proceeds were received, $70.8 million net of additional transaction costs) was funded in March 2022, and the second tranche of $25.0 million was funded in December 2022.

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million is mandatory and required to be drawn by September 30, 2024, subject to satisfaction of customary conditions. The fourth tranche of $75.0 million may be drawn at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0M tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) satisfaction of customary conditions.

In July 2023, we entered into a private placement transaction with certain institutional and other accredited investors pursuant to which we agreed to sell our ordinary shares and pre-funded warrants to purchase ordinary shares to the investors, for aggregate gross proceeds of $120.0 million ($116.1 million net of issuance cost), $115.0 million of which closed on July 28, 2023 and the remaining $5.0 million closed on August 9, 2023.

We cannot be certain that our existing resources and anticipated revenues will be sufficient to fund our planned operations and expenditures for at least the next 12 months from the date of issuance of our consolidated financial statements included elsewhere in this Annual Report. These circumstances raise substantial doubt about our ability to continue as a going concern. We will require additional capital to complete clinical trials, obtain regulatory approval for and commercialize our product candidates, and otherwise fund our operations. Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity financings, convertible debt or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to pursue nonclinical and clinical activities, and pursue regulatory approval for, and to commercialize, our pipeline product candidates.

Any additional fundraising efforts may divert the attention of our management from day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on favorable terms, if at all. Moreover, the terms of any financing may negatively impact the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than would be desirable and we may be required to relinquish rights to some of our technologies, intellectual property or product candidates or otherwise agree to terms unfavorable to us, any of which may harm our business, financial condition, cash flows, operating results and prospects.

If adequate funds are not available to us on a timely basis, we may be required or choose to:

- delay, limit, reduce or terminate nonclinical studies, clinical trials or other development activities for our product candidates or any of our future product candidates;
- delay, limit, reduce or terminate our other research and development activities; or
- delay, limit, reduce or terminate our establishment or expansion of manufacturing, sales and marketing or distribution capabilities or other activities that may be necessary to commercialize *Jelmyto* or any of our product candidates that obtain marketing approval.

We may also be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could harm our business, financial condition, cash flows and results of operations.

Our indebtedness resulting from our Loan Agreement could adversely affect our financial condition or restrict our future operations.

In March 2022, we entered into the Loan Agreement pursuant to which the Lenders funded the Term Loans to Borrower in an aggregate principal amount of $100.0 million in two tranches. In March of 2024, we amended and restated the Loan Agreement, pursuant to which the Lenders agreed to make additional term loans to the Borrower in an aggregate principal amount of up to $100.0 million to be funded in two tranches. We are required to draw the third tranche of $25.0 million by September 30, 2024. The fourth tranche of $75.0 million will become available at our option upon FDA approval of UGN-102, subject to customary bringdown conditions and deliverables. There is no assurance that the additional term loans will be funded as expected or at all.
The obligations of the Borrower under the Loan Agreement are guaranteed on a full and unconditional basis by UroGen Pharma Ltd. and the other Guarantor and are secured by substantially all of the respective Credit Parties' tangible and intangible assets and property, including intellectual property, subject to certain exceptions.

The Loan Agreement contains negative covenants that, among other things and subject to certain exceptions, restrict our ability to:

- sell or dispose of assets, including certain intellectual property;
- amend, modify or waive certain agreements or organizational documents;
- consummate certain change in control transactions;
- incur certain additional indebtedness;
- incur any non-permitted lien or other encumbrance on the Credit Parties' assets;
- pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests; and
- make payments of certain subordinated indebtedness.

In addition, we are required under the Loan Agreement to comply with various operating covenants and default clauses that may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these covenants or clauses could result in a default under the Loan Agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable, including a make whole amount and prepayment premium.

If we are unable to generate sufficient cash to repay our debt obligations when they become due and payable, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively affect our business operations and financial condition.

Covenants under our Prepaid Forward Contract with RTW restrict our ability to borrow additional capital.

In March 2021, we entered into a Prepaid Forward Contract (the "Forward Contract") with RTW, pursuant to which we are obligated to make tiered cash payments to RTW, based on the worldwide annual net product sales of *Jelmyto* and, subject to FDA approval, UGN-102, UGN-103 and UGN-104 (together, the "Products"), subject to an aggregate revenue cap of $300.0 million.

Until the earlier of such time that (i) our aggregate worldwide annual net product sales of the Products reach a certain threshold or (ii) our market capitalization reaches a certain threshold, (a) we have granted RTW a security interest in the Products and the regulatory approvals, intellectual property, material agreements, proceeds and accounts receivable related to the Products (the "Product Collateral"), (b) we are subject to a negative pledge in respect of the Product Collateral and (c) we may not incur additional indebtedness secured by Product Collateral without such secured debt provider entering into a intercreditor agreement with RTW. Upon the occurrence of an insolvency event, as defined in the Forward Contract, any remaining payment obligations under the Forward Contract will be automatically accelerated.

The Forward Contract requires us to use a significant portion of our cash flow to make payments to RTW, limits our ability to borrow additional funds for working capital, capital expenditures or other general business purposes, limits our flexibility to plan for, or react to, changes in our business and industry, places us at a competitive disadvantage compared to our competitors not subject to similar restrictions and increases our vulnerability to the impact of adverse economic industry conditions.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity, convertible debt or debt financings, as well as selectively continuing to enter into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to the ATM Sales Agreement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as an ordinary shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring and distributing dividends, and may be secured by all or a portion of our assets.

If we raise funds by selectively continuing to enter into additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish additional valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity, convertible debt or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If we are unable to raise additional funds through other collaborations, strategic alliances or licensing arrangements, we may be required to terminate product development or future commercialization efforts or to cease operations altogether.

Risks Related to Our Business and Strategy

We are highly dependent on the successful commercialization of our only approved product, Jelmyto.

Jelmyto is our first product, which we commercially launched in the United States in June 2020. We have not commercialized any other product candidates. We have invested significant efforts and financial resources in the research and development of *Jelmyto*, our first and only product approved for commercial sale. We are focusing a significant portion of our activities and resources on *Jelmyto*, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize *Jelmyto* in the United States.

Successful commercialization of *Jelmyto* is subject to many risks. We initiated our commercial launch of *Jelmyto* in June 2020, and prior to that, we had never, as an organization, launched or commercialized any product. There is no guarantee that our commercialization efforts will be successful, or that we will be able to successfully launch and commercialize any other product candidates that receive regulatory approval. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. While we have established our commercial team and have hired our U.S. sales force, we will need to maintain, further train and develop our team in order to be prepared to successfully coordinate the ongoing commercialization of *Jelmyto*. Even if we are successful in maintaining and further developing our commercial team, there are many factors that could cause the commercialization of *Jelmyto* to be unsuccessful, including a number of factors that are outside our control. We must also properly educate physicians and nurses on the skillful preparation and administration of *Jelmyto*, and develop a broad experiential knowledge base of aggregated clinician feedback from which we can refine appropriate procedures for product administration, without which there could be a risk of adverse events.

Because no drug has previously been approved by the FDA for the treatment of low-grade UTUC, it is especially difficult to estimate *Jelmyto*'s market potential. The commercial success of *Jelmyto* depends on the extent to which patients and physicians accept and adopt *Jelmyto* as a treatment for low-grade UTUC, and we do not know whether our or others' estimates in this regard will be accurate. For example, if the patient population suffering from low-grade UTUC is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to be treated with *Jelmyto* due to label warnings, adverse events associated with product administration or other reasons, the commercial potential of *Jelmyto* will be limited. Physicians may not prescribe *Jelmyto* and patients may be unwilling to be treated with *Jelmyto* if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for *Jelmyto* in our post-marketing commitments, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of *Jelmyto*. Thus, significant uncertainty remains regarding the commercial potential of *Jelmyto*.

In addition, our commercialization efforts for *Jelmyto* could be hindered by pandemics, epidemics or public health emergencies.

If *Jelmyto* sales do not meet expectations, our share price could decline significantly and the long-term success of the product and our company could be harmed.

Jelmyto has only been studied in a limited number of patients and in limited populations. Jelmyto is now available to a much larger number of patients and to a broader population, and we do not know whether the results of Jelmyto use in this larger number of patients and broader populations will be consistent with the results from our clinical studies.

Jelmyto has been administered only to a limited number of patients and in limited populations in clinical studies, including our positive pivotal Phase 3 OLYMPUS clinical trial for the treatment of adult patients with low-grade UTUC. While the FDA granted approval of *Jelmyto* based on the data included in the NDA including data from the Phase 3 OLYMPUS clinical trial, and we have subsequently presented new long-term data from OLYMPUS trial, we do not know whether the results when a larger number of patients and a broader population are exposed to *Jelmyto*, including results related to safety and efficacy, will be consistent with the results from earlier clinical studies of *Jelmyto* that served as the basis for the approval of *Jelmyto*. New data relating to *Jelmyto*, including from spontaneous adverse event reports and post-marketing studies in the United States, and from other ongoing clinical studies, may result in changes to the product label and may adversely affect sales, or result in withdrawal of *Jelmyto* from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing potential marketing applications in other jurisdictions, or imposing post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

We have limited experience as an organization in marketing and distributing products and are therefore subject to certain risks in relation to the commercialization of Jelmyto and any of our product candidates that receive regulatory approval.

Our strategy is to build and maintain a fully integrated biotechnology company to successfully execute the commercialization of *Jelmyto* in the United States. *Jelmyto* is our only product that has been approved for sale by any regulatory body, and it became available in the United States in June 2020. While we have established a commercial management team and have also established a field-based organization comprised of a sales team, reimbursement support team, clinical nurse educators, national account managers and medical science liaisons, we currently have limited experience commercializing pharmaceutical

products as an organization. In order to successfully commercialize *Jelmyto*, we must continue to develop our sales, marketing, managerial, compliance and related capabilities or make arrangements with third parties to perform these services. This involves many challenges, such as recruiting and retaining talented personnel, training employees, setting the appropriate system of incentives, managing additional headcount and integrating new business units into an existing corporate infrastructure. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully further develop these capabilities. Additionally, we will need to maintain and further develop our sales force, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to effectively develop and maintain our commercial team, including our sales force, our ability to effectively commercialize *Jelmyto* would be limited, and we would not be able to generate product revenues successfully. If we fail to establish and maintain an effective sales and marketing infrastructure, we will be unable to successfully commercialize our product candidates, which in turn would have an adverse effect on our business, financial condition and results of operations.

If we are unable to effectively train and equip our sales force, our ability to successfully commercialize Jelmyto will be harmed.

None of the members of our sales force had ever promoted *Jelmyto* prior to its launch in June 2020. In addition, *Jelmyto* is the first drug approved by the FDA for the treatment of low-grade UTUC. As a result, we are and will continue to be required to expend significant time and resources to train our sales force to be credible, persuasive, and compliant with applicable laws in marketing *Jelmyto* for the treatment of low-grade UTUC to physicians and nurses. In addition, we must train our sales force to ensure that a consistent and appropriate message about *Jelmyto* is being delivered to our customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate customers about the benefits and risks of *Jelmyto* and its proper administration, our efforts to successfully commercialize *Jelmyto* could be put in jeopardy, which would negatively impact our ability to generate product revenues.

There can be no assurance that our territory business managers will continue to have in-person access to physicians as a result of pandemics, epidemics or public health emergencies, or that digital materials and virtual engagement will be effective at growing and sustaining prescription levels of *Jelmyto*. Disruptions in the prescription volume of *Jelmyto* could also occur:

- if patients are physically quarantined or are unable or unwilling to visit healthcare providers;
- if physicians restrict access to their facilities for a material period of time;
- if healthcare providers prioritize treatment of acute or communicable illnesses over treatment of low-grade UTUC;
- if pharmacies are closed or suffering staff shortages or supply chain disruptions;
- if patients lose access to employer-sponsored health insurance due to periods of high unemployment; or
- as a result of general disruptions in the operations of payors, distributors, logistics providers and other third parties that are necessary for *Jelmyto* to be prescribed, reconstituted, instilled and reimbursed.

The market opportunities for Jelmyto and our product candidates may be smaller than we anticipate or limited to those patients who are ineligible for established therapies or for whom prior therapies have failed and may be small.

Cancer therapies are sometimes characterized as first-line, second-line or third-line. When cancer is detected early enough, first-line therapy, often chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life. Second- and third-line therapies are administered to patients when prior therapy is not or is no longer effective. For urothelial cancers, the current first-line standard of care is surgery designed to remove one or more tumors. Chemotherapy is currently used in treating urothelial cancer only as an adjuvant, or supplemental therapy, after tumor resection. We are designing our lead product candidate UGN-102 as an alternative to surgery as the standard of care for certain urothelial cancers. However, there is no guarantee that this product candidate will be approved or that we will not have to conduct additional clinical trials. Even if approved, the market opportunity for UGN-102 may be smaller than we anticipate or limited to those patients who are ineligible for established therapies or for whom prior therapies have failed. Our other or future product candidates, including UGN-103, UGN-104, UGN-201 and UGN-301, may face similar risks.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers who have previously failed prior treatments, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or third-party market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, our pivotal Phase 3 OLYMPUS clinical trial for *Jelmyto* was designed to evaluate the use of *Jelmyto* for the treatment of tumors in the renal pelvis (the funnel-like dilated part of the ureter in the kidney) and was not designed to evaluate the use of *Jelmyto* for the treatment of tumors in the ureter (the tube that connects the kidneys to the bladder). Even though *Jelmyto* is approved for the treatment of low-grade UTUC, some physicians have chosen, and physicians may choose in the future, to only use it to treat tumors in the renal pelvis and not tumors in the ureter, which would limit the degree of physician adoption and market acceptance of *Jelmyto*. Even if we obtain significant market share, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including the use of the products as first- or second-line therapy. For example, low-grade UTUC is a rare malignant tumor of the cells lining the urinary tract and there is limited scientific literature or other research on the incidence and prevalence of low-grade UTUC. If our estimates of the incidence and prevalence of low-grade UTUC are incorrect, *Jelmyto*'s commercial viability may prove to be limited, which may negatively affect our financial results.

Jelmyto and any of our product candidates that receive regulatory approval may fail to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success.

The commercial success of *Jelmyto* and any other product candidates that receive regulatory approval will depend significantly on their broad adoption and use by physicians for approved indications, including, in the case of *Jelmyto*, for the treatment of low-grade UTUC, and in the case of UGN-102, for the treatment of low-grade intermediate risk NMIBC, and for other therapeutic indications that we may seek to pursue with any of our product candidates. Physicians treating low-grade UTUC and low-grade intermediate risk NMIBC have never had to consider treatments other than surgery. The degree and rate of physician and patient adoption of *Jelmyto*, UGN-102 or any of our other product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved;
- the safety and efficacy data from the clinical trial(s) supporting the approved clinical indications;
- the approved labeling and packaging for our products, including the degree of product preparation and administration convenience and ease of use that is afforded to physicians by the approved labeling and product packaging;
- the prevalence and severity of adverse side effects and the level of benefit/risk observed in our clinical trials;
- sufficient patient satisfaction with the results and administration of our products and overall treatment experience, including relative convenience, ease of use and avoidance of, or reduction in, adverse side effects;
- the extent to which physicians recommend our products to patients;
- physicians' and patients' willingness to adopt new therapies in lieu of other products or treatments, including willingness to adopt *Jelmyto*, and our lead product candidate UGN-102 as locally-administered drug replacements to current surgical standards of care;
- the cost of treatment, safety and efficacy of our products in relation to alternative treatments, including the recurrence rate of our treatments;
- the extent to which the costs of our products are covered and reimbursed by third-party payors, including the availability of a physician reimbursement code for our treatments, and patients' willingness to pay for our products;
- whether treatment with our products, including the treatment of low-grade UTUC with *Jelmyto* and the treatment of low-grade intermediate risk NMIBC with UGN-102, if approved, will be deemed to be an elective procedure by third- party payors; if so, the cost of treatment would be borne by the patient and would be less likely to be broadly adopted;
- proper education of physicians or nurses for the skillful administration of our approved product, *Jelmyto*, and UGN-102, if approved, and development of a broad experiential knowledge base of aggregated clinician feedback from which we can refine appropriate procedures for product administration, without which there could be a risk of adverse events;
- the effectiveness of our sales and marketing efforts, especially the success of any targeted marketing efforts directed toward physicians and clinics and any direct-to-consumer marketing efforts we may initiate; and
- third-party clinical practice guidelines.

If *Jelmyto*, UGN-102 or any of our other product candidates are approved for use but fail to achieve the broad degree of physician adoption and market acceptance necessary for commercial success, our operating results and financial condition would be adversely affected.

Jelmyto and our product candidates, if approved, will face significant competition with competing technologies and our failure to compete effectively may prevent us from achieving significant market penetration.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our potential competitors include large and experienced companies that enjoy significant competitive advantages over us, such as greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition and more experience and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities. These companies may develop new drugs to treat the indications that we target or seek to have existing drugs approved for use for the treatment of the indications that we target.

We are aware of several pharmaceutical companies that are developing drugs in the general fields of urology and uro-oncology, such as AADi, LLC, Biocancell Ltd., Bristol Myers Squibb, CG Oncology Inc., enGene Holdings, Ferring Pharmaceuticals, FKD Therapies Oy, GSK, ImmunityBio, Janssen, Merck Sharp & Dohme Corp, Pfizer, Prokarium, Protara Therapeutics, Roche, Samyang Biopharma, Steba Biotech Ltd., SURGE Therapeutics, Viralytics Limited and Vyriad. We are aware that Ferring Pharmaceuticals began production of Adstiladrin, approved by the FDA for the treatment of high-risk BCG-unresponsive NMIBC, in the second half of 2023. We are also aware there are companies among this list conducting clinical trials in various phases in the same indications in which we are developing products.In addition, on February 25, 2024, we received a Paragraph IV Certification Notice Letter from Teva Pharmaceuticals, Inc. ("Teva"), providing notification that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of *Jelmyto*. In the Notice Letter, Teva alleges that two of the patents listed in the FDA Orange Book for *Jelmyto*, U.S. Patent Numbers 9,040,074 and 9,950,069 each of which expires in January 2031, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission. If we are unable to maintain patent protection for *Jelmyto*, *Jelmyto* will be subject to immediate competition from generic entrants after regulatory exclusivity expires in April 2027.

Additionally, outside of these indications where we are developing products, we are aware of other companies doing work in both bladder and upper tract cancers, but these are with agents or on targets in high-grade, metastatic, or muscle invasive cancers. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing products that are more effective, easier to administer or less costly than our product candidates.

In addition, we face competition from existing standards of treatment, surgical tumor resection procedures. If we are not able to demonstrate that our product candidates are at least as safe and effective as such courses of treatment, medical professionals may not adopt our product candidates in replacement of the existing standard of care. Generic mitomycin injectable drug products, while approved by FDA for gastric and pancreatic cancers, are neither approved for low-grade UTUC nor reconstituted with hydrogel in an FDA-approved product as *Jelmyto* is, although they may be used off-label by physicians for the treatment of low-grade UTUC, as they have been prior to the approval of *Jelmyto*.

Our ability to market Jelmyto and any of our product candidates that receive marketing approval is and will be limited to certain indications. If we want to expand the indications for which we may market our products, we will need to obtain additional regulatory approvals, which may not be granted.

Jelmyto is indicated for adult patients with low-grade UTUC. We are currently developing UGN-102, UGN-103, UGN-104, UGN-201 and UGN-301 for the treatment of various forms of bladder cancer. The FDA and other applicable regulatory agencies will restrict our ability to market or advertise our products to the scope of the approved label for the applicable product and for no other indications, which could limit physician and patient adoption. We may attempt to develop and, if approved, promote and commercialize new treatment indications for our products in the future, but we cannot predict when or if we will receive the regulatory approvals required to do so. Failure to receive such approvals will prevent us from promoting or commercializing new treatment indications. In addition, we would be required to conduct additional clinical trials or studies to support approvals for additional indications, which would be time consuming and expensive, and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

If we are found to have improperly promoted off-label uses of Jelmyto or any of our product candidates that receive regulatory approval, or if physicians misuse our products, we may become subject to prohibitions on the sale or marketing of our products, significant sanctions, and product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and may not be promoted based on overstated efficacy or omission of important safety information. For example, we cannot promote the use of our product *Jelmyto* in a manner that is inconsistent with the approved label, but we are permitted to share truthful and non-misleading information that is otherwise consistent with the product's FDA approved labeling. However, physicians are able, in their independent medical judgment, to use *Jelmyto* on their patients in an off-label manner, such as for the treatment of other urology indications. If we are found to have promoted such off-label uses, we may receive warning letters and become subject to significant liability, which would harm our business. The federal government has levied large administrative, civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation with physicians, patients and caregivers, and our position within the industry.

Physicians may also misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our products are misused or used with improper technique, we may become subject to costly litigation. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. We currently carry product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. In addition, while we have established product liability insurance relating to our commercialization of *Jelmyto*, there can be no assurance that we will be able to maintain this insurance on commercially reasonable terms or that this insurance will be sufficient. Furthermore, the use of our products for conditions other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

In addition to Jelmyto, we are dependent on the success of our lead product candidate, UGN-102, and our other product candidates, including obtaining regulatory approval to market our product candidates in the United States.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA and by foreign regulatory authorities. These regulations differ from country to country. To gain approval to market our product candidates, we must provide clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication. Other than *Jelmyto*, all of our product candidates, including our lead product candidate, UGN-102, remain in clinical development and have not yet received regulatory approval from the FDA or any other regulatory agency in the United States or any other country. Our business depends upon obtaining these regulatory approvals. There are no drugs that have been approved by the FDA for the primary treatment of low-grade intermediate risk NMIBC, and only a limited number of drugs have been approved by the FDA as adjuvant treatment for BCG unresponsive NMIBC. The FDA can delay, limit or deny approval of our product candidates for many reasons.

While we announced on October 3, 2023 that the FDA agreed with our plan for a rolling NDA submission for UGN-102, there is no guarantee that the FDA will accept the NDA for filing once the rolling submission is complete or eventually approve UGN-102 for the indication and patient population that we request or approve the labeling that we believe is necessary or desirable for the successful commercialization of UGN-102, as the FDA has the authority to refuse to file or approve NDAs for a variety of reasons.

The success of our product candidates is subject to significant risks, including risks associated with successfully completing current and future clinical trials, such as:

- the FDA's acceptance of our parameters for regulatory approval relating to UGN-102 and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways, and proposed labeling and packaging;
- our ability to successfully complete the FDA requirements related to CMC, for UGN-102 and our other product candidates, and if completed, their sufficiency to support an NDA;
- the FDA's timely acceptance of our INDs, for our product candidates and our inability to commence clinical trials in the United States without such IND acceptances;
- the FDA's acceptance of the design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from nonclinical studies or clinical trials;
- the FDA's acceptance of the population studied in our clinical trials being sufficiently large, broad and representative to assess efficacy and safety in the patient population for which we seek approval;
- our ability to successfully complete the clinical trials of our product candidates, including timely patient enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of the product candidates undergoing such clinical trials;
- our ability to demonstrate meaningful clinical or other benefits which outweigh any safety or other perceived risks, through the completion of our clinical trials for our product candidates;
- the FDA's need to schedule an advisory committee meeting, and to conduct such meeting, in a timely manner to evaluate and decide on the approval of our potential future NDA for UGN-102;
- if applicable, the recommendation of the FDA's advisory committee to approve our applications to market UGN-102 and our other product candidates in the United States, without limiting the approved labeling, specifications, distribution or use of the products, or imposing other restrictions;
- the FDA's determination of safety and efficacy of our product candidates;
- the FDA's determination that the Section 505(b)(2) is available for our product candidates;
- the prevalence and severity of adverse events associated with our product candidates, including UGN-102, as there are no drugs and related drug administration procedures approved for the primary treatment of low-grade NMIBC, that are based on *RTGel* technology;
- the timely and satisfactory performance by third-party contractors of their obligations in relation to our clinical trials;
- our success in educating physicians and patients about the benefits, risks, administration and use of our product candidates, if approved, particularly in light of the fact that there are no drugs that have been approved by the FDA for the primary treatment of low-grade NMIBC, and only a limited number of drugs have been approved by the FDA as adjuvant treatment for high-grade NMIBC;
- the availability, perceived advantages, relative cost, safety and efficacy of alternative and competing treatments for the indications addressed by our product candidates;
- the effectiveness of our marketing, sales and distribution strategy, and operations, as well as that of any current and future licensees;
- the FDA's acceptance of the quality of our drug substance or drug product, formulation, labeling, packaging, or the specifications of our product candidates is sufficient for approval;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP;

- the FDA's acceptance of the manufacturing processes or facilities of third-party manufacturers with which we contract;
- our ability to secure supplies for our product candidates to support clinical trials and commercial use;
- our ability to manufacture or secure finished product from third-party suppliers for product candidates, including UGN-102, if approved;
- our ability to obtain, maintain, protect and enforce our intellectual property rights with respect to our product candidates;
- the extent to which the costs of our products, once approved, are covered and reimbursed by third-party payors, including the availability of a physician reimbursement code for our treatments, and patients' willingness to pay for our products; and
- our ability to properly train physicians or nurses for the skillful preparation and administration of any of our product candidates that receive approval, including UGN-102, and our ability to develop a broad experiential knowledge base of aggregated clinician feedback from which we can refine appropriate procedures for product administration, without which there could be a risk of adverse events.

Many of these clinical, regulatory and commercial risks are beyond our control. Further, these risks and uncertainties impact all of our clinical programs that we pursue and may be amplified by pandemics, epidemics or public health emergencies, as described below. Accordingly, we cannot assure you that we will be able to advance any more of our product candidates through clinical development, or to obtain additional regulatory approval of any of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would thus negatively impact our business, results of operations and prospects. Even if we receive approval of any of the product candidates in our pipeline or future product candidates, there is no assurance that we will be able to successfully commercialize any of them.

UGN-102 may not meet its secondary endpoint in the ongoing Phase 3 ENVISION trial.

On July 27, 2023, we announced that UGN-102 met its primary endpoints in the Phase 3 ATLAS and ENVISION trials. Additional data evaluating the secondary endpoint of duration of response from ENVISION are anticipated in 2024. If UGN-102 does not meet its secondary endpoint or we receive other data that negatively impacts the efficacy and safety profile of UGN-102, then our ability to seek and potentially obtain regulatory approval of UGN-102 may be adversely affected.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as patient data become available and following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. In particular, interim data may reflect small sample sizes, be subject to substantial variability and may not be indicative of either future interim results or final results. Publications based on interim data may differ from FDA approved product labeling. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our ordinary shares. See the description of risks under the heading "Risks Related to Ownership of our Ordinary Shares" for additional disclosures related to the risk of volatility in the price of our ordinary shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Furthermore, we may report interim analyses of only certain endpoints rather than all endpoints. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, UGN-102 or any other investigational product candidate may be harmed, which could harm our business, financial condition, results of operations and prospects.

We have limited experience in conducting clinical trials and obtaining approval for product candidates and may be unable to do so successfully.

As a company, we have limited experience in conducting clinical trials and have progressed only one product candidate through to regulatory approval. In part because of this lack of experience, our clinical trials may require more time and incur greater costs than we anticipate. We cannot be certain that the planned clinical trials will begin or conclude on time, if at all. Large-scale trials will require significant additional financial and management resources. Third-party clinical investigators do not operate under our control. Any performance failure on the part of such third parties could delay the clinical development of our product candidates or delay or prevent us from obtaining regulatory approval or commercializing our current or future product candidates, depriving us of potential product revenue and resulting in additional losses.

We have not yet applied for regulatory approvals to market UGN-102 or the other product candidates in our pipeline, and we may be delayed in obtaining or failing to obtain such regulatory approvals and to commercialize our product candidates.

The process of developing, obtaining regulatory approval for and commercializing our product candidates is long, complex, costly and uncertain, and delays or failure can occur at any stage. The research, testing, manufacturing, labeling, marketing, sale and distribution of drugs are subject to extensive and rigorous regulation by the FDA and foreign regulatory agencies, as applicable. These regulations are agency-specific and differ by jurisdiction. We are not permitted to market any product candidate in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory agencies in such countries. To gain approval of an NDA or other equivalent regulatory approval, we must provide the FDA or relevant foreign regulatory authority with nonclinical and clinical data that demonstrates the safety and efficacy of the product for the intended indication.

Before we can submit an NDA to the FDA or comparable similar applications to foreign regulatory authorities, we must conduct Phase 3 clinical trials, or a pivotal/registration trial equivalent, for each product candidate. After submission of an NDA, the FDA may raise additional questions on any data contained in the application. These questions may come in the form of information requests or in the NDA 74-day letter as review issues. We must address these questions during the review, but we do not know whether our responses will be acceptable to the FDA. We cannot assure you that the FDA will not decide to require us to perform additional clinical trials, including potentially requiring us to perform an additional pivotal study with a control arm, before approving, or as a condition of approving, NDAs for our product candidates.

Phase 3 clinical trials often produce unsatisfactory results even though prior clinical trials were successful. Moreover, the results of clinical trials may be unsatisfactory to the FDA or foreign regulatory authorities even if we believe those clinical trials to be successful. The FDA or applicable foreign regulatory agencies may suspend one or all of our clinical trials or require that we conduct additional clinical, nonclinical, manufacturing, validation or drug product quality studies and submit that data before considering or reconsidering any NDA or comparable foreign regulatory application that we may submit. Depending on the extent of these additional studies, approval of any applications that we submit may be significantly delayed or may cause the termination of such programs or may require us to expend more resources than we have available.

If any of these outcomes occur, we may not receive regulatory approval for the corresponding product candidates, and our business would not be able to generate revenue from the sale of any such product candidates.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may not be able to advance our nonclinical product candidates into clinical development and through regulatory approval and commercialization.

Certain of our product candidates are currently in nonclinical development and are therefore currently subject to the risks associated with nonclinical development, including the risks associated with:

- generating adequate and sufficient nonclinical safety and efficacy data in a timely fashion to support the initiation of clinical trials;
- obtaining regulatory approval to commence clinical trials in any jurisdiction, including the submission and acceptance of INDs;
- contracting with the necessary parties to conduct a clinical trial;
- enrolling sufficient numbers of patients in clinical trials in timely fashion, if at all; and
- timely manufacture of sufficient quantities of the product candidate for use in clinical trials.

These risks and uncertainties impact all of our nonclinical programs that we pursue. If we are unsuccessful in advancing our nonclinical product candidates into clinical trials in a timely fashion, our business may be harmed. Even if we are successful in advancing our nonclinical product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this Annual Report and our other filings with the SEC. Accordingly, we cannot assure you that we will be able to develop, obtain regulatory approval for, commercialize or generate significant revenue from our product candidates.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. We do not know whether our ongoing and future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- generate sufficient nonclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval or feedback on trial design, in order to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, and have such CROs and sites effect the proper and timely conduct of our clinical trials;
- obtain and maintain institutional review board ("IRB") approval at each clinical trial site;
- identify, recruit, enroll and retain suitable patients to participate in a trial;
- have a sufficient number of patients enrolled, complete a trial or return for post-treatment follow-up;
- ensure clinical investigators and clinical trial sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- manufacture sufficient quantities at the required quality of product candidate for use in clinical trials; or
- raise sufficient capital to fund a trial.

Patient enrollment is a significant factor in the timing and success of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be developed or approved for the indications we are investigating.

We may also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the trial's data safety monitoring board, by the FDA or by the applicable foreign regulatory authorities. Such authorities may suspend or terminate one or more of our clinical trials due to a number of factors, including our failure to conduct the clinical trial in accordance with relevant regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA or foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in carrying out or completing any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed.

In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business and financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Jelmyto or any of our product candidates may produce undesirable side effects that we may not have detected in our previous nonclinical studies and clinical trials or that are not expected with mitomycin treatment or inconsistent with catheter administration procedures. This could prevent us from gaining marketing approval or market acceptance for these product candidates, or from maintaining such approval and acceptance, and could substantially increase commercialization costs and even force us to cease operations.

As with most pharmaceutical products, *Jelmyto* and our product candidates may be associated with side effects or adverse events that can vary in severity and frequency. Side effects or adverse events associated with the use of *Jelmyto* or any of our product candidates, including UGN-102, may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval or market our product candidates. To date, in our nonclinical testing, Compassionate Use Program for *Jelmyto,* clinical trials and post-marketing experience, we have observed several adverse events and SAEs, including ureteric obstruction, ureteral stenosis, inhibition of urine flow, rash, flank pain, kidney swelling, kidney infection, renal dysfunction, hematuria, fatigue, nausea, abdominal pain, dysuria, vomiting, urinary tract infection, urgency in urination and pain during urination. In addition, we have observed transient perturbation of laboratory measures of renal and hematopoietic function. These adverse events are known mitomycin or procedure-related adverse events and many are indicated as potential side effects of mitomycin usage on the mitomycin label. However, we cannot assure you that we will not observe additional drug or procedure-related adverse events or SAEs in the future or that the FDA will not determine them as such. Side effects such as toxicity or other safety issues associated with the use of *Jelmyto* or our product candidates could require us to perform additional studies or halt development or sale of *Jelmyto* or our product candidates or expose us to product liability lawsuits, which will harm our business.

Furthermore, our Phase 2b clinical trial for UGN-102 involved larger patient bases than in our prior studies of these candidates, and the commercial marketing of *Jelmyto* and, if approved, UGN-102, will further expand the clinical exposure of the drugs to a wider and more diverse group of patients than those participating in the clinical trials, which may identify undesirable side effects caused by these products that were not previously observed or reported.

The FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if our products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date upon which we become aware of the adverse event as well as the nature and severity of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action including enforcing a hold on or cessation of clinical trials, withdrawal of approved drugs from the market, criminal prosecution, the imposition of civil monetary penalties or seizure of our products.

Additionally, in the event we discover the existence of adverse medical events or side effects caused by one of our products or product candidates, a number of other potentially significant negative consequences could result, including:

- our inability to submit an NDA or similar application for our product candidates because of insufficient risk-reward, or the denial of such application by the FDA or foreign regulatory authorities;
- the FDA or foreign regulatory authorities suspending or terminating our clinical trials or suspending or withdrawing their approval of the product;
- the FDA or foreign regulatory authorities requiring the addition of labeling statements, such as boxed or other warnings or contraindications or distribution and use restrictions;
- the FDA or foreign regulatory authorities requiring us to issue specific communications to healthcare professionals, such as letters alerting them to new safety information about our product, changes in dosage or other important information;
- the FDA or foreign regulatory authorities issuing negative publicity regarding the affected product, including safety communications;
- our being limited with respect to the safety-related claims that we can make in our marketing or promotional materials;
- our being required to change the way the product is administered, conduct additional nonclinical studies or clinical trials or restrict or cease the distribution or use of the product; and
- our being sued and held liable for harm caused to patients.

Any of these events could prevent us from achieving market acceptance or approval of the affected product or product candidate and could substantially increase development or commercialization costs, force us to withdraw from the market any approved product, or even force us to cease operations. We cannot assure you that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition.

We may face future developmental and regulatory difficulties related to Jelmyto and any of our product candidates that receive marketing approval. In addition, we are subject to government regulations and we may experience delays in obtaining required regulatory approvals to market our proposed product candidates.

We are subject to certain post-marketing commitments related to *Jelmyto*, including a requirement for a period of five years to provide annual updates for the duration of response for all patients with ongoing CRs enrolled in the Phase 3 OLYMPUS trial. With respect to our current and future candidates, even if we complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA or applicable foreign regulatory agency may grant approval contingent on the performance of additional costly post-approval clinical trials, risk mitigation requirements and surveillance requirements to monitor the safety or efficacy of the product, which could negatively impact us by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. Absence of long-term safety data may further limit the approved uses of our products, if any.

The FDA or applicable foreign regulatory agency also may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Furthermore, any such approved product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping.

If we fail to comply with the regulatory requirements of the FDA or other applicable foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including the following:

- suspension or imposition of restrictions on operations, including costly new manufacturing requirements;
- regulatory agency refusal to approve pending applications or supplements to applications;
- suspension of any ongoing clinical trials;
- suspension or withdrawal of marketing approval;
- an injunction or imposition of civil or criminal penalties or monetary fines;
- seizure or detention of products;
- bans or restrictions on imports and exports;
- issuance of warning letters or untitled letters;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- refusal of regulatory authorities to approve pending applications or supplements to applications.

In addition, various aspects of our operations are subject to federal, state or local laws, rules and regulations, any of which may change from time to time. Costs arising out of any regulatory developments could be time-consuming and expensive and could divert management resources and attention and, consequently, could adversely affect our business, financial condition, cash flows and results of operations.

If we are not successful in developing, receiving regulatory approval for and commercializing our nonclinical and clinical product candidates, our ability to expand our business and achieve our strategic objectives could be impaired.

Although we have received FDA approval of *Jelmyto* for pyelocalyceal solution, for the treatment of adult patients with low-grade UTUC, and we plan to devote a substantial portion of our resources to the continued clinical testing and potential approval of UGN-102 for the treatment of low-grade intermediate risk NMIBC. Another key element of our strategy is to discover, develop and commercialize a portfolio of products to serve additional therapeutic markets. We are seeking to do so through our internal research programs, but our resources are limited, and those that we have are geared towards clinical testing and seeking regulatory approval of UGN-102 and our other existing product candidates. We may also explore strategic collaborations for the development or acquisition of new products, but we may not be successful in entering into such relationships. Research programs to identify product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- a product candidate may in a subsequent trial be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable; and
- intellectual property or other proprietary rights of third parties for product candidates we develop may potentially block our entry into certain markets or make such entry economically impracticable.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed, and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidates.

We have entered into collaboration and licensing agreements and in the future may enter into collaboration and licensing arrangements with other third parties for the development or commercialization of our product candidates. If our collaboration and licensing arrangements are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may utilize a variety of types of licensing, collaboration, distribution and other marketing arrangements with third parties to develop our product candidates and commercialize our approved product candidates, if any. We are not currently party to any such arrangement that we consider material. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Any collaborations that we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- product candidates developed by collaborators may not perform sufficiently in clinical trials to be determined to be safe and effective, thereby delaying or terminating the drug approval process and reducing or eliminating milestone payments to which we would otherwise be entitled if the product candidates had successfully met their endpoints and/or received FDA approval;
- clinical trials conducted by collaborators could give rise to new safety concerns;
- collaborators may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaborations may not lead to development or commercialization of product candidates in the most efficient manner, or at all, and may otherwise experience challenges. For example, in August 2020, we announced that the Phase 2 APOLLO trial of BOTOX/*RTGel* for the treatment of overactive bladder, which was conducted by Allergan Pharmaceuticals Limited ("Allergan"), did not meet the primary endpoint. The data suggested that this result may have been due to BOTOX not effectively permeating the urothelium. In November 2021 our arrangement with Allergan was terminated.

If any future material collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed, and we may need additional resources to develop our product candidates. All the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a business combination, it might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and perception of us in the business and financial communities could be harmed.

We currently contract with third-party subcontractors and single-source suppliers for certain raw materials, compounds and components necessary to produce Jelmyto for commercial use, and to produce UGN-102, UGN-103, UGN-104, UGN-201 and UGN-301 for nonclinical studies and clinical trials, and expect to continue to do so to support commercial scale production of UGN-102, UGN-103, UGN-104 and UGN-201, if approved, as well as UGN-301 if approved as a monotherapy or for any approved product that includes UGN-301. There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers, including single-source suppliers. Furthermore, our existing third-party subcontractors and single-source suppliers may not be able to meet the increased need for certain raw materials, compounds and components that may result from our commercialization efforts. This increases the risk that we will not have sufficient quantities of Jelmyto, UGN-102, UGN-103, UGN-104, UGN-201 or UGN-301 or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third party subcontractors and suppliers for certain compounds and components necessary to produce *Jelmyto* for commercial use and UGN-102, UGN-103, UGN-104, UGN-201 and UGN-301 for our nonclinical studies and clinical trials, and expect to rely on third party subcontractors and suppliers for commercial use for any of our drug candidates that receive regulatory approval. We currently depend on Teva Pharmaceuticals Industries Ltd, as our single-source supplier of mitomycin active pharmaceutical ingredient ("API") for *Jelmyto* and UGN-102. We currently rely on Cenexi-Laboratories Thissen s.a. for the mitomycin contained in *Jelmyto* and UGN-102. We depend on Isotopia Molecular Imaging Ltd. as our single contracted suppliers for the hydrogel contained in *Jelmyto* and UGN-102. We also currently depend on a single source supplier for imiquimod for UGN-201 and zalifrelimab for UGN-301. We have entered into a supply agreement with medac, and pending successful completion of development we will depend on medac as our supplier for UGN-103 and UGN-104. Because there are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce *Jelmyto* for commercial sale and our product candidates for our clinical trials and their subsequent commercial sale, if approved. Even if we are able to engage alternate suppliers on reasonable terms, we may face delays or increased costs in our supply chain that could jeopardize the commercialization of *Jelmyto* and the development of UGN-102. We do not have any control over the availability of these compounds and components beyond our existing contractual arrangements. If we or our suppliers and manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development and commercialization of our product candidates or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of *Jelmyto* or any other approved products.

We expect to continue to rely on these or other subcontractors and suppliers to support our commercial requirements for *Jelmyto*, as well as UGN-102 or any of our other product candidates if approved for marketing by the FDA or foreign regulatory authorities. We plan to continue to rely on third parties for the manufacture of mitomycin API, the hydrogel contained in *Jelmyto,* UGN-102, UGN-103, UGN-104 and UGN-301, and for imiquimod for UGN-201, and for zalifrelimab for UGN-301, as well as for the raw materials, compounds and components necessary to produce our product candidates and for nonclinical studies and clinical trials.

Even though we are approved as a commercial supplier of *Jelmyto*, we have limited experience as a company in the commercial supply of drugs and may never be successful as a commercial supplier of drug products containing mitomycin. In addition, cost-overruns, unexpected delays, equipment failures, logistics breakdowns, labor shortages, natural disasters, power failures, production failures or product recalls, and numerous other factors could prevent us from realizing the intended benefits of our sales strategy and have a material adverse effect on our business. Further, although we commercially supply *Jelmyto*, further build-out is required and establishing such commercial-scale supply capabilities requires additional investment, is time-consuming and may be subject to delays, including because of shortage of labor, compliance with regulatory requirements or receipt of necessary regulatory approvals. In addition, building out our *Jelmyto* commercial supply capabilities may cost more than we currently anticipate, and delays or problems may adversely impact our ability to provide sufficient quantities of *Jelmyto* to support our commercialization of *Jelmyto* and planned future commercialization of UGN-102, if approved, as well as our financial condition.

While we currently have over 12 months of mitomycin API and/or *Jelmyto* finished product on hand to continue our commercial and clinical operations as planned, we may face such delays or costs in future years. Although we believe we have sufficient quantities of bulk mitomycin API for planned manufacturing operations through 2024, a prolonged supply interruption of certain components could adversely affect our ability to conduct commercialization activities and planned clinical trials. If any third party in our supply or distribution chain for materials or finished product is adversely impacted by restrictions resulting from pandemics, epidemics or public health emergencies or other disruptions caused by the outbreak of war, terrorist attacks or other acts of hostility, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture and distribute *Jelmyto* for commercial sales and our product candidates for our clinical trials and research and development operations.

In addition, before we can begin to commercially manufacture any product candidates that receive regulatory approval in the future other than *Jelmyto*, whether in a third-party facility or in our own facility, once established, we must obtain regulatory approval from the FDA for our manufacturing process and facility in order to sell such products in the United States. A manufacturing authorization would also have to be obtained from the appropriate European Union regulatory authorities in order to sell such products in the European Union. In order to obtain approval, we will need to ensure that all of the processes, methods and equipment of such manufacturing facilities are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any vendors, contract laboratories or suppliers are found to be out of compliance with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any product candidate that we may develop.

Our continuing reliance on third party subcontractors and suppliers entails a number of risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing or supply agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third party subcontractors and suppliers may not be able to comply with cGMP or quality system regulation ("QSR") or similar regulatory requirements outside the United States. If any of these risks transpire, we may be unable to timely retain alternate subcontractors or suppliers on acceptable terms and with sufficient quality standards and production capacity, which may disrupt and delay our clinical trials or the manufacture and commercial sale of our in-line or investigational product candidates, if approved.

Our failure or the failure of our third-party subcontractors and suppliers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of *Jelmyto*, UGN-102 or any of our other product candidates that we may develop. Any failure or refusal to supply or any interruption in supply of the components for *Jelmyto*, UGN-102 or any other product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

We currently use single source suppliers relative to production of the *RTGel* products, the ureteral catheter and injector which are required to be used with *Jelmyto*. Both the ureteral catheter and injector are used as part of the delivery of *Jelmyto*. We are assessing second source suppliers regarding certain components of *Jelmyto* and are advancing these conversations as a means to ensure both a second source and potential future reductions in cost of revenues. However, there can be no assurance that we will be able to secure any second-source suppliers for these key components on a timely basis, on favorable terms, or at all.

We rely on third party transportation to deliver materials to our facilities and ship products to our customers. Transport operators are exposed to various risks, such as extreme weather conditions, natural disasters, outbreaks of war, terrorist attacks or other acts of hostility, work stoppages, personnel shortages, and operating hazards, as well as interstate and international transportation requirements. In addition, transport operators were affected by the impact of COVID-19 and the related shipping crisis and backlog, which led to increased shipping costs and supply chain disruptions, and any future pandemics, epidemics or public health emergencies may cause similar disruptions that may impact our operations in the future.

If we experience transportation problems, or if there are other significant changes in the cost of these services, we may not be able to arrange efficient alternatives and timely means to obtain materials or ship products to our customers. Our failure to obtain such materials, ship products or maintain sufficient buffer inventory could materially and adversely impact our business, financial condition and results of operations.

We may need to enter into agreements with additional distributors or suppliers, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. If we are unable to maintain and, if needed, expand, our network of specialty distributors or suppliers, this would expose us to substantial risk in our clinical development or commercialization efforts.

Failure to obtain marketing approval in international jurisdictions would prevent our approved product, Jelmyto, and our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. Regulatory approval processes outside the United States generally include all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be commercialized in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to submit for marketing approvals and may not receive the necessary approvals to commercialize our product candidates in any particular market. Even though *Jelmyto* is fully approved for marketing in Israel, there can be no assurance that it will achieve the broad degree of physician adoption and use, reimbursement and market acceptance necessary for commercial success.

We rely on third parties and consultants to assist us in conducting our clinical trials for our product candidates. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize UGN-102 or any of our other product candidates.

We do not have the ability to independently conduct many of our nonclinical studies or our clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs to conduct clinical trials on our product candidates. Third parties play a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. Due to the limited drug development for non-muscle invasive urothelial cancers over the past 15 years, neither we nor any third-party clinical investigators, CROs and/or consultants are likely to have extensive experience conducting clinical trials for the indications we are targeting. If our CROs or any other third parties upon which we rely for administration and conduct of our clinical trials do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, or if they otherwise perform in a substandard manner, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to complete development of, obtain regulatory approval for, or successfully commercialize UGN-102 or any of our other product candidates.

We and the third parties upon whom we rely are required to comply with Good Clinical Practice ("GCP"), regulations, which are regulations and guidelines enforced by regulatory authorities around the world for products in clinical development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or our third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed, or the regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, a regulatory authority will determine that any of our clinical trials comply or complied with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under current GMP regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be impacted if our CROs, clinical investigators or other third parties violate federal or state fraud and abuse or false claims laws and regulations; healthcare privacy and security laws; and bribery and anti-corruption laws.

In order for our clinical trials to be carried out effectively and efficiently, it is imperative that our CROs and other third parties communicate and coordinate with one another. Moreover, our CROs and other third parties may also have relationships with other commercial entities, some of which may compete with us. Our CROs and other third parties may terminate their agreements with us upon as few as 30 days' notice under certain circumstances. If our CROs or other third parties conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs, clinical investigators or other third parties on commercially reasonable terms, or at all. Switching or adding CROs, clinical investigators or other third parties can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationship with our CROs, clinical investigators and other third parties, there can be no assurance that we will not encounter such challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, prospects, financial condition or results of operations.

If in the future we acquire or in-license technologies or product candidates, we may incur various costs, may have integration difficulties and may experience other risks that could harm our business and results of operations.

In the future, we may acquire or in-license additional product candidates and technologies. Any product candidate or technologies we in-license or acquire will likely require additional development efforts prior to commercial sale, including extensive nonclinical or clinical testing, or both, and approval by the FDA and applicable foreign regulatory authorities, if any. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate, or product developed based on in-licensed technology, will not be shown to be sufficiently safe and effective for approval by regulatory authorities. If intellectual property related to product candidates or technologies we in-license is not adequate, we may not be able to commercialize the affected products even after expending resources on their development. In addition, we may not be able to economically manufacture or successfully commercialize any product candidate that we develop based on acquired or in-licensed technology that is granted regulatory approval, and such products may not gain wide acceptance or be competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed product candidates could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, our business may be materially harmed.

We will need to continue to increase the size of our organization. If we fail to manage our growth effectively, our business could be disrupted.

As of January 31, 2024, we had 201 employees, of whom 40 are based in Israel and 161 are based in the United States. We will need to continue to expand our development, quality, managerial, operational, finance, marketing, sales and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

As we continue to grow as an organization, including by expanding our development efforts and building out and developing our commercial capabilities to support our commercialization of *Jelmyto*, we will evaluate, and may implement, changes to our organization that may be appropriate in order to properly manage and direct our growth and transformation into a commercial-stage company. Due to our limited financial resources and our limited experience in managing a larger company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion or other significant changes to our organization could delay the execution of our development, commercialization and strategic objectives or disrupt our operations; and if we are not successful in commercializing our approved product or any of our product candidates that may receive regulatory approval, either on our own or through collaborations with one or more third parties, our revenues will suffer, and we would incur significant additional losses.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any of our other products we develop.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and face or will face an even greater risk with the commercialization of *Jelmyto* and any investigational product candidates that receive marketing approval. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for *Jelmyto* and our investigational product candidates we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation, which may be only partially recoverable even in the event of successful defenses;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues;
- exhaustion of any available insurance and our capital resources; and
- the inability to commercialize any product we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of products we may develop. We currently carry general clinical trial product liability insurance in an amount that we believe is adequate to cover the scope of our ongoing clinical programs. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. As a result of receiving marketing approval of *Jelmyto*, we have expanded our insurance coverage to include the commercialization of *Jelmyto*; however, we may be unable to continue to obtain this liability insurance on commercially reasonable terms and such insurance may be insufficient to cover our exposure. In addition, if and when we obtain approval for marketing UGN-102 or any other product candidate, we intend to further expand our insurance coverage to include the commercialization of UGN-102 or any other approved product; however, we may be unable to obtain this additional liability insurance on commercially reasonable terms.

If we fail to attract and keep senior management and key personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize any of the products we develop.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical, scientific and other personnel. We believe that our future success is highly dependent upon the contributions of members of our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

Although we have not historically experienced unique difficulties in attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the pharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

If our information technology systems or data, or those of third parties upon whom we rely, are or were compromised, this could result in adverse consequences resulting from such compromise including but not limited to regulatory investigations or actions; litigation; fines and penalties; a material disruption of our drug development program; compromise sensitive information related to our business; harm our reputation; triggering our breach notification obligations; prevent us from accessing critical information; disruptions of our business operations; loss of revenue or profits; loss of customers or sales and expose us to liability or other adverse effects to our business.

In the ordinary course of our business, we, and the third parties upon which we rely, process proprietary, confidential and sensitive information, including personal data (such as health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties (collectively, sensitive information).

We, our CROs and other contractors, consultants, third-party vendors, and other third parties on which we rely, depend on information technology, telecommunication systems and data processing for significant elements of our operations, including, for example, systems handling human resources, financial reporting and controls, regulatory compliance and other infrastructure operations. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI, and other similar threats.

In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, disruption of clinical trials, loss of data (including data related to clinical trials), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, ransomware attack victims may prefer to make payment demands, but if we were to be a victim of such an attack, we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach or disruption of our systems and networks or the systems or networks of third parties that support us. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely), but we may be unable to detect and remediate all vulnerabilities on a timely basis in our information technology systems because such threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Therefore, such vulnerabilities could be exploited and result in a security incident, which may not be detected until after the incident has occurred.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information

technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Additionally, applicable data privacy and security obligations and public company disclosure obligations may require us to notify relevant stakeholders, including affected individuals, regulators and investors, of certain security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. For example, failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of sensitive information, including preventing us from conducting clinical trials, tests or research and development activities and preventing us from managing the administrative aspects of our business. In addition, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. If the information technology systems of our third-party vendors and other contractors become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. In addition, whether a cybersecurity incident is reportable to our investors may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure we provide. Moreover, experiencing a material cybersecurity incident and any mandatory disclosures could lead to negative publicity, loss of investor, customer or partner confidence in the effectiveness of our cybersecurity measures, diversion of management's attention, governmental investigations, lawsuits, and the expenditure of significant capital and other resources.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Under applicable employment laws, we may not be able to enforce covenants not to compete.

We generally enter into non-competition agreements as part of our employment agreements with our employees. These agreements generally prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work, and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us.

For example, Israeli labor courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts as justification for the enforcement of non-compete undertakings, such as the protection of a company's trade secrets or other intellectual property.

Additionally, on July 9, 2021, President Biden signed an executive order encouraging the Federal Trade Commission ("FTC") to curtail unfair use of non-compete agreements and other agreements that may unfairly limit worker mobility. While we cannot predict how the initiatives set forth in the executive order will be implemented or, as a result, the impact that the executive order will have on our operations, there is now increased uncertainty regarding the long-term enforceability of our non-compete agreements. In January 2023, the FTC proposed a rule that, if enacted, would prohibit employers from entering into non-compete clauses with workers and require employers to rescind existing non-complete clauses. Moreover, the law governing non-compete agreements and other forms of restrictive covenants varies from state to state within the U.S. and some states are reluctant to strictly enforce non-compete agreements.

Our employees, independent contractors, clinical investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, clinical investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct, breach of contract or other unauthorized activities that violate: FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws; buying or selling of our ordinary shares while in possession of material non-public information; or laws that require the reporting of financial information or data accurately.

Specifically, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. Activities subject to these laws also include the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Corporate Code of Ethics and Conduct and a Compliance Program, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, even if we are successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business. Violations of such laws subject us to numerous penalties, including, but not limited to, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Most states also have statutes or regulations similar to these federal laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. We and/or our future partners may be subject to administrative, civil and criminal sanctions for violations of any of these federal and state laws. Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, improper consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations, which could have a significant impact on the conduct of our business.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party subcontractors' and suppliers' activities involve the controlled storage, use, transportation and disposal of hazardous materials owned by us, including mitomycin, key components of our product candidates, and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Despite our efforts, we cannot eliminate the risk of contamination. This could cause an interruption of our commercialization efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our subcontractors and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations.

Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Exchange rate fluctuations between the U.S. Dollar and the New Israeli Shekel may negatively affect our earnings.

The U.S. dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in NIS, which is the lawful currency of the State of Israel. As a result, we are exposed to the risks that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. For example, the dollar appreciated against the NIS during 2023 by a total of 2.4%. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the dollar. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected.

Our business could be adversely affected by the effects of health pandemics, epidemics or other public health emergencies.

A pandemic, epidemic or other public health emergencies pose the risk that we or our employees, contractors, suppliers, customers, and other partners may be prevented from conducting certain business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. For example, COVID-19 and mitigation measures to slow its spread had an adverse impact on global economic conditions. While it is not possible at this time to estimate the impact that any such pandemic, epidemic or other public health emergency could have on our business, if such an event were to occur, it could have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The measures that may be taken by various governments, in response to a pandemic, epidemic or other public health emergency could disrupt the supply chain of material needed for our product candidates and our approved product, *Jelmyto*, interrupt healthcare services, delay coverage decisions from Medicare and third party payors, delay ongoing and planned clinical trials involving our product candidates, curtail access to hospitals, surgery centers, clinics, healthcare providers and pharmacies by our sales force and have a material adverse effect on our business, financial condition and results of operations.

To the extent any future pandemics, epidemics or public health emergencies adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in the “Risk Factors” section of this report.

Certain of our clinical trials and other significant operations (including our Israeli corporate offices and contract manufacturers) are located outside of the United States and, therefore, our results may be adversely affected by geopolitical, economic and military instability.

Certain of our clinical trials operate outside the U.S. and certain of our research and development facilities and key vendors and suppliers are located in Israel. If any of these current or future trials or the related facilities or our or our vendors' and suppliers' facilities in Israel were to be damaged, destroyed or otherwise unable to operate, whether due to war, acts of hostility, earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, pandemic, power outages or otherwise, or if performance of our clinical trials are disrupted for any other reason, such an event could cause significant development and product delays. If we experience delays in achieving our development objectives within a timeframe that meets our prospective customers’ expectations, our business, prospects, financial results and reputation could be harmed.

Geopolitical, economic and military conditions around the world may directly affect our business. Any hostilities involving any of the countries in which we operate, including terrorist activities, political instability or violence in the region or the interruption or curtailment of trade or transport between such country and its trading partners could adversely affect our operations and results of operations and adversely affect the market price of our ordinary shares.

Our business activities may be subject to the* FCPA *and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

We currently dedicate certain resources to comply with numerous laws and regulations in each jurisdiction in which we operate outside of the United States. Our business activities in these foreign countries may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate.

The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and U.S. Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

In addition, our product and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our product, or our failure to obtain any required import or export authorization for our product, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our product may create delays in the introduction of our product in international markets or, in some cases, prevent the export of our product to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or product targeted by such regulations, could result in decreased use of our product by, or in our decreased ability to export our product to existing or potential customers with international operations. Any decreased use of our product or limitation on our ability to export or sell access to our product would likely significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our product candidates and technologies are not adequate, we may not be able to compete effectively, and we otherwise may be harmed.

Our commercial success depends in part upon our ability to obtain and maintain patent protection and utilize trade secret protection for our proprietary technologies, our products and their uses, as well as our ability to operate without infringing upon the proprietary rights of others. We rely upon a combination of patents, trade secret protection and confidentiality agreements, assignment of invention agreements and other contractual arrangements to protect the intellectual property related to hydrogel-based pharmaceutical compositions for optimal delivery of a drug in internal cavities such as the bladder, the method for treating cancer, in particular urothelial and bladder cancer using hydrogel-based compositions, the method for treating overactive bladder topically without the need for injections, including an in-dwelling ureter catheter system for optimal delivery of a drug into the renal cavity.

We seek patent protection for our product candidates, and we hold a broad collection of intellectual property comprised of issued patents, in-licensed patents, pending patent applications, trade secrets and trademarks covering our proprietary *RTGel* technology, the pharmaceutical compositions, methods of use and manufacturing aspects of our product candidates. In the United States, we currently hold 19 granted patents that are directed to protect our approved product, *Jelmyto* and our lead product candidate, UGN-102, as well as UGN-103 and UGN-104, a proprietary *RTGel* technology, local compositions comprising different active ingredients, inter alia compositions comprising a Botulinum Toxin, UGN-201, the use of UGN-201 and UGN-301, and our future product candidates that are under company research. These IP rights relate to certain aspects of cancer treatment. These issued patents are set to expire between 2024 and 2037. In total, our IP portfolio includes 43 granted patents worldwide, and more than 45 pending patent applications filed in the U.S., Europe, Israel, Japan, Canada, China, Mexico and Australia that are directed to cover various methods, systems and compositions for treating cancer locally, by intravesical means, utilize various active ingredients and the combinations thereof. These patent applications, if issued, are set to expire between 2031 and 2043.

Limitations on the scope of our intellectual property rights may limit our ability to prevent third parties from designing around such rights and competing against us. For example, our patents do not claim a new compound. Rather, the active pharmaceutical ingredients of our products are known compounds and our patents and pending patent applications are directed inter alia to novel formulations of these known compounds with our proprietary *RTGel* technology. Accordingly, other parties may compete with us, for example, by independently developing or obtaining competing topical formulations that design around our patent claims, but which may contain the same active ingredients, or by seeking to invalidate our patents. Any disclosure of or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in the market.

We will not necessarily seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

One or more of the patent applications that we filed, or license may fail to result in granted patents in the United States or foreign jurisdictions, or if granted may fail to prevent a potential infringer from marketing its product or be deemed invalid and unenforceable by a court. Competitors in the field of reverse thermal gel therapies have created a substantial amount of scientific publications, patents and patent applications and other materials relating to their technologies. Our ability to obtain and maintain valid and enforceable patents depends on various factors, including interpretation of our technology and the prior art and whether the differences between them allow our technology to be patentable. Patent applications and granted patents are complex, lengthy and highly technical documents that are often prepared under limited time constraints and may not be free from errors that make their interpretation uncertain. The existence of errors in a patent may have an adverse effect on the patent, its scope and its enforceability. Our pending patent applications may not issue, and the scope of the claims of patent applications that do issue may be too narrow to adequately protect our competitive advantage. Also, our granted patents may be subject to challenges or narrowly construed and may not provide adequate protection.

We may be subject to claims that we infringe, misappropriate or otherwise violate the intellectual property rights of third parties.

Even if our patents do successfully issue, third parties may challenge the validity, enforceability or scope of such granted patents or any other granted patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant. Also, patents granted by the USPTO may be subject to reexamination and other challenges.

Pharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position. There is significant litigation activity in the pharmaceutical industry regarding patent and other intellectual property rights. Such litigation could result in substantial costs and be a distraction to management and other employees.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering pharmaceutical compositions may be uncertain and difficult to determine and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. Furthermore, even if they are not challenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. To meet such challenges, which are part of the risks and uncertainties of developing and marketing product candidates, we may need to evaluate third party intellectual property rights and, if appropriate, to seek licenses for such third party intellectual property or to challenge such third party intellectual property, which may be costly and may or may not be successful, which could also have an adverse effect on the commercial potential for *Jelmyto*, UGN-102 and any of our other product candidates.

We may receive only limited protection, or no protection, from our issued patents and patent applications.

There can be no assurance that the patent applications will be granted. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained.

The patent application process, also known as patent prosecution, is expensive and time consuming, and we or any future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or any future licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects that we believe are of material import. If we or any future licensors or licensees fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or in-license may fail to result in issued patents in the United States or foreign countries with claims that cover our product candidates. Even if patents do successfully issue from the patent applications that we own or in-license, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be challenged, also known as opposed, by any person within nine months from the publication of their grant. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our product candidates, provide exclusivity for our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize our product candidates.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. On February 25, 2024, we received a Paragraph IV Certification Notice Letter from Teva, providing notification that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of *Jelmyto*. In the Notice Letter, Teva alleges that two of the patents listed in the FDA Orange Book for *Jelmyto*, U.S. Patent Numbers 9,040,074 and 9,950,069 each of which expires in January 2031, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission. If we are unable to maintain patent protection for *Jelmyto*, *Jelmyto* will be subject to immediate competition from generic entrants after regulatory exclusivity expires in April 2027. Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

A considerable number of our patents and patent applications are entitled to effective filing dates prior to March 16, 2013. For U.S. patent applications in which patent claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party, for example a competitor, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by those patent claims. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management.

Our trade secrets may not have sufficient intellectual property protection.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our product candidates, and our product development processes (such as manufacturing and formulation technologies) that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have an adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, advisors, and any other third parties that have access to our proprietary know-how, information or technology, for example, third parties involved in the formulation and manufacture of our product candidates, and third parties involved in our clinical trials to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us is kept confidential and not disclosed to third parties. However, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed despite having such confidentiality agreements. Adequate remedies may not exist in the event of unauthorized use or disclosure of our trade secrets. In addition, in some situations, these confidentiality agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by third parties in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. If we are unable to prevent unauthorized material disclosure of our trade secrets to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could harm our business, operating results and financial condition.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the America Invents Act ("AIA"), was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in a United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process.

Periodic maintenance fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications directed to our product candidates, our competitors might be able to enter the market earlier than should otherwise have been the case, which could harm our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

If we are unable to protect our trademarks from infringement, our business prospects may be harmed.

We filed applications for trademarks (*Jelmyto*®, *RTGel*®, and UroGen®) that identify our branding elements, such as *Jelmyto* and our unique technology in the United States, Europe, Japan and China. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights or the patents of our licensors, which could be expensive and time consuming.

Third parties may infringe or misappropriate our intellectual property, including our existing patents, patents that may issue to us in the future, or the patents of our licensors to which we have a license. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Drug manufacturers may develop, seek approval for, and launch generic versions of our products. For example, in February 2024, we received a Paragraph IV certification notice letter from Teva Pharmaceuticals, Inc. ("Teva") providing notification to us that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of *Jelmyto*. If we do not file a patent infringement lawsuit against a generic manufacturer within 45 days of receiving notice of its Paragraph IV certification, the ANDA applicant may not be subject to a 30-month stay. If we file an infringement action against a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

In addition, if we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

Furthermore, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the pharmaceutical industry. Recently, the AIA introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including challenges by competitors who perceive our patents as blocking entry into the market for their products, and the outcome of such challenges.

Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patents such that they do not cover our product candidates. They may also put our pending patent applications at risk of not issuing or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a negative impact on our business.

Enforcing our or our licensors' intellectual property rights through litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition or results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our ordinary shares could be significantly harmed.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our employees during their employment. Our employees execute agreements that assign to us any ownership interest in a patent or patent application created in the scope of the employee's employment. In Israel, the Israeli Patent Law, 5727-1967, or the Patent Law, provides that inventions conceived by an employee during the scope of his or her employment with a company are regarded as "service inventions." Accordingly, our employees in Israel also enter into agreements that, among other things, waive the right to special remuneration for service inventions created in the scope of their employment or engagement. The Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, has previously held, in certain cases, that employees may be entitled to remuneration for service inventions that they develop during their service for a company despite their explicit waiver of such right. Therefore, although we enter into agreements with our Israeli employees that waive their right to special remuneration for service inventions created in the scope of their employment or engagement, we may nonetheless face claims by employees demanding remuneration beyond their regular salary and benefits.

Third-party claims alleging intellectual property infringement may adversely affect our business.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, for example, the intellectual property rights of competitors. Our commercialization activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidates may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates will not infringe existing or future patents. We may unknowingly infringe existing patents by commercialization of our product candidates. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our product candidates. Nevertheless, we are not aware of any issued patents that we believe would prevent us from marketing our product candidates, if approved. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us.

Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Defense of these claims, regardless of their merit, would cause us to incur substantial expenses, and would be a substantial diversion of management time and employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (i) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (ii) obtain one or more licenses from the third party; (iii) pay royalties to the third party; and/or (iv) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditures. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our product candidates, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Defending ourselves or our licensors in litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition or results of operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a negative impact on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Government Regulation

If the FDA does not conclude that UGN-102 satisfies the requirements under 505(b)(2), or if the requirements for our product candidates are not as we expect, the approval pathway for these product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), added 505(b)(2) to the FDCA. 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant, and for which the applicant has not received a right of reference, which could expedite the development program for UGN-102 and our other product candidates by potentially decreasing the amount of nonclinical and clinical data that we would need to generate in order to obtain FDA approval. However, while we believe that our product candidates are reformulations of existing drugs and, therefore, will not be treated as NCEs, the submission of an NDA under the 505(b)(2) pathway does not preclude the FDA from determining that the product candidate that is the subject of such submission is an NCE and therefore not eligible for review under such regulatory pathway.

If the FDA does not allow us to pursue the 505(b)(2) pathway as anticipated, we may need to conduct additional nonclinical experiments and clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely increase significantly. Moreover, inability to pursue the 505(b)(2) pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) pathway, our product candidates may not receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under 505(b)(2) certain competitors and others have objected to the FDA's interpretation of 505(b)(2). If the FDA's interpretation of 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our potential future NDAs for up to 30 months depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the 505(b)(2) regulatory pathway for our product candidates, there is no guarantee this would ultimately lead to faster product development or earlier approval.

Moreover, even if these product candidates are approved under the 505(b)(2) pathway, as the case may be, the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

In addition, there have been a number of recent regulatory and legislative initiatives designed to encourage generic competition for pharmaceutical products, including expedited review procedures for generic manufacturers and incentives designed to spur generic competition of branded drugs. In particular, the FDA and the FTC have been focused on brand companies' denial of drug supply to potential generic competitors for testing. In December 2019, the CREATES Act was enacted, which provides a legislatively defined private right of action under which generic companies can bring suit against companies who refuse access to product for the bioequivalence testing needed to support approval of a generic product.

We cannot currently predict the specific outcome or impact on our business of such regulatory and legislative initiatives, litigation or investigation. However, it is our policy, which is in compliance with the CREATES Act, to evaluate requests for samples of our approved product, and to provide samples in response to bona fide requests from qualified third parties, including generic manufacturers, subject to specified conditions. We have provided samples of *Jelmyto* to certain generic manufacturers.

We expect current and future legislation affecting the healthcare industry, including healthcare reform, to impact our business generally and to increase limitations on reimbursement, rebates and other payments, which could adversely affect third-party coverage of our products, our operations, and/or how much or under what circumstances healthcare providers will prescribe or administer our products, if approved.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), laws intended, among other things, to broaden access to health insurance, improve quality of care, and reduce or constrain the growth of healthcare spending.

There have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear any such challenges, other litigation and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which started in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, and the Consolidated Appropriations Act of 2023, will stay in effect until 2032, unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's AMP, for single source and innovator multiple source drugs, beginning January 1, 2024.

Additionally, there have been several recent U.S. presidential executive orders, Congressional inquiries and proposed and enacted legislation at the federal and state levels designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, for example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, on November 15, 2021, President Biden signed into law the Infrastructure Investment and Jobs Act. Beginning on January 1, 2023, manufacturers will be required to pay quarterly refunds to CMS for discarded amounts of certain single-dose container and single-use package drugs payable under part B of the Medicare program. Refunds will generally be based on the discarded volume above 10% of the total allowed amount. However, in unique circumstances, CMS will increase the applicable threshold to 35%. At this time, CMS has determined that *Jelmyto* fits within this unique circumstance classification. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. If healthcare policies or reforms intended to curb healthcare costs are adopted, or if we experience negative publicity with respect to the pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

These laws may result in additional reductions in healthcare funding, which could have an adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether regulations, guidance or interpretations will be changed, or what the impact of such changes on our operations, including the marketing approvals of UGN-102 or our other product candidates may be.

Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products. This could adversely affect our business by reducing our ability to generate revenues, raise capital, obtain additional licensees and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

We may be unable to obtain Orphan Drug Designation or exclusivity for future product candidates we may develop. If our competitors are able to obtain orphan drug exclusivity for their products that are for the same indication as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Under the Orphan Drug Act of 1983 (the "Orphan Drug Act"), the FDA may designate a product as an orphan drug if it is intended to treat an orphan disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the United States, Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has Orphan Drug Designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Although the FDA has granted orphan drug exclusivity to *Jelmyto* for the treatment of UTUC, we may not receive orphan drug exclusivity for any of our other product candidates that have received orphan designation.

Although the FDA has granted Orphan Drug Designation to *Jelmyto* and UGN-201 for treatment of UTUC and CIS, respectively, we may not receive Orphan Drug Designation for any of our other product candidates. If our competitors are able to obtain orphan drug exclusivity for their products that are the same or similar to our product candidates before our drug candidates are approved, we may not be able to have competing product candidates approved by the FDA for a significant period of time. Any delay in our ability to bring our product candidates to market would negatively impact our business, revenue, cash flows and operations.

Orphan Drug Designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug exclusivity for our product candidates, we may be subject to earlier competition and our potential revenue will be reduced.

Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax advantages, user-fee waivers and market exclusivity for certain periods of time.

Jelmyto and UGN-201 have been granted Orphan Drug Designation for the treatment of UTUC and CIS, respectively, in the United States. Even if we obtain Orphan Drug Designation for our other product candidates, we may not be the first to obtain regulatory approval for any particular orphan indication due to the uncertainties associated with developing biotechnology products. Further, even if we obtain Orphan Drug Designation for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate we are pursuing for the same indication, approval of our product candidate would be blocked during the period of marketing exclusivity unless we could demonstrate that our product candidate is clinically superior to the approved product. Conversely, even if we are granted orphan exclusivity, a competitor that demonstrates clinical superiority with the same active moiety may obtain approval prior to expiration of our exclusivity. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate, we are pursuing for a different orphan indication, this may negatively impact the market opportunity for our product candidate. There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, and future challenges could lead to changes that affect the protections afforded our product candidates in ways that are difficult to predict.

Jelmyto and any of our product candidates that receive regulatory approval will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses, limit or withdraw regulatory approval and subject us to penalties if we fail to comply with applicable regulatory requirements.

Jelmyto and any of our product candidates that receive regulatory approval will be subject to continual regulatory review by the FDA and/or foreign regulatory authorities. Additionally, *Jelmyto* and any of our product candidates that receive regulatory approval will be subject to extensive and ongoing regulatory requirements, including labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

The FDA approval of *Jelmyto* is, and any regulatory approvals that we receive for our product candidates may be, subject to limitations on the approved indications for which the product may be marketed or to the conditions of approval. In addition, any regulatory approvals that we receive for our current or future product candidates may contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for *Jelmyto* is, and any of our product candidates that receive regulatory approval will be, subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval.

Later discovery of previously unknown problems with our products or product candidates, including adverse events of unanticipated severity or frequency, or problems with our third-party manufacturers' processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us, or suspension or revocation of product license approvals; and
- product seizure or detention, or refusal to permit the import or export of products; and injunctions or the imposition of civil or criminal penalties.

Our ongoing regulatory requirements may also change from time to time, potentially harming or making costlier our commercialization efforts. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business.

Our relationships with healthcare professionals, independent contractors, clinical investigators, CROs, consultants and vendors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face significant penalties.

We are subject to various U.S. federal, state and foreign health care laws, including those intended to prevent health care fraud and abuse. These laws may impact, among other things, our clinical research, sales and marketing activities, and constrain the business or financial arrangements with healthcare providers, physicians, and other parties that have the ability to directly or indirectly influence the prescribing, ordering, marketing, or distribution of products for which we obtain marketing approval.

The federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, by a federal healthcare program such as Medicare and Medicaid. Remuneration has been broadly defined to include anything of value, including, but not limited to, cash, improper discounts, and free or reduced-price items and services.

Federal false claims laws, including the federal civil False Claims Act (the "FCA"), and civil monetary penalties law impose penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or making a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. The FCA has been used to, among other things, prosecute persons and entities submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims.

Many states have similar fraud and abuse statutes and regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. State and federal authorities have aggressively targeted pharmaceutical companies for, among other things, alleged violations of these anti-fraud statutes, based on among other things, unlawful financial inducements paid to prescribers and beneficiaries, as well as impermissible promotional practices, including certain marketing arrangements that rely on volume-based pricing and off-label promotion of FDA-approved products.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), among other things, imposes civil and criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including public and private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their implementing regulations, impose, among other things, specified requirements on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their business associates as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information, including mandatory contractual terms and required implementation of certain safeguards of such information. Among other things, HITECH makes HIPAA’s security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways, may not have the same effect and may not be preempted by HIPAA, thus complicating compliance efforts.

Our operations are also subject to the federal Open Payments program pursuant to the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to annually report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members to CMS. We may also be subject to state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, drug pricing, and/or state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidelines promulgated by the federal government.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any payor, including commercial insurers. In addition, we may be subject to certain foreign healthcare laws that are analogous to the U.S. healthcare laws described above. If any of our business activities, including but not limited to our relationships with healthcare providers, are found to violate any of the aforementioned laws, we may be subject to significant administrative, civil and criminal penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and future earnings and curtailment or restructuring of our operations.

Also, the FCPA and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Legislative or regulatory healthcare reforms in the United States or abroad may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates or any future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress in the United States or by governments in foreign jurisdictions that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA or foreign regulatory agency regulations and guidance are often revised or reinterpreted by the FDA or the applicable foreign regulatory agency in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our product candidates or any future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

We are subject to stringent and changing U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, self-regulatory schemes, government regulation, policies, standards, and other obligations related to data privacy and security. The actual or perceived failure by us, our customers, partners or vendors to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; or otherwise adversely affect our business.

In the ordinary course of our business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") proprietary, confidential, and sensitive data, including personal data, intellectual property, and trade secrets (collectively, "sensitive information"). Our data processing activities are subject to numerous data privacy and security obligations, such as domestic and foreign laws and regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to privacy, data protection, and data security.

In the United States, federal, state, and local governments have enacted numerous privacy, data protection, and data security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, as further described above, HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 as amended by the California Privacy Rights Act of 2020 (collectively "CCPA") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered at the federal, state, and local levels and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts and increase legal risk and compliance costs for us, the third parties upon whom we rely. Furthermore, we may be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws. These laws demonstrate our vulnerability to the evolving regulatory environment related to personal data. As we expand our operations, these and similar laws may increase our compliance costs and potential liability.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to privacy, data protection, and data security. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") impose strict requirements for processing personal data. Our upcoming clinical trial will include sites in the EU, which will increase our exposure to potential liability under the EU GDPR. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. We anticipate that over time we may expand our business to include additional operations outside of the United States and Israel. With such expansion, we would be subject to increased governmental regulation in other countries in which we might operate, including the EU GDPR. Assisting our customers, partners, and vendors in complying with the EU GDPR or other foreign laws, or complying with such laws ourselves, may cause us to incur substantial operational costs or require us to change our business practices. Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. Our inability or failure to do so could result in adverse consequences, including class action litigation and mass arbitration demands.

Moreover, in the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Inability to import personal data from Europe to the United States may limit our ability to conduct clinical trial activities in Europe, limit our ability to collaborate with contract research organizations, service providers, contractors and other entities subject to European data protection laws, adversely impact our operations, product development and ability to provide our products, and require us to increase our data processing capabilities in Europe at significant expense. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Our employees and personnel may use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. We may also use AI or machine learning ("ML") to assist us in making certain decisions, which is regulated by certain privacy laws. Due to inaccuracies or flaws in the inputs, outputs, or logic of the

AI/ML, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model. Our business model materially depends on our ability to process personal data, so we are particularly exposed to the risks associated with the rapidly changing legal landscape. For example, we may be at heightened risk of regulatory scrutiny, and any changes in the regulatory framework could require us to fundamentally change our business model. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could negatively impact our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We maintain workers compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

It may be difficult for us to profitably sell our product candidates if coverage and reimbursement for these products is limited by government authorities and/or third-party payor policies.

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of *Jelmyto*, UGN-102 and our other product candidates, if approved, will depend on the coverage and reimbursement policies of third-party payors, like government authorities, private health insurers, and managed care organizations. Third-party payors decide which medications they will cover and separately establish reimbursement levels. In October 2020, a Medicare C-Code was issued for *Jelmyto* and we have obtained pass-through status for two years, no more than three. CMS has established a permanent and product-specific J-code for *Jelmyto* that took effect on January 1, 2021. Our existing pass-through status was set to expire in the fourth quarter of 2023. However, CMS granted *Jelmyto* a New Technology APC (Ambulatory Payment Classification), effective from October 1, 2023. A service is separately for paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. This generally occurs within two to three years from the time a new HCPCS code becomes effective. However, if CMS are able to collect sufficient claims data in less than two years, CMS may consider reassigning the service to an appropriate APC, or, if CMS does not have sufficient data at the end of three years upon which to base its reassignment to an appropriate clinical APC, CMS may keep the service in a New Technology APC until adequate data become available. Loss of our New Technology APC may result in Medicare beneficiaries losing access to *Jelmyto* in the hospital outpatient setting and *Jelmyto* becoming packaged into a comprehensive ambulatory payment classification.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government and other third-party payors are increasingly challenging the prices charged for health care products, examining the cost effectiveness of drugs in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement for prescription drugs. Although our experience to date has demonstrated coverage for *Jelmyto*, we cannot be sure that adequate coverage will be available for UGN-102 or our other product candidates, if approved, or, if coverage is available, the level of reimbursement will be adequate to make our products affordable for patients or profitable for us. In addition, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass price increases on to our customers due to the process by which healthcare providers are reimbursed for our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, decisions about reimbursement for new medicines under Medicare are made by CMS, as the administrator for the Medicare program. Private third-party payors often use CMS as a model for their coverage and reimbursement decisions, but also have their own methods and approval process apart from CMS's determinations. Our experience to date has demonstrated coverage with CMS and commercial payors for *Jelmyto*, and we have established written policies with certain commercial providers. However, it is difficult to predict what CMS as well as other third-party payors will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products.

Reimbursement may impact the demand for, and/or the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover all or a significant portion of the cost of our products. Moreover, for products administered under the supervision of a physician, obtaining and maintaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or applicable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

Reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining and maintaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. We may not be able to provide data sufficient to gain acceptance with respect to coverage and/or sufficient reimbursement levels.

Although we have obtained written policy coverage in commercial plans as well as coverage for government plans for *Jelmyto* to date, we cannot be sure that adequate coverage or reimbursement will continue to be available for *Jelmyto*, or be available for UGN-102 or any of our other product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize *Jelmyto*, UGN-102 or our other product candidates, or achieve profitably at all, even if approved. Additionally, coverage policies and reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for any of our products or product candidates that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. For example, beginning on January 1, 2023, manufacturers will be required to pay quarterly refunds to CMS for discarded amounts of single-dose container and single-use package drugs covered under Medicare Part B. Rebates will generally be based on the discarded volume above 10% of the total allowed amount. CMS has been receptive to evaluating the feasibility of the 10% threshold, and where appropriate, has modified the discarded volume threshold accordingly. In unique circumstances, CMS will increase the applicable threshold to 35%. At this time, CMS has determined that *Jelmyto* fits within this unique circumstance. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement for our products, the commercial success of our products may be greatly hindered and our financial condition and results of operations may be materially and adversely affected.

Risks Related to Ownership of Our Ordinary Shares

The market price of our ordinary shares has been and may continue to be subject to fluctuation and you could lose all or part of your investment.

The stock market in general has been, and the market price of our ordinary shares in particular has been and may continue to be, subject to fluctuation, whether due to, or irrespective of, our operating results and financial condition. The market price of our ordinary shares on the Nasdaq Global Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to:

- the commercial success of *Jelmyto*;
- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- physician and market acceptance of *Jelmyto* or any other approved product;
- the mix of products that we sell;
- any voluntary or mandatory recall of *Jelmyto* or any other approved product, or the imposition of any additional labeling, marketing or promotional restrictions;
- our success or failure to obtain approval for and commercialize our product candidates;
- changes in the structure of healthcare payment systems;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of nonclinical or clinical trials for *Jelmyto*, UGN-102 or our other product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced product candidates and the generation of sales from those products;
- developments concerning intellectual property rights;
- the announcement of, or developments in, any litigation matters, including any product liability claims related to *Jelmyto* or any of our product candidates;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our products;
- our sale or proposed sale, or the sale by our significant shareholders, of our ordinary shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our ordinary shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may negatively impact the market price of our ordinary shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company shareholders have often instituted securities class action litigation. If we were to become involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business.

Future sales of our ordinary shares could reduce the market price of our ordinary shares.

If our existing shareholders, particularly our directors, their affiliates, or our executive officers, sell a substantial number of our ordinary shares in the public market, the market price of our ordinary shares could decrease significantly. The perception in the public market that our shareholders might sell our ordinary shares could also depress the market price of our ordinary shares and could impair our future ability to obtain capital, especially through an offering of equity securities.

In addition, our sale of additional ordinary shares or other securities in order to raise capital might have a similar negative impact on the share price of our ordinary shares. A decline in the price of our ordinary shares might impede our ability to raise capital through the issuance of additional ordinary shares or other equity securities and may cause you to lose part or all of your investment in our ordinary shares.

Future equity offerings could result in future dilution and could cause the price of our ordinary shares to decline.

In order to raise additional capital, we may in the future offer additional ordinary shares or other securities convertible into or exchangeable for our ordinary shares at prices that we determine from time to time, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. We may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. On December 20, 2019, we entered into the ATM Sales Agreement pursuant to which we may from time to time offer and sell our ordinary shares, having an aggregate offering price of up to $100.0 million, to or through Cowen, acting as sales agent or principal, in any manner deemed to be an "at-the market offering". As of February 29, 2024, $56.8 million remain available for sale under the ATM Sales Agreement. The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 filed with the SEC on November 15, 2022, which was declared effective on November 29, 2022.

The significant share ownership position of our officers, directors and entities affiliated with certain of our directors may limit your ability to influence corporate matters.

Our officers, directors and entities affiliated with certain of our directors beneficially own a significant portion of our outstanding ordinary shares. Accordingly, these persons are able to significantly influence, though not independently determine, the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our board of directors, and the outcome of any proposed merger or consolidation of our company. These interests may not be consistent with those of our other shareholders. In addition, these persons' significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our ordinary shares.

We have never paid cash dividends on our share capital, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our share capital, nor do we anticipate paying any cash dividends on our share capital in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our ordinary shares will be investors' sole source of gain for the foreseeable future. In addition, Israeli law limits our ability to declare and pay dividends and may subject our dividends to Israeli withholding taxes. The Loan Agreement also restricts our ability to pay dividends.

If we are classified as a passive foreign investment company ("PFIC"), our U.S. shareholders may suffer adverse tax consequences.

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a PFIC for U.S. federal income tax purposes.

The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our ordinary shares from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering.

Based on our analysis of our income, assets, activities and market capitalization, we do not believe that we were a PFIC for the taxable year ended December 31, 2023. However, because the determination of whether or not we are a PFIC is a fact-intensive determination made on an annual basis, and because the applicable law is subject to varying interpretation, we cannot provide any assurances regarding our PFIC status for any past, current or future taxable years. Our U.S. tax counsel has not provided any opinion regarding our PFIC status in any taxable year.

If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. shareholders who are individuals, having interest charges apply to distributions by us and gains from the sales of our shares, and additional reporting requirements under U.S. federal income tax laws and regulations. A U.S. Holder that (i) owns our ordinary shares at any point during a year in which we are characterized as a PFIC and (ii) does not timely make a QEF election (as described below) will treat such ordinary shares as stock in a PFIC for all subsequent tax years, even if we no longer qualify as a PFIC under the relevant tests in such subsequent tax years. A U.S. shareholder of a PFIC generally may mitigate these adverse U.S. federal income tax consequences by making a qualified electing fund ("QEF") election, or, in some circumstances, a "mark to market" election. However, there is no assurance that we will provide the information required by the IRS in order to enable U.S. shareholders to make a timely QEF election. Moreover, there is no assurance that we will have timely knowledge of our status as a PFIC in the future. Accordingly, U.S. shareholders may be unable to make a timely QEF election with respect to our ordinary shares.

Changes to tax laws could have a material adverse effect on us and reduce net returns to our shareholders.

Our tax treatment is subject to changes in tax laws, regulations and treaties, or the interpretation thereof, as well as tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, including those related to the Organisation for Economic Co-Operation and Development's ("OECD") Base Erosion and Profit Shifting ("BEPS") Project (including "BEPS 2.0"), and the European Commission's state aid investigations and other initiatives.

Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or, in the specific context of withholding tax, dividends paid. The OECD has published a package of measures for reform as a product of BEPS, which include the reallocation of global profits of large multinational companies to market jurisdictions based on customer location as well as the introduction of a global minimum tax. Many of the package's proposed measures require amendments to the domestic tax legislation of various jurisdictions.

We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. For example, effective in 2022, the U.S. Tax Cuts and Jobs Act of 2017 eliminates the option to deduct research and development expenditures in the current period and requires U.S. taxpayers to capitalize and amortize them over five or fifteen years pursuant to Internal Revenue Code Section 174. Although Congress may defer, modify, or repeal this provision, potentially with retroactive effect, we have no assurance that Congress will take any action with respect to this provision. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future tax expenses.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable nexus, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

If a United States person is treated as owning at least 10% of our ordinary shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a "United States person" (as defined by the Internal Revenue Code of 1986, as amended (the "Code")) is treated as owning (directly, indirectly or constructively) at least 10% of the total combined voting power of all classes of our stock entitled to vote or 10% or more of the total value of all classes of our stock, such United States person may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" ("CFC") in our group (if any). Each United States shareholder of a CFC may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by the CFC, regardless of whether the CFC makes any distributions. In addition, a United States shareholder that realizes gain from the sale or exchange of shares in a CFC may be required to classify a portion of such gain as dividend income rather than capital gain. An individual who is a United States shareholder with respect to a CFC generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. A non-U.S. corporation generally will be classified as a CFC for U.S. federal income tax purposes if United States shareholders own, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. Because our group includes at least one U.S. subsidiary (UroGen Pharma, Inc.), if we were to form or acquire any non-U.S. subsidiaries in the future, attribution rules could cause them to be treated as CFCs with respect to any United States person owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares.

We cannot provide any assurances that we will assist investors in determining whether we or any non-U.S. subsidiaries that we may form or acquire in the future would be treated as a CFC or whether such investor would be treated as a United States shareholder with respect to any such CFC. Further, we cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations discussed above. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. shareholders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares.

Our ability to use our U.S. net operating loss carryforwards and certain other tax attributes to offset future taxable income and taxes may be limited.

Under U.S. federal income tax law, federal net operating losses ("NOLs") incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to utilize its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code has occurred for UroGen Pharma, Inc. If we undergo or have undergone an ownership change, our ability to utilize NOLs and other tax attributes could be limited by Sections 382 and 383 of the Code. Future changes in our share ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could negatively impact our future cash flows. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to our Operations in Israel

Our research and development and other significant operations are located in Israel and, therefore, our results may be adversely affected by political, economic and military instability in Israel.

Our research and development facility is located in Ra'anana, Israel, and certain of our key vendors and suppliers, including Isotopia Molecular Imaging Ltd., our single contracted supplier for the hydrogel contained in *Jelmyto* and UGN-102, are located within Israel. If these or any future facilities in Israel were to be damaged, destroyed or otherwise unable to operate, whether due to war, acts of hostility, earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, pandemic, power outages or otherwise, or if performance of our research and development is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved and we choose to manufacture all or any part of them internally, jeopardize our ability to manufacture our products as promptly as our prospective customers will likely expect, or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our prospective customers' expectations, our business, prospects, financial results and reputation could be harmed.

In addition, several countries, principally in the Middle East, restrict doing business with Israel, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise. Any hostilities involving Israel, terrorist activities, political instability or violence in the region or the interruption or curtailment of trade or transport between Israel and its trading partners could adversely affect our operations and results of operations and adversely affect the market price of our ordinary shares.

In October 2023, Hamas initiated an attack against Israel, provoking a state of war and the risk of a larger conflict. The intensity and duration of Israel's current war against Hamas is difficult to predict, as are such war's economic implications on our business and operations and on Israel's economy in general.

Additionally, the newly elected Israeli government has announced plans to significantly reduce the Israeli Supreme Court's judicial oversight, including reducing its ability to strike down legislation that it deems unreasonable, and plans to increase political influence over the selection of judges. These plans have prompted protests of Israeli citizens and criticism of leading Israeli business leaders as well as some foreign leaders. If such government plans are eventually enacted, they may cause operational challenges for us. In addition, if foreign policy is negatively impacted with regard to Israel, this could impact our business with suppliers and customers which could in turn adversely impact our reputation, results of operations or financial condition.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, there can be no assurance that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition and results of operations.

Further, our operations could be disrupted by the obligations of our employees to perform military service. As of January 31, 2024, we had 40 employees based in Israel. Of these employees, some may be military reservists, and may be called upon to perform military reserve duty of up to 36 days per year (and in some cases more) until they reach the age of 40 (and in some cases, up to the age of 45 or older). Since October 7, 2023, the Israeli Defense Force has called up more than 350,000 of its reserve forces to serve. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows.

Provisions of Israeli law and our articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, us, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to such types of transactions. For example, a tender offer for all of a company's issued and outstanding shares can only be completed if shareholders not accepting the tender offer hold less than 5% of the issued share capital. Completion of the tender offer also requires approval of a majority of the offerees that do not have a personal interest in the tender offer, unless shareholders not accepting the tender offer hold less than 2% of the company's outstanding shares. Furthermore, the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition an Israeli court to alter the consideration for the acquisition, unless the acquirer stipulated in its tender offer that a shareholder that accepts the offer may not seek such appraisal rights.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred. These provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

It may be difficult to enforce a judgment of a U.S. court against us, our officers and directors or the Israeli experts named in our reports filed with the SEC in Israel or the United States, to assert U.S. securities laws claims in Israel or to serve process on our officers and directors and these experts.

We are incorporated in Israel. One of our directors resides outside of the United States, and most of the assets of this director are located outside of the United States. Therefore, a judgment obtained against us, or this director, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It may also be difficult for you to effect service of process on this director in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

There is little binding case law in Israel that addresses the matters described above. As a result of the difficulty associated with enforcing a judgment against us in Israel, you may not be able to collect any damages awarded by either a U.S. or foreign court.

Your rights and responsibilities as a shareholder will be governed by Israeli law, which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

The rights and responsibilities of the holders of our ordinary shares are governed by our articles of association and by Israeli law. These rights and responsibilities differ in some material respects from the rights and responsibilities of shareholders in U.S. companies. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders, and to refrain from abusing its power in the company, including, among other things, in voting at a general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and related party transactions requiring shareholder approval, as well as a general duty to refrain from discriminating against other shareholders. In addition, a shareholder who is aware that it possesses the power to determine the outcome of a vote at a meeting of the shareholders or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company.

There is limited case law available to assist us in understanding the nature of these duties or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares that are not typically imposed on shareholders of U.S. companies.

Risks Related to Our Management and Employees

We depend on our executive officers and key clinical, technical and commercial personnel to operate our business effectively, and we must attract and retain highly skilled employees in order to succeed.

Our success depends upon the continued service and performance of our executive officers who are essential to our growth and development. The loss of one or more of our executive officers could delay or prevent the continued successful implementation of our growth strategy, could affect our ability to manage our company effectively and to carry out our business plan, or could otherwise be detrimental to us. As of January 31, 2024, we had 201 employees. Therefore, knowledge of our product candidates and clinical trials is concentrated among a small number of individuals. Members of our executive team as well as key clinical, scientific, technical and commercial personnel may resign at any time and there can be no assurance that we will be able to continue to retain such personnel. If we cannot recruit suitable replacements in a timely manner, our business will be adversely impacted.

Our growth and continued success will also depend on our ability to attract and retain additional highly qualified and skilled research and development, operational, managerial and finance personnel. However, we face significant competition for experienced personnel in the pharmaceutical field. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to quality candidates than what we have to offer. If we cannot retain our existing skilled scientific and operational personnel and attract and retain sufficiently skilled additional scientific and operational personnel, as required, for our research and development and manufacturing operations on acceptable terms, we may not be able to continue to develop and commercialize our existing product candidates or new products. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company.

General Risk Factors

If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our ordinary shares, the price of our ordinary shares could decline.

The trading market for our ordinary shares relies in part on the research and reports that equity research analysts publish about us and our business, if at all. We do not have control over these analysts, and we do not have commitments from them to write research reports about us. The price of our ordinary shares could decline if no research reports are published about us or our business, or if one or more equity research analysts downgrade our ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Our business could be negatively affected as a result of actions of activist shareholders, and such activism could impact the trading value of our securities.

Shareholders may, from time to time, engage in proxy solicitations or advance shareholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our shareholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our share price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. It is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

Unstable market, economic and geo-political conditions may have serious adverse consequences on our business, financial condition and share price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past. These disruptions can result in severely diminished liquidity and credit availability, increase in inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates, further bank failures and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, higher inflation, bank failures or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our portfolio of corporate and government bonds could also be adversely impacted. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and share price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget.

Other international and geo-political events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. In October 2023, Hamas initiated an attack against Israel, provoking a state of war and the risk of a larger conflict. While we cannot predict the broader consequences, these conflicts and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs,

disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

Our business could be negatively impacted by environmental, social and corporate governance matters or our reporting of such matters.

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning environmental, social and corporate governance ("ESG") matters. We may be, or be perceived to be, not acting responsibly in connection with these matters, which could negatively impact us. For instance, the SEC has recently proposed climate change and ESG reporting requirements, which, if approved, would significantly increase our costs. In addition, we currently do not report our environmental emissions, and lack of reporting or future reporting could result in certain investors from declining to invest in our ordinary shares.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third-party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, clinical trial data, customer data, manufacturing data, and confidential information that is proprietary, strategic or competitive in nature ("Information Systems and Data").

Our Chief Financial Officer supervises our Information Technology Department (the "IT Department") which coordinates with third-party service providers that perform security management roles, including those of a chief information security officer, to identify, assess and manage our cybersecurity threats and risks. Our IT Department and security management team, including third-party service providers, identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example: manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting scans of the threat environment, internal audits relating to cybersecurity, conducting threat assessments for internal and external threats, third-party threat assessments, conducting vulnerability assessments to identify vulnerabilities, use of external intelligence feeds, evaluating our and our industry's risk profile, and evaluating threats reported to us.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: a cybersecurity incident response policy; asset management, tracking and disposal; incident detection and response; systems monitoring; vulnerability management policy; risk assessments; encryption of certain of our data; third-party cybersecurity staff; network security controls; segregation of certain of our data; access controls; physical security; employee training; penetration testing; and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our IT Department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are expected to be more likely to lead to a material impact to our business. In addition, our management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of our board of directors, which, together with our board of directors, evaluates our overall enterprise risk.

We use third-party service providers to assist us to identify, assess, and manage material risks from cybersecurity threats, including, for example: a third-party IT and cybersecurity consultant; professional services firms, including legal counsel; threat intelligence service providers; cybersecurity software providers; managed cybersecurity service providers; penetration testing firms; dark web monitoring services; and forensic investigators.

We use third-party service providers to perform a variety of functions throughout our business, such as: conducting nonclinical and clinical trials; supplying certain raw materials, compounds and components; delivering materials to our facilities; and shipping products to our customers. Additionally, we rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and content delivery. Third-party service providers we rely on include: application providers, distributors, hosting companies, supply chain resources, contract research organizations, and contract manufacturing organizations. Our vendor assessment process is generally limited to reputational due diligence of the vendor and, in some cases, examination of the vendor's security certifications.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part I, Item 1A. Risk Factors in this Annual Report on Form 10-K, including "*Risk Factors – If our information technology systems or data, or those of third parties upon whom we rely, are or were compromised, this could result in adverse consequences resulting from such compromise including but not limited to regulatory investigations or actions; litigation; fines and penalties; a material disruption of our drug development program; compromise sensitive information related to our business; harm our reputation; triggering our breach notification obligations; prevent us from accessing critical information; disruptions of our business operations; loss of revenue or profits; loss of customers or sales and expose us to liability or other adverse effects to our business.*"

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The audit committee of our board of directors is responsible for overseeing our cybersecurity risk management processes, including oversight of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of our management, including, among others, the Chief Financial Officer, Head of IT, and Associate Director of IT Operations. Our Head of IT is an IT security professional and members of our IT Department have certain credentialling in cybersecurity. We also rely on third-party security analysts who have certain certifications related to cybersecurity.

Our Chief Financial Officer and Head of IT are responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Additionally, they are responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including our Chief Financial Officer and General Counsel and Chief Compliance Officer. Our management works with our incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our cybersecurity incident response policy includes reporting to the audit committee of our board of directors for certain cybersecurity incidents.

The audit committee periodically reviews and discusses with the appropriate members of our management material risks relating to cybersecurity threats and our processes for assessing, identifying, and managing material risks from cybersecurity threats, as well as our internal controls and disclosure controls and procedures relating to cybersecurity incidents. Our board of directors and audit committee are also provided with reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties

Effective November 2019, we leased approximately 20,913 square feet of space in Princeton, NJ, which serves as our principal executive offices and is used for commercial and marketing as well as general and administrative purposes. We lease an approximately 11,495 square foot facility in Israel, which is used primarily as research and development laboratories as well as for administrative purposes. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities

Market Information

Our ordinary shares have been traded on the Nasdaq Global Market since May 4, 2017 under the symbol URGN. Prior to such time, there was no public market for our ordinary shares.

Holders

As of March 7, 2024, there were 16 registered holders of record of our ordinary shares.

Dividend Policy

We have not paid any dividends on our ordinary shares since our inception and do not expect to pay dividends on our ordinary shares in the foreseeable future. The Loan Agreement with Pharmakon restricts our ability to pay dividends. In addition, Israeli law limits our ability to declare and pay dividends and may subject our dividends to Israeli withholding taxes. We currently intend to retain all available funds as well as future earnings, if any, to fund the development and expansion of our operations.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with the historical consolidated financial statements and the notes thereto included in "Financial Statements and Supplementary Data". This discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. You should carefully read "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

Overview

We are a biotechnology company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers. We have developed *RTGel* reverse-thermal hydrogel, a proprietary sustained release, hydrogel-based technology that has the potential to improve therapeutic profiles of existing drugs. Our technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. Our approved product *Jelmyto* (mitomycin) for pyelocalyceal solution, and our investigational candidate, UGN-102 (mitomycin) for intravesical solution, are designed to ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial cancer ("low-grade UTUC") and low-grade intermediate risk non-muscle invasive bladder cancer ("low-grade intermediate risk NMIBC"), respectively. In addition, our immuno-uro-oncology pipeline includes UGN-301 (zalifrelimab), an anti-CTLA-4 antibody, which we intend to study as both monotherapy and combination therapy.

We estimate that the annual treatable patient population of low-grade UTUC in the United States is approximately 6,000 to 7,000 and the annual treatable population of low-grade intermediate risk NMIBC is approximately 80,000.

RTGel is a novel proprietary polymeric biocompatible, reverse thermal gelation hydrogel technology, which, unlike the general characteristics of most forms of matter, is liquid at lower temperatures and converts into gel form when warmed to body temperature. We believe that these characteristics promote ease of delivery into and retention of drugs in body cavities, including the bladder and the upper urinary tract, forming a transient reservoir of drug that dissolves over time while preventing rapid excretion, providing for increased dwell time. *RTGel* leverages the physiologic flow of urine to provide a natural exit from the body.

We believe that *RTGel*, when formulated with an active drug, may allow for the improved efficacy of treatment of various types of urothelial and specialty cancers and urologic diseases without compromising the safety of the patient or interfering with the natural flow of fluids in the urinary tract. *RTGel* achieves this by:

- increasing the exposure of active drugs in the bladder and upper urinary tract by significantly extending the dwell time of the active drug while conforming to the anatomy of the bladder and the upper urinary tract, which allows for enhanced drug tissue coverage. For example, the average dwell time of the standard aqueous mitomycin formulation, currently used as adjuvant treatment, in the upper urinary tract is approximately five minutes, compared to approximately six hours when mitomycin is formulated with *RTGel*;
- administering higher doses of an active drug than would otherwise be possible using standard water-based formulations. For instance, it is only possible to dissolve 0.5 mg of mitomycin in 1 mL of water while it is possible to formulate up to 8 mg of mitomycin with 1 mL of *RTGel*; and
- maintaining the active drug's molecular structure and mode of action.

These characteristics of *RTGel* enable sustained release of mitomycin in the urinary tract for both *Jelmyto* and UGN-102. Further, *RTGel* may be particularly effective in the bladder and upper urinary tract where tumor visibility and access are challenging, and where there exists a significant amount of urine flow and voiding. We believe that these characteristics of *RTGel* may prove useful for the local delivery of active drugs to other bodily cavities in addition to the bladder and upper urinary tract.

Jelmyto

On April 15, 2020, the FDA approved our NDA for *Jelmyto* (mitomycin) for pyelocalyceal solution, formerly known as UGN-101, for the treatment of adult patients with low-grade UTUC. *Jelmyto* consists of mitomycin, an established chemotherapy, and sterile hydrogel, using our proprietary sustained release *RTGel* technology. It has been designed to prolong exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. New product exclusivity for *Jelmyto* expired on April 15, 2023, however, Orphan Drug exclusivity extends until April 15, 2027. Additionally, the main patents that protect *Jelmyto* in the United States are set to expire in January 2031. These patents were listed in the FDA's Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

Low-grade UTUC is a rare cancer that develops in the lining of the upper urinary tract, ureters and kidneys. In the United States, there are approximately 6,000 - 7,000 new or recurrent low-grade UTUC patients annually. It is a challenging condition to treat due to the complex anatomy of the urinary tract system. Prior to *Jelmyto*, the current standard of care included endoscopic resection(s) and RNU, the latter which involves the removal of the renal pelvis, kidney, ureter and bladder cuff. Treatment is further complicated by the fact that low-grade UTUC is most commonly diagnosed in patients over 70 years of age, who may already have compromised kidney function and may suffer further complications as a result of a major surgery. We are focused on changing the way urothelial cancers are treated, an area in which there has been no significant advancements in recent years. *Jelmyto* is the first drug therapy of its kind, providing an alternative to endoscopic resection(s) and/or RNU.

The FDA approval was based on results from our Phase 3 OLYMPUS trial showing *Jelmyto* achieved clinically significant disease eradication in adults with low-grade UTUC. Findings from the final study results include:

- CR (primary endpoint) of 58% (41/71) in the intent-to-treat population and in the sub-population of patients who were deemed not capable of surgical removal at diagnosis.
- At the 12-month time point for assessment of durability, 23 patients remained in CR of a total of 41 patients, eight had experienced recurrence of disease and ten patients were unable to be evaluated.
- Durability of response was estimated to be 81.8% at 12 months by Kaplan-Meier analysis. The median duration of response was not reached.
- The most commonly reported adverse events (≥ 20%) were ureteric obstruction, flank pain, urinary tract infection, hematuria, abdominal pain, fatigue, renal dysfunction, nausea, dysuria and vomiting. Most adverse events were mild to moderate and manageable. No treatment-related deaths occurred.

In December 2022, we presented new data from a follow up study to the OLYMPUS trial designed to obtain long-term data on *Jelmyto*. Based on data available for 16 of the 23 patients who had remained in CR at the end of the OLYMPUS study, the median duration of response in that subset of patients was 28.9 months. Thirteen patients remained in CR, two patients had recurrence of low grade-UTUC on the same side as treated in OLYMPUS, and one patient underwent RNU due to ureteral stricture without evidence of UTUC at the time of surgery. No patient had progressed to high-grade disease.

In June 2020, we initiated our commercial launch of *Jelmyto* in the United States. We have staffed, trained and prepared a customer-facing team that includes territory business managers with deep experience in both urology and oncology. These territory business manager positions are led by seven regional business director positions, who are in turn supported by seven regional operations manager positions. Each region is additionally supported by one to two clinical nurse educators to provide education and training around instillation, as well as a field reimbursement manager to help ensure access and reimbursement for appropriate patients and key account directors who engage with C-suite individuals to introduce a *Jelmyto* service line. In addition, our organization currently includes several medical science liaisons who appropriately engage with physicians interested in learning more about UroGen, *Jelmyto* and our technology, both in person and virtually. In total, our customer-facing team comprises approximately 80 representatives.

We are committed to helping patients access *Jelmyto*. Our market access teams have laid the foundation for coverage and reimbursement, meeting multiple times with payors. Medicare patients with supplemental coverage are covered and the vast majority of commercial plans have policies in place, in whole covering over 150 million lives. In addition to reimbursement and access, we have also been focused on ensuring seamless integration into physician practices. We have implemented processes to help make *Jelmyto* preparation and administration seamless for practitioners and patients, including entering into agreements with various national, regional and local specialty pharmacies under which the pharmacy, following receipt of a patient prescription, prepares and dispenses the *Jelmyto* admixture on our behalf. In September 2022, the FDA authorized an extension of the in-use period for the *Jelmyto* admixture from eight hours to 96 hours (four days) following reconstitution of the product, adding convenience and flexibility in managing patient care.

In October 2020, a Medicare C-Code was issued for *Jelmyto*. The Centers for Medicare & Medicaid Services established a permanent and product-specific J-code for *Jelmyto* that took effect on January 1, 2021 and replaced the C-Code. CMS has granted *Jelmyto* a New Technology APC (Ambulatory Payment Classification), effective from October 1, 2023. We have also launched a registry to capture data and evaluate real world outcomes in patients with low-grade UTUC that have been or will be treated with *Jelmyto*. The purpose of the registry is to study the use of *Jelmyto* in clinical practice in the United States and address specific clinical questions.

In the first three fiscal years beginning after the initiation of our commercial launch of *Jelmyto* in June 2020, we have experienced a moderate decline in revenue during the third quarter from the preceding quarter. We believe this result is primarily attributable to the nature of low-grade disease, which does not require immediate treatment and therefore we believe there is an impact in the summer months. However, it is too early to say with confidence whether this seasonality trend will continue in future periods. Moreover, our future *Jelmyto* revenue will be impacted by various factors and we expect our *Jelmyto* revenue to fluctuate quarter-to-quarter for the foreseeable future.

UGN-102 (mitomycin) for intravesical solution

UGN-102 is our sustained-release formulation of mitomycin that we are developing for the treatment of low-grade intermediate risk NMIBC.

UGN-102 is administered locally using the standard practice of intravesical instillation directly into the bladder via a catheter. The instillation into the bladder is expected to take place in a physician's office as a non-operative outpatient treatment, in comparison with TURBT or similar surgical procedures, which are operations often conducted under general anesthesia and may require an overnight stay. Complete surgical tumor removal often has limited success due to the inability to properly identify, reach and resect all tumors. We believe that an effective chemoablation agent can potentially provide better eradication of tumors irrespective of the detectability and location of the tumors. In addition, by reducing the need for surgery, patients may avoid potential complications associated with surgery and anesthesia.

In October 2021, we reported final data from the Phase 2b OPTIMA II trial. The single-arm, open label trial completed enrollment of 63 patients at clinical sites across the United States and Israel in September 2019. Patients were treated with six weekly instillations of UGN-102 and underwent assessment of CR (the primary endpoint) four to six weeks following the last instillation; 65%, or 41 out of 63 patients, treated with UGN-102 achieved a CR three months after the start of therapy. In this subset of patients, 39 (95%), 30 (73%), and 25 (61%) remained disease-free at six, nine, and 12 months after treatment initiation, respectively. The probability of durable response nine months after CR (12 months after treatment initiation) was estimated to be 72.5% by Kaplan-Meier analysis. Thirteen patients had documented recurrences. Fifty-seven of 63 (90%) patients completed all six instillations of UGN-102 according to the study protocol. Median duration of response was not reached. The most common adverse events, greater than 10%, were most often reported as mild to moderate in severity and include dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection. The final data was published online in The Journal of Urology in October 2021 and was included in the January 2022 print edition.

In December 2022 we presented new data from a follow up study to the OPTIMA II study designed to obtain long-term data on UGN-102 that shows median duration of response of 24.4 months based on available data for 15 out of 25 patients who achieved a CR in OPTIMA II. Seven patients remained in CR, six patients had recurrence of low-grade disease, one patient had progression to high-grade disease and one patient withdrew consent but remained in CR at the last evaluation prior to discontinuation. All patients were alive at the last contact, and five patients were known to have had post-study treatment with TURBT or fulguration.

We initiated our Phase 3 ATLAS trial in December 2020 and until November 2021, were enrolling patients in this trial comparing UGN-102 with or without TURBT to standard of care, TURBT. In parallel, we continued to engage in discussions with the FDA and based on this dialogue, we designed a trial in order to demonstrate the efficacy and safety of UGN-102. This Phase 3 ENVISION trial is a single-arm, multinational, multicenter study evaluating the efficacy and safety of UGN-102 as primary chemoablative therapy in patients with low-grade intermediate risk NMIBC. The design of the Phase 3 ENVISION trial is similar to our Phase 2 OPTIMA II trial in that the patient population has similar clinical characteristics, receives the same investigational treatment regimen and undergoes similar efficacy and safety assessments and qualitative follow-up. Study participants receive six once-weekly intravesical instillations of UGN-102. The primary endpoint is CR rate at three months after the first instillation, and the key secondary endpoint is durability of response in patients who achieve CR at the three-month assessment.

In February 2022, we announced the initiation of the Phase 3 ENVISION trial, targeting enrollment of 220 patients across 90 sites. In December 2022, we completed our target enrollment of the Phase 3 ENVISION trial. As a result of the FDA's acceptance of a single arm approach, we stopped enrollment of the Phase 3 ATLAS trial. However, at the time enrollment was stopped, patients who had signed an informed consent were able to complete screening, and if eligible were randomized into the trial.

On July 27, 2023, we announced topline data from our Phase 3 trials, ATLAS and ENVISION. In the ATLAS trial, UGN-102 met its primary endpoint of disease-free survival, reducing risk of recurrence, progression, or death by 55%. Results of the ATLAS trial also showed a 64.8% CR rate at three months for patients who only received UGN-102, compared to a 63.6% CR rate at three months for patients who only received a TURBT. The ENVISION trial met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.2% rate of CR at three-months following the initial treatment. Additional data evaluating the secondary endpoint of duration of response from ENVISION is anticipated in 2024. In both trials, the safety profile of UGN-102 was acceptable, with a safety profile comparable to that observed in previous clinical trials of UGN-102.

We also initiated a Phase 3b study with the objective of demonstrating whether UGN-102 can be administered at home by a qualified home health professional, avoiding the need for repeated visits to a healthcare setting for instillation. As per the study design, patients in this study received six once-weekly intravesical instillations of UGN-102 with the initial treatment visit occurring at the investigative site and instillation performed by a qualified physician. Treatment visits two to six took place at the patient's home and instillations were performed by a properly trained and qualified home health professional. The primary endpoints of the study include safety and tolerability, discontinuations from at home study treatment and feedback from patients, home health professionals and investigators via standardized questionnaires. The study completed enrollment with a total of eight patients across four centers and all study visits for these enrolled patients have been completed. Preliminary results were reported through a press release in February 2023, finding that UGN-102 was suitable to administer at home by a visiting nurse under the supervision of a treating physician and resulted in 75% of patients achieving a CR, defined as no detectable disease three months after starting treatment. Patients, nurses and investigators also completed home instillation feasibility questionnaires. These standardized feasibility questionnaires highlighted that all eight patients preferred at-home to in-office treatment, and five of six patients recommended UGN-102 home instillation instead of TURBT. Home instillation was reported as feasible for visiting nurses, and three of four investigators considered at-home treatment “not different” than in-office treatment.

In October 2023 we announced our agreement with the FDA on plans for submission of an NDA for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of CR at 12 months from the pivotal ENVISION trial, will support submission of an NDA for the treatment of low-grade intermediate risk NMIBC. The FDA indicated that it may seek the advice of the Oncology Drug Advisory Committee as part of the NDA review process. The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the CMC sections of the NDA, which we submitted in January 2024. Based on our agreement with the FDA, we expect to complete the submission of the rolling NDA for UGN-102 in September 2024.

In January 2024 we entered into a licensing and supply agreement with medac Gesellschaft für klinische Spezialpräparate m.b.H. (“medac”) to develop UGN-103 and UGN-104 which are intended to be a next-generation formulation of UGN-102 and *Jelmyto*, respectively, that combine medac’s proprietary mitomycin formulation technology with our *RTGel* technology, which we believe will provide advantages related to production, cost, supply and product convenience. We plan to initiate a Phase 3 study in 2024 to explore the safety and efficacy of UGN-103 in low-grade intermediate risk NMIBC. We also plan to initiate a Phase 3 study in 2024 to explore the safety and efficacy of UGN-104 in low-grade UTUC.

UGN-301 (zalifrelimab) intravesical solution

Our immuno-uro-oncology pipeline includes UGN-301, an anti-CTLA-4 monoclonal antibody, which we intend to study as a standalone agent and as a combination therapy. UGN-301 is delivered using our proprietary *RTGel* technology, which has been designed to significantly improve the effectiveness of certain intravesical therapies.

High-grade NMIBC is a highly aggressive form of bladder cancer. TURBT followed by adjuvant intravesical immunotherapy with BCG is the current standard of care therapy for high-grade NMIBC. However, the high rates of recurrence and significant risk of progression to muscle-invasive tumors are particularly dangerous. Radical cystectomy, or bladder removal is strongly advocated in patients with BCG-unresponsive NMIBC (i.e., patients with BCG-refractory and BCG-relapsing tumors in whom further BCG therapy is not recommended) or for patients who cannot tolerate BCG.

The first combination we are investigating clinically involves the sequential use of UGN-201 (imiquimod), a TLR 7 agonist, and UGN-301 in high-grade NMIBC. UGN-201 is a liquid formulation of imiquimod for intravesical administration that has been optimized for delivery in the urinary tract. The second combination we are investigating clinically involves the sequential administration of gemcitabine and UGN-301 to the bladder in high-grade NMIBC. Gemcitabine is a chemotherapy that is used intravesically to treat high grade NMIBC where it is administered as a liquid formulation. We believe these two combinations could elicit both an innate and adaptive immune response, which may translate into a long-lasting acquired immune response, and potentially represent a valid post-TURBT adjuvant treatment of high-grade NMIBC. UGN-301 is delivered using our proprietary *RTGel* technology, which has been designed to significantly improve the effectiveness of certain intravesical therapy. We believe that these combinations make local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effects.

In March 2022, we announced FDA clearance of our IND to begin a novel Phase 1 clinical study of UGN-301 in patients with recurrent NMIBC. The novel study design utilizes a Master Protocol that we believe is a more efficient and streamlined approach to development. It will provide more flexibility to add study arms as the trial progresses and is expected to increase efficiency and potentially reduce costs. We expect the Master Protocol will allow us to more quickly evaluate safety, tolerability and dosing of UGN-301 in combination with additional immunomodulators and chemotherapies, with the goal of developing optimized treatment regimens for patients. The multi-arm Phase 1 study, which is expected to support the development of UGN-301 in high-grade NMIBC, was initiated in April 2022 and is actively enrolling. We expect safety and tolerability data from this Phase 1 study in mid-2024.

Research and Development and License Agreements

Agenus Agreement

In November 2019, we entered into a license agreement with Agenus, pursuant to which Agenus granted us an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary monoclonal antibody of Agenus known as AGEN1884 (zalifrelimab), an anti-CTLA-4 antagonist, for the treatment of cancers of the urinary tract via intravesical delivery. UGN-301 is a formulation of zalifrelimab administered using *RTGel* technology that is in Phase 1 clinical development for high-grade NMIBC.

MD Anderson Agreement

In January 2021, we announced that we had entered into a three-year strategic research collaboration agreement with MD Anderson focusing on the sequential use of UGN-201 and UGN-301 as an investigational treatment for high-grade NMIBC. Pursuant to the agreement, we have made bi-annual payments totaling $2.0 million to MD Anderson to fund the collaboration, recognized evenly over the associated period through research and development expenses. In July 2022, we determined that we had achieved the objectives that we established when the agreement was initiated, and notified MD Anderson that we were exercising our right to conclude the collaboration in 2022 as we did not foresee initiating further development activities as part of the collaboration, although we will continue to collaborate on existing joint projects. As a result of this notification, we were not responsible for any further fixed bi-annual funding payments in 2023, although we are responsible for costs related to existing joint projects to the extent they exceed the payments already made to MD Anderson.

For additional information regarding our research and development and license agreements, see Note 13 to our consolidated financial statements appearing elsewhere in this Annual Report.

Components of Operating Results

Revenue

During the year ended December 31, 2023 and December 31, 2022, we recognized $ 82.7 million and $64.4 million of revenue, respectively, from sales of our product, *Jelmyto*.

Cost of Revenue

Cost of revenue consists primarily of inventory and related costs associated with the manufacturing, distribution, warehousing and preparation of *Jelmyto,* including inventory write-downs. In periods prior to receiving FDA approval for *Jelmyto*, we recognized inventory and related costs associated with the manufacture of *Jelmyto* as research and development expense.

Research and Development Expenses

Research and development expenses, net consists primarily of:

- salaries and related costs, including share-based compensation expense, for our personnel in research and development functions;
- facility and equipment costs, including depreciation expense, maintenance and allocated direct and indirect overhead costs;
- expense incurred under agreements with third parties, including CROs, subcontractors, suppliers and consultants, nonclinical studies and clinical trials;
- expense incurred to acquire, develop and manufacture nonclinical study and clinical trial materials; and
- expense incurred to purchase API in support of R&D activities and other related manufacturing costs.

We manage and prioritize our research and development expenses based on scientific data, probability of successful technical development and regulatory approval, market potential and unmet medical need, available human and capital resources and other considerations. We regularly review our research and development activities and, as necessary, reallocate resources among our program, product candidates and external opportunities that we believe will best support the long-term growth of our business. We do not track total research and development expenses by program, product candidates, or development phase.

The following table provides a breakout of expenses by major cost type:

(in thousands)	**2023**	**2022**
Personnel, facility and equipment, and other overhead costs	16,245	16,993
Clinical and other development costs	29,369	35,913
Total	$ 45,614	$ 52,906

We expense all research and development costs as incurred. We estimate nonclinical study and clinical trial expense based on the services performed pursuant to contracts with research institutions and contract research organizations that conduct and manage nonclinical studies and clinical trials on our behalf based on actual time and expense incurred by them.

We recognize costs incurred as the services are being provided by monitoring the status of the trial or project and the invoices received from our external service providers. We adjust our accrual as actual costs become known. Where at risk contingent milestone payments are due to third parties under research and development and collaboration agreements, the milestone payment obligations are expensed when such development milestone results are achieved.

License fees and development milestone payments related to in-licensed products and technology are expensed as incurred, or achieved in the case of milestones, if it is determined at that point that they have no established alternative future use.

We are currently focused on advancing our product candidates, and our future research and development expense will depend on their clinical success. Research and development expense will continue to be significant.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We do not believe that it is possible at this time to accurately project total expenses required for us to reach commercialization of our product candidates. Due to the inherently unpredictable nature of nonclinical and clinical development, we are unable to estimate with certainty the costs we will incur and the timelines that will be required in the continued development and approval of our product candidates. Clinical and nonclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, if and when such arrangements will be entered into, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect our research and development expense to increase over the next several years as our clinical programs progress and as we seek to initiate clinical trials of additional product candidates. We also expect to incur increased research and development expense as we selectively identify and develop additional product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;
- the number of patients that participate in the trials;

- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidates.

In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

Other than *Jelmyto*, which was approved by the FDA in April 2020, we have not received approval of any of our product candidates. UGN-102 and UGN-301 are still in clinical development. As such, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. We expect to finance our cash needs through revenue from commercial sales of *Jelmyto* and a combination of equity or debt financings and collaboration arrangements.

Selling and Marketing Expenses

To date, selling and marketing expenses consist primarily of commercial personnel costs (including share-based compensation) along with pre-commercialization and commercialization activities related to *Jelmyto*, formerly known as UGN-101.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs (including share-based compensation related to directors, executives, finance, medical affairs, business development, investor relations, and human resource functions). Other significant costs include medical affairs services, external professional service costs, facility costs, accounting and audit services, legal services, and other consulting fees.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation is comprised of financing expense related to the RTW Transaction (see Note 9 to our consolidated financial statements appearing elsewhere in this Annual Report).

Interest Expense

Interest expense is comprised of interest related to our long-term debt with Pharmakon (see Note 10 to our consolidated financial statements appearing elsewhere in this Annual Report).

Interest and Other Income, Net

Interest and other income, net, consisted primarily of interest income, net losses on foreign exchange and bank commissions.

Income Taxes

We have yet to generate taxable income in Israel. We have historically incurred operating losses resulting in carry forward tax losses totaling approximately $452.0 million as of December 31, 2023. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. We have provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses. Income tax expense also consists of our estimate of uncertain tax positions, and related interest and penalties. See Note 17 to our consolidated financial statements appearing elsewhere in this Annual Report for further information.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022.

	Year Ended December 31,		
	2023	2022	Change
		(in thousands)	
Revenue	$ 82,713	$ 64,357	$ 18,356
Cost of revenue	9,361	7,654	1,707
Gross profit	73,352	56,703	16,649
Operating expenses:			
Research and development	45,614	52,906	(7,292)
Selling and marketing	54,703	51,920	2,783
General and administrative	38,571	30,918	7,653
Total operating expenses	138,888	135,744	3,144
Operating loss	(65,536)	(79,041)	13,505
Financing on prepaid forward obligation	(21,552)	(21,559)	7
Interest expense on long-term debt	(14,715)	(8,438)	(6,277)
Interest and other income, net	3,479	1,010	2,469
Loss before income taxes	(98,324)	(108,028)	9,704
Income tax expense	(3,920)	(1,755)	(2,165)
Net loss	$ (102,244)	$ (109,783)	$ 7,539

Revenue

Revenues were $82.7 million and $64.4 million for the years ended December 31, 2023 and 2022, respectively. The increase of $18.3 million was primarily driven by the increased volume of sales of *Jelmyto*. 2023 full-year *Jelmyto* net revenues also include higher revenue reserves driven by 340B chargebacks and estimated Medicare refunds for discarded drugs, offset by $4.4 million in CREATES Act sales, of which $2.4 million was realized in the fourth quarter of 2023.

Cost of Revenue

Cost of revenue was $9.4 million and $7.7 million for the years ended December 31, 2023 and 2022, respectively. In periods prior to receiving FDA approval for *Jelmyto*, we recognized inventory and related costs associated with the manufacture of *Jelmyto* as research and development expense. The overall increase of $1.7 million is primarily attributable to the increased volume of sales of *Jelmyto* and partially attributable to the full depletion of inventories that we had expensed prior to receiving FDA approval.

Research and Development Expenses

Research and development expenses were $45.6 million and $52.9 million for the years ended December 31, 2023 and 2022, respectively. The decrease in research and development expenses of $7.3 million is primarily attributable to lower research and development expenses due to the conclusion of the ATLAS trial, lower cost related to the Phase 3 ENVISION trial for UGN-102, and the ending of our collaboration with MD Anderson, partially offset by higher research and development expenses related to our Phase 1 study for UGN-301, cost incurred related to research into ingredient scale-up and production for UGN-102, and clinical compensation expenses.

Selling and Marketing Expenses

Selling and marketing expenses were $54.7 million and $51.9 million for the years ended December 31, 2023 and 2022, respectively. The increase in selling and marketing expenses of $2.8 million is primarily attributable to brand marketing related expenses and commercial operation advertisement, conferences and trainings, and commercial compensation expenses, partially offset by lower commercial back-office services and support expenses.

General and Administrative Expenses

General and administrative expenses were $38.6 million and $30.9 million for the years ended December 31, 2023 and 2022, respectively. The increase in general and administrative expenses of $7.7 million resulted primarily from higher compensation expenses, third-party advisory providers, recruiting fees, certain media and meeting expenses, and ongoing managed services.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation was $21.6 million and $21.6 million for the years ended December 31, 2023 and 2022, respectively. The measurement of financing on prepaid forward obligation is an accounting estimate under the "imputed interest method" of accounting (see Note 9 to our consolidated financial statements appearing elsewhere in this Annual Report) which is affected by estimated future payments to RTW, which are based on a percentage of revenues.

Interest Expense on Long-term Debt

Interest expense was $14.7 million and $8.4 million for the years ended December 31, 2023 and 2022, respectively. The cost in 2023 relates to interest expense on the Pharmakon loan for four full quarters versus the prior year given the funding of the first tranche and second tranche of the Term Loans was in March 2022 and in December 2022, respectively. In addition, the increase was attributable to increase in interest rates related to the Pharmakon loan.

Interest and Other Income, Net

Interest and other income, net was $3.5 million and $1.0 million for the years ended December 31, 2023 and 2022, respectively. The increase in interest and other income, net was primarily due to higher cash and investment balance earning interest and changes in the overall interest rate environment.

Liquidity and Capital Resources

As of December 31, 2023, we had $141.5 million in cash and cash equivalents and marketable securities. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation, and is held primarily in U.S. dollars.

Through December 31, 2023, we funded our operations primarily through public equity offerings, private placements of equity securities and our funding arrangements with RTW and Pharmakon.

In December 2019, we entered into the ATM Sales Agreement with Cowen pursuant to which we may from time to time offer and sell our ordinary shares having an aggregate offering price of up to $100.0 million. The remaining capacity under the ATM Sales Agreement was approximately $83.4 million as of December 31, 2023, and subsequent to December 31, 2023, we sold approximately $26.6 million of our ordinary shares pursuant to the ATM Sales Agreement. The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 filed with the SEC on November 15, 2022, which was declared effective on November 29, 2022.

In March 2021, we entered into a prepaid forward agreement with RTW, pursuant to which RTW agreed to provide us with an upfront cash payment of $75.0 million to support the launch of *Jelmyto* and the development of UGN-102, and we agreed to provide RTW with tiered future payments based on global annual net product sales of *Jelmyto* and UGN-102, if approved. In May 2021, following the receipt of necessary regulatory approvals, we received the $75.0 million prepaid forward payment ($72.4 million net of transaction costs) from RTW.

On March 7, 2022, we entered into the Loan Agreement with Pharmakon for a senior secured term loan of up to $100.0 million in two tranches. The first tranche of $75.0 million ($72.6 million of proceeds were received, $70.8 million net of additional transaction costs) was funded in March 2022, and the second tranche of $25.0 million was funded in December 2022.

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million is mandatory and required to be drawn by September 30, 2024, subject to satisfaction of customary conditions. The fourth tranche of $75.0 million may be drawn at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0M tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) satisfaction of customary conditions.

On July 26, 2023, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain institutional and other accredited investors (the “Purchasers”), pursuant to which we agreed to sell and issue to the Purchasers 12,579,156 ordinary shares of the Company (“Shares”) (or in lieu of Shares, pre-funded warrants to purchase ordinary shares of the Company) at a purchase price of $9.54 per Share (or $9.539 for each ordinary share underlying a pre-funded warrant), in a private placement transaction that closed on July 28, 2023 and August 9, 2023 (the “Private Placement”) for aggregate gross proceeds of $120.0 million, before deducting fees to placement agents and financial advisors and before other expenses. Each pre-funded warrant has an exercise price of $0.001 per ordinary share, subject to customary adjustments, and became exercisable upon original issuance and will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation. The aggregate fee paid by us to placement agents and financial advisors was $3.6 million, plus the reimbursement of certain expenses.

We have incurred losses since our inception and negative cash flows from our operations, and as of December 31, 2023 we had an accumulated deficit of $679.3 million. We anticipate that we will continue to incur losses for the reasonably foreseeable future. Our primary uses of capital are, and we expect will continue to be, commercialization activities, research and development expense, including third-party clinical research and development services, laboratory and related supplies, clinical costs, including manufacturing costs, legal and other regulatory expense and general and administrative costs, partially offset by proceeds from sales of *Jelmyto*.

We routinely evaluate our liquidity needs, including assessment of our current financial condition, sources of liquidity including current cash and cash equivalents and marketable securities and management's cash flow projections. Our ability to continue as a going concern is expected to be impacted by our ability to raise additional capital to fund our operations, produce cash inflows from *Jelmyto* product sales and develop UGN-102. We believe that absent sufficient proceeds received from equity, financing, or business development transactions, we will not have sufficient cash and cash equivalents to fund our operations beyond one year from the issuance of our consolidated financial statements included elsewhere in this Annual Report. We estimate that our existing resources and projected revenues will only be sufficient to fund our planned operations until the first quarter of 2025. Accordingly, we will, within the next 12 months, require significant additional financing to continue our operations. In addition, there can be no assurances that we will be able to secure such additional financing if at all, on terms that are satisfactory to us, and in amounts sufficient to meet our needs. These factors raise substantial doubt about our ability to continue as a going concern. Failure to successfully receive additional financing will require us to delay, limit or reduce product development and commercialization efforts.

We cannot estimate the actual amounts necessary to successfully commercialize any approved products, or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods set forth below:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (76,376)	$ (87,559)
Investing activities	(953)	1,060
Financing activities	116,931	97,134
Net change in cash and cash equivalents	$ 39,602	$ 10,635

Operating Activities

Net cash used in operating activities was $76.4 million during the year ended December 31, 2023, compared to $87.6 million used in operating activities during the year ended December 31, 2022. The $11.2 million decrease was attributable primarily to timing of certain accruals and cash payments, as well as increase in net sales of our product *Jelmyto* during 2023 and higher inventory purchases, including non-current inventory, in 2022, partially offset by increase in interest on long-term debt.

Investing Activities

Net cash used in investing activities was $1.0 million during the year ended December 31, 2023, compared to net cash provided by investing activities of $1.1 million during the year ended December 31, 2022. The decrease of $2.1 million is attributable primarily to proportionately less maturities to purchases of marketable securities during 2023 as compared to 2022.

Financing Activities

Net cash provided by financing activities was $116.9 million during the year ended December 31, 2023, compared to net cash provided by financing activities of $97.1 million during the year ended December 31, 2022. The increase of $19.8 is attributable primarily to proceeds from the Private Placement in the current year as compared to proceeds from the Pharmakon loan in the prior year.

Funding and Material Cash Requirements

Our present and future funding and material cash requirements will depend on many factors, including, among other things:

- the progress, timing and completion of clinical trials for UGN-102 and UGN-301;
- nonclinical studies and clinical trials for any of our other product candidates;
- the costs related to obtaining regulatory approval UGN-102 and UGN-301 and any of our other product candidates, and any delays we may encounter as a result of regulatory requirements or adverse clinical trial results with respect to any of these product candidates;
- selling, marketing and patent-related activities undertaken in connection with the commercialization of *Jelmyto* and UGN-102 and any of our other product candidates, and costs involved in the continued development of an effective sales and marketing organization;
- the costs involved in filing and prosecuting patent applications and obtaining, maintaining and enforcing patents or defending against claims or infringements raised by third parties, and license royalties or other amounts we may be required to pay to obtain rights to third party intellectual property rights;
- potential new product candidates we identify and attempt to develop;
- revenues we may derive either directly or in the form of royalty payments from future sales of *Jelmyto*, UGN-102, UGN-301, *RTGel* reverse thermal hydrogel technology and any other product candidates; and
- the repayment of outstanding debt.

Accordingly, we will need to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants that further limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, the terms of the Forward Contract with RTW and the Loan Agreement limit our ability to take certain actions, including incurring additional indebtedness.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

For more information as to the risks associated with our future funding needs, see “Item 1.A – Risk Factors.”We will require additional financing to achieve our goals, and a failure to obtain this capital when needed and on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

Contractual Obligations and Commitments

In April 2016, we signed an addendum to our November 2014 lease agreement for our executive offices located in Israel, in order to increase the office space rented and to extend the rent period until 2019. In March 2019, we utilized the agreement extension option and extended the rent period for an additional three years until August 2022. In July 2022, we signed a lease extension agreement extending the term of the lease through September 2025.

In April 2018, we entered into a new lease agreement for an office in Los Angeles, CA. The lease commencement date was July 10, 2018 and terminated in March 2024. In November 2019, we subleased our offices in Los Angeles, CA. The lease commencement date was January 1, 2020 and terminated in March 2024. The subtenants exercised their early access clause and moved into the premises at the end of November 2019.

Also, in November 2019, we entered into a new lease agreement, dated effective October 31, 2019, for an office in Princeton, NJ. The lease commencement date was November 29, 2019 and the lease term is 38 months. In June 2022, we signed an amendment to our November 2019 lease agreement to extend the term for an additional three years through January 31, 2026.

The total obligation for future minimum lease payments under our operating leases is $1.8 million as of December 31, 2023. See Note 11 to the consolidated financial statements appearing elsewhere in this Annual Report for further information.

On March 7, 2022, we entered into the Loan Agreement with Pharmakon for a senior secured term loan of up to $100.0 million in two tranches. The first tranche of $75.0 million ($72.6 million of proceeds were received, $70.8 million net of additional transaction costs) was funded in March 2022, and the second tranche of $25.0 million was funded in December 2022.

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million is mandatory and required to be drawn by September 30, 2024, subject to satisfaction of customary conditions. The fourth tranche of $75.0 million may be drawn at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0M tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) satisfaction of customary conditions.

All outstanding loans with Pharmakon accrue interest using a benchmark rate of 3-month SOFR plus 7.25% plus an additional adjustment of 0.26161%. All outstanding principal will be required to be repaid in four equal quarterly installments commencing in the second quarter of 2026, with a one-year extension upon FDA approval of an NDA for UGN-102. All outstanding loans with Pharmakon can be prepaid in whole at the Company's discretion, at any time, subject to prepayment premiums, make-whole amounts and fees.

The obligations of the Borrower under the Loan Agreement are guaranteed on a full and unconditional basis by UroGen Pharma Ltd. and the other Guarantor and are secured by substantially all of the respective Credit Parties’ tangible and intangible assets and property, including intellectual property, subject to certain exceptions.

Critical Accounting Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of revenue and expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 3 to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following are the critical accounting policies used in the preparation of our financial statements.

Revenue

Product sales from *Jelmyto* are recognized as revenue under ASC 606 at the point in time that control of the product has been transferred to the customer, generally at the point the product has been delivered to the treating physician. All product sales of *Jelmyto* are recognized through our arrangement with a single customer, a third-party national specialty distributor. Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customer, chargebacks relating to differences between the wholesale acquisition cost and the contracted price offered to the end consumer, chargebacks relating to 340B drug pricing programs and other government sponsored programs, Medicaid drug rebate programs, our co-pay assistance program, and Medicare refunds for discarded drug, which are estimated based on our historical experience.

Share-Based Compensation

We account for employees' and directors' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, which is equal to the vesting period. For performance stock units ("PSUs"), cost is measured at the grant date based on the fair value of the award and is recognized over any relevant service period as expense when the achievement of the performance condition is probable. The fair value of options is determined using the Black-Scholes option-pricing model. The fair value of a restricted stock unit ("RSU") or a PSU equals the closing price of our ordinary shares on the grant date. We account for forfeitures as they occur in accordance with ASC Topic 718, "Compensation—Stock Compensation".

We elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the straight-line method and to value the awards based on the single-option award approach. Performance based awards are expensed over the requisite service period when the achievement of performance criteria is probable.

Prepaid Forward Obligation

Under the RTW Transaction, we received funds to support the continued launch of *Jelmyto* and the development of UGN-102 in return for tiered, future cash payments based on net sales of *Jelmyto* and UGN-102*,* if approved by the FDA. The net proceeds received under the RTW Transaction were recognized as a long-term liability. We recognize the current cash payable amounts under the arrangement within other current liabilities on the consolidated balance sheets. The subsequent measurement for the liability follows the accounting principles defined in ASC Topic 835-30*,* "Imputation of Interest". Each period we make a payment to RTW, an expense is recognized related to financing on the prepaid forward obligation based on an imputed rate derived from the expected future payments. Management reassesses the effective rate each period based on the current carrying value of the obligation and the revised estimated future payments. Changes in future payments from previous estimates are included in future financing expense.

Income Taxes

We provide for income taxes based on pretax income, if any, and applicable tax rates available in the various jurisdictions in which we operate, including Israel and the U.S. Deferred taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

We follow a two-step approach in recognizing and measuring uncertain tax positions. After concluding that a particular filing position can be recognized (i.e., has a more-likely-than-not chance of being sustained), ASC 740-10-30-7 requires that the amount of benefit recognized be measured using a methodology based on the concept of cumulative probability. Under this methodology, the amount of benefit recorded represents the largest amount of tax benefit that is greater than 50% likely to be realized upon settlement with a taxing authority that has full knowledge of all relevant information.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

Interest Rate Fluctuation Risk

Some of the securities in which we invest have market risk in that a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents. As of December 31, 2023, we had approximately $141.5 million in cash, cash equivalents and marketable securities. We invest our cash primarily in money market accounts, certificates of deposit, commercial paper and debt instruments of U.S. government-sponsored agencies, the U.S. Treasury, financial institutions, and corporations. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. If a 10% change in interest rates were to have occurred on December 31, 2023, this change would not have had a material effect on the fair value of our cash and cash equivalents as of that date.

Inflation Risk

Inflation generally may affect us by increasing our cost of labor and clinical trial costs. Inflation did not have a material effect on our business, financial condition or results of operations during the year ended December 31, 2023.

Foreign Currency Exchange Risk

The U.S. dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in NIS. As a result, we are exposed to the risk that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation, if any, of the NIS against the dollar. For example, the dollar appreciated against the NIS during 2023 by a total of 2.4%. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

We do not currently engage in currency hedging activities in order to reduce this currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

Item 8. Financial Statements and Supplementary Data

UroGen Pharma Ltd.

Index to financial statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of UroGen Pharma Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of UroGen Pharma Ltd. and its subsidiary (the "Company") as of December 31, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, of shareholders' deficit and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred losses and experienced negative operating cash flows since its inception that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition - Gross Revenue from Product Sales

As described in Notes 1, 3 and 12 to the consolidated financial statements, product sales from the Company's commercial product, Jelmyto, are recognized as revenue at the point in time that control of the product has been transferred to the customer, generally at the point the product has been delivered to the treating physician. All product sales of Jelmyto are recognized through the Company's arrangement with a single customer, a third-party national specialty distributor. Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customer, chargebacks relating to differences between the wholesale acquisition cost and the contracted price offered to the end consumer, chargebacks relating to 340B drug pricing programs and other government sponsored programs, Medicaid drug rebate programs, the Company's copay assistance program, and Medicare refunds for discarded drug. The Company's consolidated net revenue was $82.7 million for the year ended December 31, 2023, of which gross revenue from product sales represented a majority.

The principal consideration for our determination that performing procedures relating to revenue recognition for gross revenue from product sales is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's revenue recognition.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others (i) testing the Company's reconciliation of gross revenue recognized from product sales to third-party information, (ii) evaluating reconciling items, as applicable, (iii) confirming sales terms with the Company's single customer, (iv) confirming accounts receivable from product sales of *Jelmyto* with the Company's single customer, and (v) evaluating a sample of gross revenue transactions by obtaining and inspecting source documents, including the customer contract, purchase orders, invoices, proof of delivery, cash remittances, and bank statements, as applicable.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
March 14, 2024

We have served as the Company's auditor since 2020.

UROGEN PHARMA LTD.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts and par value)

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 95,002	$ 55,408
Marketable securities	41,966	44,556
Restricted cash	821	813
Accounts receivable	15,443	12,704
Inventories	5,673	4,325
Prepaid expenses and other current assets	10,281	11,101
Total current assets	169,186	128,907
Non-current assets:		
Property and equipment, net	689	1,297
Restricted deposit	225	223
Right-of-use assets	1,671	2,452
Marketable securities	4,502	—
Other non-current assets	2,038	2,740
Total Assets	$ 178,311	$ 135,619
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 16,538	$ 12,383
Employee related accrued expenses	10,814	8,257
Other current liabilities	3,860	3,276
Total current liabilities:	31,212	23,916
Non-current liabilities:		
Prepaid forward obligation	109,722	98,923
Long-term debt	98,551	97,537
Long-term lease liabilities	844	1,586
Uncertain tax positions liability	3,194	3,018
Total Liabilities	243,523	224,980
Commitments and Contingencies (Note 19)		
Shareholders' Deficit:		
Ordinary shares, NIS 0.01 par value; 100,000,000 shares authorized at December 31, 2023 and 2022; 32,490,119 and 23,129,953 shares issued and outstanding as of December 31, 2023 and 2022, respectively	89	63
Additional paid-in capital	614,035	487,787
Accumulated deficit	(679,348)	(577,104)
Accumulated other comprehensive income (loss)	12	(107)
Total Shareholders' Deficit	(65,212)	(89,361)
Total Liabilities and Shareholders' Deficit	$ 178,311	$ 135,619

The accompanying notes are an integral part of these consolidated financial statements.

UROGEN PHARMA LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	**2022**
Revenue	$ 82,713	$ 64,357
Cost of revenue	9,361	7,654
Gross profit	73,352	56,703
Operating expenses:		
Research and development expenses	45,614	52,906
Selling, general and administrative expenses	93,274	82,838
Operating loss	(65,536)	(79,041)
Financing on prepaid forward obligation	(21,552)	(21,559)
Interest expense on long-term debt	(14,715)	(8,438)
Interest and other income, net	3,479	1,010
Loss before income taxes	(98,324)	(108,028)
Income tax expense	(3,920)	(1,755)
Net Loss	$ (102,244)	$ (109,783)
Statements of Comprehensive Loss		
Net loss	$ (102,244)	$ (109,783)
Other comprehensive income (loss)		
Unrealized gain (loss) on investments	119	(82)
Comprehensive Loss	$ (102,125)	$ (109,865)
Net loss per ordinary share - basic and diluted	$ (3.55)	$ (4.81)
Weighted average number of shares outstanding used in computation of basic and diluted loss per ordinary share	28,834,303	22,806,812

The accompanying notes are an integral part of these consolidated financial statements.

UROGEN PHARMA LTD.
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT
(in thousands, except share amounts)

	Ordinary Shares		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Number of Shares	Amount	Amounts			
Balance as of December 31, 2021	22,462,995	$ 61	$ 475,698	$ (467,321)	$ (25)	$ 8,413
Changes During 2022						
Exercise of options into ordinary shares	666,958	2	1,509			1,511
Share-based compensation			10,580			10,580
Other comprehensive loss					(82)	(82)
Net loss				(109,783)		(109,783)
Balance as of December 31, 2022	23,129,953	$ 63	$ 487,787	$ (577,104)	$ (107)	$ (89,361)
Changes during 2023						
Exercise of options into ordinary shares	460,053	1	872			873
Share-based compensation			9,343			9,343
Issuance of pre-funded warrants, net of issuance costs			48,700			48,700
Conversion of pre-funded warrants into ordinary shares	1,599,733	5	(5)			—
Issuance of ordinary shares, net of issuance costs	7,300,380	20	67,338			67,358
Other comprehensive income					119	119
Net loss				(102,244)		(102,244)
Balance as of December 31, 2023	32,490,119	$ 89	$ 614,035	$ (679,348)	$ 12	$ (65,212)

The accompanying notes are an integral part of these consolidated financial statements.

UROGEN PHARMA LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Cash Flows From Operating Activities		
Net loss	$ (102,244)	$ (109,783)
Adjustment to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	802	924
Inventory Obsolescence	—	870
Accrued financing on prepaid forward obligation	11,504	14,007
(Accretion) on marketable securities	(1,034)	(498)
Share-based compensation	9,343	10,580
Amortization (accretion) of discount on long-term debt	1,014	1,754
Amortization of right-of-use assets	903	893
Changes in operating assets and liabilities:		
Inventory	(1,348)	(362)
Accounts receivable	(2,739)	(987)
Prepaid expenses and other current assets	820	(3,626)
Other non-current assets	702	(1,269)
Accounts payable and accrued expenses	4,155	281
Employee related accrued expenses	2,557	1,309
Other current liabilities	—	(703)
Lease liabilities	(987)	(1,125)
Uncertain tax positions	176	176
Net cash used in operating activities	(76,376)	(87,559)
Cash Flows From Investing Activities		
Purchases of marketable securities	(49,832)	(63,009)
Maturities of marketable securities	49,073	64,323
Purchases of property and equipment	(194)	(254)
Net cash (used in) provided by investing activities	(953)	1,060
Cash Flows From Financing Activities		
Proceeds from exercise of options into ordinary shares	873	1,511
Proceeds from issuance of long-term debt	—	95,783
Proceeds from pre-funded warrant issuance, net of $1,654 of issuance costs	48,700	—
Proceeds from ordinary share issuance, net of $2,288 of issuance costs	67,358	—
Issuance cost related to at-the-market issuances	—	(160)
Net cash provided by financing activities	116,931	97,134
Increase in Cash and Cash Equivalents	39,602	10,635
Cash, Cash Equivalents and Restricted Cash at Beginning of Year	56,221	45,586
Cash, Cash Equivalents and Restricted Cash at End of Year	$ 95,823	$ 56,221
Supplemental Disclosures of Non-Cash Activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 122	$ 2,165

The accompanying notes are an integral part of these consolidated financial statements.

UROGEN PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – BUSINESS AND NATURE OF OPERATIONS

Nature of Operations

UroGen Pharma Ltd. is an Israeli company incorporated in April 2004 ("UPL").

UroGen Pharma, Inc., a wholly owned subsidiary of UPL, was incorporated in Delaware in October 2015 and began operating in February 2016 ("UPI").

UPL and UPI (together the "Company") is a biotechnology company dedicated to developing and commercializing innovative solutions that treat urothelial and specialty cancers. Since commencing operations, the Company has devoted substantially all of its efforts to securing intellectual property rights, performing research and development activities, including conducting clinical trials and manufacturing activities, hiring personnel, launching the Company's first commercial product, *Jelmyto* (mitomycin) for pyelocalyceal solution, formerly known as UGN-101, clinical development of UGN-102, and raising capital to support and expand these activities.

On April 15, 2020, the U.S. Food and Drug Administration ("FDA") granted expedited approval for *Jelmyto*, a first-in-class treatment indicated for adults with low-grade upper tract urothelial cancer ("low-grade UTUC"). *Jelmyto* consists of mitomycin, an established chemotherapy, and sterile hydrogel, using our proprietary sustained release *RTGel* technology. It has been designed to enable longer exposure of urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means.

NOTE 2 – BASIS OF PRESENTATION

The Company has experienced net losses since its inception and has an accumulated deficit of $679.3 million and $577.1 million as of December 31, 2023 and 2022, respectively. The Company expects to incur losses and have negative net cash flows from operating activities as it executes on its strategy including engaging in further research and development activities, particularly conducting non-clinical studies and clinical trials. The success of the Company depends on the ability to successfully commercialize its technologies to support its operations and strategic plan.

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The consolidated financial statements include the accounts of UPL and its wholly owned subsidiary UPI. All material intercompany balances and transactions have been eliminated during consolidation.

In accordance with the accounting guidance related to the presentation of financial statements, management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the date the financial statements are issued. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, and do not include any adjustments relating to the carrying amounts and classification of assets and liabilities that may be necessary should the Company be unable to continue as a going concern. The Company's ability to continue as a going concern is expected to be impacted by its ability to raise additional capital to fund its operations, produce cash inflows from *Jelmyto* product sales and develop UGN-102.

The Company believes that absent sufficient proceeds received from equity, financing, or business development transactions, the Company will not have sufficient cash and cash equivalents to fund its operations beyond one year from the issuance of these financial statements. Accordingly, the Company will, over the next twelve months, require significant additional financing to continue its operations. In addition, there can be no assurances that the Company will be able to secure such additional financing if at all, on terms that are satisfactory to the Company, and in amounts sufficient to meet its needs. These factors raise substantial doubt about the ability of the Company to continue as a going concern. Failure to successfully receive additional financing will require the Company to delay, limit or reduce product development and commercialization efforts.

NOTE 3 – SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The Company's consolidated financial statements include the accounts of UPL and its subsidiary, UPI. Intercompany balances and transactions have been eliminated during consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results may differ from those estimates. As applicable to the consolidated financial statements, the critical accounting estimates relate to the fair value of share-based compensation, measurement of revenue, estimate of uncertain tax positions, and measurement of liabilities accounted for under the interest method.

Functional Currency

The U.S. dollar ("Dollar") is the currency of the primary economic environment in which the operations of the Company are conducted. Therefore, the functional currency of the Company is the Dollar.

Accordingly, transactions in currencies other than the Dollar are measured and recorded in the functional currency using the exchange rate in effect at the date of the transaction. At the balance sheet date, monetary assets and liabilities that are denominated in currencies other than the Dollar are measured using the official exchange rate at the balance sheet date. The effects of foreign currency re-measurements are recorded in the consolidated statements of operations as "Interest and other income, net."

Cash and Cash Equivalents; Marketable Securities

The Company presents all highly liquid investments with an original maturity of three months or less when purchased as cash equivalents. Cash and cash equivalents generally consist of money market funds and bank money market accounts and are stated at cost, which approximates fair value.

Cash and cash equivalents and marketable securities totaled $141.5 million as of December 31, 2023. The Company accounts for its investments, which include cash equivalents and marketable securities, as available-for-sale in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, "Investments — Debt and Equity Securities". Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported in other comprehensive income/loss within shareholders' equity. Realized gains and losses are recorded as a component of interest and other income, net. The cost of securities sold is based on the specific-identification method.

Certain short-term investments are valued using models or other valuation methodologies that use Level 2 inputs. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, volatility factors, default rates, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. The majority of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

For individual debt securities classified as available-for-sale securities where there has been a decline in fair value below amortized cost, the Company determines whether the decline resulted from a credit loss or other factors. The Company records impairment relating to credit losses through an allowance for credit losses, limited by the amount that the fair value is less than the amortized cost basis. Impairment that has not been recorded through an allowance for credit losses is recorded through other comprehensive income, net of applicable taxes.

Restricted cash is related primarily to cash held to secure corporate credit cards; restricted deposits are related to cash held to secure leases.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents and marketable securities. The primary objectives for the Company's investment portfolio are the preservation of capital and the maintenance of liquidity. The Company does not enter into any investment transaction for trading or speculative purposes.

The Company's investment policy limits investments to certain types of instruments such as certificates of deposit, money market instruments, obligations issued by the U.S. government and U.S. government agencies as well as corporate debt securities, and places restrictions on maturities and concentration by type and issuer. The Company maintains cash balances in excess of amounts insured by the Federal Deposit Insurance Corporation and concentrated within a limited number of financial institutions. The accounts are monitored by management to mitigate the risk.

The Company's product sales are recognized through the Company's arrangement with a single customer, a third-party national specialty distributor. The Company assesses the need for an allowance for doubtful accounts primarily based on creditworthiness, historical payment experience and general economic conditions. The Company has not experienced any credit losses related to this customer and has not currently recognized any allowance for doubtful accounts.

Income Taxes

The Company provides for income taxes based on pretax income, if any, and applicable tax rates available in the various jurisdictions in which it operates, including Israel and the United States. Deferred taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future.

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. After concluding that a particular filing position can be recognized (i.e., has a more-likely-than-not chance of being sustained), ASC 740-10-30-7 requires that the amount of benefit recognized be measured using a methodology based on the concept of cumulative probability. Under this methodology, the amount of benefit recorded represents the largest amount of tax benefit that is greater than 50% likely to be realized upon settlement with a taxing authority that has full knowledge of all relevant information. See Note 17 for further discussion related to income taxes.

Inventory

The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, status of regulatory approval, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. For *Jelmyto*, the Company commenced capitalization of inventory at the receipt of FDA approval.

The Company values its inventory at the lower of cost or net realizable value. The Company measures inventory approximating actual cost under a first-in, first-out basis. The Company assesses recoverability of inventory each reporting period to determine any write down to net realizable value resulting from excess or obsolete inventories.

Property and Equipment

Property and equipment are recorded at historical cost, net of accumulated depreciation, amortization and, if applicable, impairment charges. The Company reviews its property and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Property and equipment are depreciated over the following useful lives (in years):

	Useful Lives
Computers and software	3
Laboratory equipment	3 - 6.5
Furniture	5 - 16.5
Manufacturing equipment	2 - 10

Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 8 for further discussion regarding property and equipment.

Prepaid Forward Obligation

The Company is party to a transaction with RTW Investments (the “RTW Transaction”) in which the Company received funds to support the continued launch of *Jelmyto* and the development of UGN-102 in return for tiered, future cash payments based on net sales of *Jelmyto* and UGN-102*,* if approved by the FDA. The net proceeds received under the RTW Transaction were recognized as a long-term liability. The Company recognizes the current cash payable amounts under the arrangement within other current liabilities on the consolidated balance sheets. The subsequent measurement for the liability follows the accounting principles defined in ASC Topic *835-30,* “Imputation of Interest”. See Note 9 for further discussion related to the prepaid forward obligation.

Long-Term Debt

The Company is party to a loan agreement with funds managed by Pharmakon Advisors, L.P. (“Pharmakon”). The Company recognizes interest expense in current earnings, and accrued interest within other current liabilities on the consolidated balance sheets. The Company recognizes capitalized financing expenses as a direct offset to the long-term debt on the Company's consolidated balance sheets, and amortizes them over the term of the debt using the effective interest method. See Note 10 for further discussion related to long-term debt.

Leases

The Company is a lessee in several noncancelable operating leases, primarily for office space, office equipment and vehicles. The Company currently has no finance leases.

The Company accounts for leases in accordance with ASC Topic 842, “Leases”. The Company determines if an arrangement is a lease at inception. Right-of-use (“ROU”) assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term as of the commencement date. Operating lease ROU assets are presented as right-of-use assets on the consolidated balance sheets. The current portion of operating lease liabilities is included in other current liabilities and the long-term portion is presented separately as long-term lease liabilities on the consolidated balance sheets.

UROGEN PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Lease expense is recognized on a straight-line basis for operating leases. Variable lease payments associated with the Company's leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed occurs. Variable lease payments are presented as operating expense on the consolidated statements of operations in the same line item as expense arising from fixed lease payments.

The Company's lease terms may include options to extend the lease. The lease extensions are included in the measurement of the right-of-use asset and lease liability when it is reasonably certain that it will exercise that option.

Because most of the Company's leases do not provide an implicit rate of return, an incremental borrowing rate is used based on the information available at the commencement date in determining the present value of lease payments on an individual lease basis. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms.

ROU assets for operating leases are periodically reviewed for impairment losses under ASC 360-10, "Property, Plant, and Equipment," to determine whether an ROU asset is impaired, and if so, the amount of the impairment loss to recognize.

Revenue

Product sales from *Jelmyto* are recognized as revenue under ASC 606 at the point in time that control of the product has been transferred to the customer, generally at the point the product has been delivered to the treating physician. All product sales of *Jelmyto* are recognized through the Company's arrangement with a single customer, a third-party national specialty distributor. Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customer, chargebacks relating to differences between the wholesale acquisition cost and the contracted price offered to the end consumer, chargebacks relating to 340B drug pricing programs and other government sponsored programs, Medicaid drug rebate programs, the Company's copay assistance program, and Medicare refunds for discarded drug, which are estimated based on the Company's historical experience.

Research and Development Expenses

Research and development costs are expensed as incurred and consist primarily of the cost of salaries, share-based compensation expenses, payroll taxes and other employee benefits, subcontractors and materials used for research and development activities, including nonclinical studies, clinical trials, manufacturing costs and professional services. The costs of services performed by others in connection with the research and development activities of the Company, including research and development conducted by others on behalf of the Company, shall be included in research and development costs and expensed as the contracted work is performed. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or project and the invoices received from its external service providers. The Company adjusts its accrual as actual costs become known. Where contingent milestone payments are due to third parties under research and development arrangements or license agreements, the milestone payment obligations are expensed when such development milestone results are achieved.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel costs (including share-based compensation related to directors, employees and consultants). Other significant costs include commercial, medical affairs, external professional service costs, facility costs, accounting and audit services, legal services and other consulting fees. Selling, general and administrative costs are expensed as incurred, and the Company accrues for services provided by third parties related to the above expenses by monitoring the status of services provided and receiving estimates from its service providers and adjusting its accruals as actual costs become known.

Share-Based Compensation

Share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the required service period, which is equal to the vesting period. For performance stock units ("PSUs"), cost is measured at the grant date based on the fair value of the award and is recognized over any relevant service period as expense when the achievement of the performance condition is probable. The fair value of options is determined using the Black-Scholes option-pricing model. The fair value of a restricted stock unit ("RSU") or a PSU equals the closing price of the Company's ordinary shares on the grant date. The Company accounts for forfeitures as they occur in accordance with ASC Topic 718, "Compensation—Stock Compensation".

The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the straight-line method and to value the awards based on the single-option award approach.

Pre-funded Warrants

The Company issued pre-funded warrants in connection with a private placement transaction that are accounted for as a freestanding equity-linked financial instrument that meets the criteria for equity classification under ASC 480, "Distinguishing Liabilities from Equity," and ASC 815, "Derivatives and Hedging." Accordingly, the Company classifies the pre-funded warrants as a component of permanent shareholders' equity within additional paid-in capital and records them at the issuance date using a relative fair value allocation method. The Company valued the pre-funded warrants at issuance, concluding that their sales price approximated their fair value, and allocated the net sales proceeds from the private placement transaction proportionately to the ordinary shares and pre-funded warrants. See Note 15 for further discussion related to the private placement transaction.

Net Loss per Ordinary Share

Basic net loss per share is computed by dividing the net loss attributable to ordinary shareholders by the weighted-average number of ordinary shares outstanding. Diluted net loss per share is computed similarly to basic net loss per share except that the denominator is increased to include the number of additional ordinary shares that would have been outstanding if the potential ordinary shares had been issued and if the additional ordinary shares were dilutive.

For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted loss per share as their effect is anti-dilutive.

The Company's pre-funded warrants requires the holder to pay nominal consideration to receive the Company's ordinary shares and are therefore considered outstanding shares in determining basic and diluted earnings per share in accordance with ASC Topic 260, "Earnings per Share".

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The following table summarizes the calculation of basic and diluted loss per ordinary share for the periods presented (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	2022
Basic and diluted:		
Loss attributable to equity holders of the Company	$ (102,244)	$ (109,783)
Weighted-average number of ordinary shares	28,834,303	22,806,812
Loss per ordinary share	$ (3.55)	$ (4.81)

Recently Adopted or Issued Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which provides guidance to improve the disclosures about a public entity's reportable segments and address requests from investors for additional, more detailed information about a reportable segment's expenses. Public entities must adopt the new guidance for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The amendments in this ASU must be applied on a retrospective basis to all prior periods presented in the financial statements and early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of ASU 2023-07 on the Company's financial disclosures.

In December 2023, the FASB issued Accounting Standards Update No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"), which will require the Company to disclose specified additional information in its income tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. ASU 2023-09 will also require the Company to disaggregate its income taxes paid disclosure by federal, state and foreign taxes, with further disaggregation required for significant individual jurisdictions. The Company will adopt ASU 2023-09 for the 2025 year-end and is currently evaluating the potential impact of the adoption on the Company's financial disclosures. ASU 2023-09 allows for adoption using either a prospective or retrospective transition method.

The Company has reviewed other Accounting Standards Updates recently issued by the FASB, and determined that none of these pronouncements will have a significant impact on the Company's consolidated financial statements and related disclosures.

NOTE 4 – OTHER FINANCIAL INFORMATION

Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Accounts payable	$ 6,514	$ 5,527
Accrued sales reserves	4,391	618
Accrued clinical expenses	1,246	2,853
Accrued research and development expenses	1,049	1,285
Accrued selling, general and administrative expenses	2,752	1,609
Accrued other expenses	586	491
Total accounts payable and accrued expenses	$ 16,538	$ 12,383

Interest and Other Income, Net

Interest and other income, net consisted of the following for the year ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Interest income	$ 2,641	$ 938
Other income, net	838	72
Total interest and other income, net	$ 3,479	$ 1,010

NOTE 5 – INVENTORIES

Inventories consisted of the following as of December 31, 2023 and December 31, 2022 (in thousands):

	December 31, 2023	December 31, 2022
Raw materials (1)	$ 4,464	$ 4,676
Finished goods	2,877	2,019
Total inventories	$ 7,341	$ 6,695

(1) $1.7 million and $2.4 million of raw materials are included within other non-current assets on the consolidated balance sheets at December 31, 2023 and December 31, 2022, respectively. Changes in non-current assets are reflected on the consolidated statements of cash flows within the caption of other non-current assets.

NOTE 6 – FAIR VALUE MEASUREMENTS

The Company follows authoritative accounting guidance, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

The carrying amounts of the Company's cash, restricted cash, other current assets, accounts payable and accrued liabilities are generally considered to be representative of their fair value because of the short-term nature of these assets and liabilities.

The carrying value of the prepaid forward obligation (See Note 9 - Prepaid Forward Obligation) approximates its fair value. The Company estimated the fair value of the prepaid forward obligation using Level 3 inputs, including internally developed financial forecasts and management's estimate of probability of success related to product candidates, and determined that the effective interest rate in the obligation approximates market rates for loans with similar terms and risk characteristics.

The Company estimated the fair value of long-term debt (see Note 10 - Long-Term Debt) using the income approach with Level 3 inputs. The Company estimated future floating rate interest payments using a forward curve of a three-month benchmark rate, and estimated fair value based on publicly available data reported in the financial statements of publicly traded venture lending companies. Based on a reasonable range of yields for debt instruments of similar tenor in a similar industry, the Company determined that the carrying value of the long-term debt on the Company's balance sheet approximates its fair value.

No transfers between levels have occurred during the periods presented.

Assets measured at fair value on a recurring basis based on Level 1 and Level 2 fair value measurement criteria as of December 31, 2023 are as follows (in thousands):

		Fair Value Measurements Using	
	Balance as of December 31, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash equivalents			
Money market funds	$ 9,704	$ 9,704	$ —
Marketable securities			
U.S. government	$ 28,634	$ 28,634	$ —
Corporate bonds	6,738	—	6,738
Commercial paper	7,101	—	7,101
Certificates of deposit	3,995	—	3,995
Total marketable securities	$ 46,468	$ 28,634	$ 17,834
Total assets at fair value	$ 56,172	$ 38,338	$ 17,834

Assets measured at fair value on a recurring basis based on Level 1 and Level 2 fair value measurement criteria as of December 31, 2022 are as follows (in thousands):

		Fair Value Measurements Using	
	Balance as of December 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Marketable securities			
U.S. government	$ 28,693	$ 28,693	$ —
Corporate bonds	2,387	—	2,387
Commercial paper	9,392	—	9,392
Certificates of deposit	4,084	—	4,084
Total marketable securities	$ 44,556	$ 28,693	$ 15,863

The Company's investments in U.S. government bonds and money market funds are measured based on publicly available quoted market prices for identical securities as of December 31, 2023 and 2022. The Company's investments in corporate bonds, commercial paper and certificates of deposits are measured based on quotes from market makers for similar items in active markets.

NOTE 7 – INVESTMENTS

The following table summarizes the Company's investments as of December 31, 2023 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Assets:				
Cash equivalents				
Money market funds	$ 9,704	$ —	$ —	$ 9,704
Marketable securities				
U.S. government	$ 28,618	$ 36	$ (20)	$ 28,634
Corporate bonds	6,756	2	(20)	6,738
Commercial paper	7,094	8	(1)	7,101
Certificates of deposit	3,988	7	—	3,995
Total marketable securities	$ 46,456	$ 53	$ (41)	$ 46,468
Total assets at fair value	$ 56,160	$ 53	$ (41)	$ 56,172

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The following table summarizes the Company's investments as of December 31, 2022 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities				
U.S. government	$ 28,742	$ —	$ (49)	$ 28,693
Corporate bonds	2,392	—	(5)	2,387
Commercial paper	9,417	—	(25)	9,392
Certificates of deposit	4,112	—	(28)	4,084
Total marketable securities	$ 44,663	$ —	$ (107)	$ 44,556

The Company classifies its investments as available-for-sale, and they consist entirely of debt securities. As of December 31, 2023, the amortized cost of investments included an immaterial amount of accrued interest. As of December 31, 2023, marketable securities were in a net unrealized gain position. Unrealized gains and losses on available-for-sale debt securities are included as a component of comprehensive loss.

As of December 31, 2023, the aggregate fair value of investments held by the Company in an unrealized loss position was $22.9 million which consisted of 30 securities. The unrealized loss was primarily driven by rising interest rates. The Company does not expect to settle the debentures at a price less than the amortized cost basis of the investment; the Company expects to recover the entire amortized cost basis of the security. In accordance with the Company's general investment strategy, the Company does not intend to sell the investments before maturity. As of December 31, 2023, the Company believes the cost basis for its marketable securities were recoverable in all material aspects and no allowance for credit losses were recognized in the period.

The Company's investments as of December 31, 2023 mature at various dates through January 2026. The fair values of investments by contractual maturity consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Maturities within one year	$ 51,670	$ 44,556
Maturities after one year through three years	4,502	—
Total investments	$ 56,172	$ 44,556

NOTE 8 – PROPERTY AND EQUIPMENT

Property and equipment, consists of the following as of December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Laboratory equipment	$ 464	$ 452
Computer equipment and software	2,293	2,168
Furniture	612	602
Leasehold improvements	617	617
Manufacturing equipment	655	608
	4,641	4,447
Less: accumulated depreciation and amortization	(3,952)	(3,150)
Property and equipment, net	$ 689	$ 1,297

Depreciation and amortization expense was $0.8 million and $0.9 million for the years ended December 31, 2023 and 2022, respectively.

NOTE 9 – PREPAID FORWARD OBLIGATION

In March 2021, the Company entered into a prepaid forward agreement with RTW Investments ("RTW"). Under the terms of the RTW Transaction, the Company received $75.0 million ($72.4 million net of transaction costs) to support the continued launch of *Jelmyto* and the development of UGN-102. In return for the transferred funds, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of *Jelmyto* in an amount equal to: (i) 9.5% of annual net sales up to $200 million, (ii) 3.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 1.0% of annual net sales for annual net sales above $300 million. If certain revenue thresholds for *Jelmyto* aggregate worldwide annual net sales are not met, the future cash payments to RTW with respect to *Jelmyto* annual net sales up to $200 million will increase by 3.5%, and may decrease back to 9.5% dependent on the Company meeting certain subsequent *Jelmyto* aggregate worldwide annual net sales thresholds. The rate in effect for the year ended December 31, 2023 for annual net sales up to $200 million was 13.0%.

In addition, subject to FDA approval of UGN-102, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of UGN-102 in an amount equal to: (i) 2.5% of annual net sales up to $200 million, (ii) 1.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 0.5% of annual net sales for annual net sales above $300 million. If the Company does not receive FDA approval for UGN-102 by a specified date, the future cash payments to RTW with respect to aggregate worldwide annual net sales of *Jelmyto* across all *Jelmyto* annual net sales tiers will increase by 1.5%.

In accordance with the prepaid forward agreement, the Company will be required to make payments of amounts owed to RTW each calendar quarter, through and until the quarter in which the aggregate cash payments received by RTW are equal to or greater than $300 million. As security for the payment and fulfilment of these amounts throughout the arrangement, the Company has granted RTW a first priority security interest in *Jelmyto* and UGN-102, including the regulatory approvals, intellectual property, material agreements, proceeds and accounts receivable related to these products.

In May 2021, following the receipt of necessary regulatory approvals, the Company received the $75.0 million prepaid forward payment ($72.4 million net of transaction costs) from RTW and recognized an associated prepaid forward obligation liability. Each period the Company makes a payment to RTW, an expense is recognized related to financing on the prepaid forward obligation based on an imputed rate derived from the expected future payments. Management reassesses the effective rate each period based on the current carrying value of the obligation and the revised estimated future payments. Changes in future payments from previous estimates are included in future financing expense. The Company does not expect to make any principal payments in the next 12 months.

The following table shows the activity with respect to the carrying value of the prepaid forward liability for the year ended December 31, 2023 and 2022 (in thousands):

Carrying value of prepaid forward obligation as of December 31, 2021	$	85,713
Financing on prepaid forward obligation		21,559
Amounts paid and payable (1)		(8,349)
Carrying value of prepaid forward obligation as of December 31, 2022		98,923
Financing on prepaid forward obligation		21,552
Amounts paid and payable (1)		(10,753)
Carrying value of prepaid forward obligation as of December 31, 2023	$	109,722

(1) $3.0 million and $2.3 million of the Amounts paid and payable are included as current portion of the prepaid forward obligation within other current liabilities on the consolidated balance sheets as of December 31, 2023 and December 31, 2022, respectively.

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NOTE 10 – LONG-TERM DEBT

On March 7, 2022, the Company entered into a loan agreement with Pharmakon for a senior secured term loan of up to $100 million in two tranches. The first tranche of $75 million was funded in March 2022. The second tranche of $25 million was funded in December 2022. The facility will mature five years from initial funding and can be prepaid in whole at the Company's discretion, at any time, subject to prepayment premiums and make-whole amounts. The loan will require interest-only payments for the first 48 months followed by principal and interest payments with interest accruing using 3-month London Inter-Bank Offered Rate ("LIBOR") (with a 1.25% floor) plus 8.25%. On June 29, 2023, the loan agreement with Pharmakon was amended to replace the benchmark governing the interest rate with a rate based on the secured overnight financing rate ("SOFR") published by the Federal Reserve Bank of New York. Effective July 2023, the loan will accrues interest using a benchmark rate of 3-month SOFR plus a 0.26161% adjustment. The Company is not required to maintain any financial covenants.

The Company incurred financing expenses of $4.2 million which are recognized as a direct offset to the long-term debt on the Company's consolidated balance sheets. These debt issuance costs are amortized over the term of the debt using the effective interest method, and are recorded in the consolidated statements of operations as "Interest expense".

The following table shows the activity with respect to the carrying value of the long-term debt, in thousands:

Long-term debt at closing of Pharmakon loan	$	100,000
Capitalized costs and discounts		(4,217)
Interest expense		8,438
Amounts paid		(6,685)
Carrying value of Pharmakon loan as of December 31, 2022		97,537
Interest expense		14,715
Amounts paid		(13,701)
Carrying value of Pharmakon loan as of December 31, 2023	$	98,551

NOTE 11 – LEASES

Operating Leases

The Company had the following office and laboratory facility leases as of December 31, 2023:

- In April 2016, UPL signed an addendum to its November 2014 lease agreement for the Company's offices located in Israel, in order to increase the office space rented and to extend the rent period for an additional three years until August 2022. In July 2022, the Company signed a lease extension agreement for the Company's offices located in Israel, extending the term of the lease through September 2025. The Company's remaining contractual obligation under this lease is approximately $0.5 million as of December 31, 2023.

- In April 2018, UPI entered into a new lease agreement for an office in Los Angeles, California. The lease commencement date was July 10, 2018 and terminated in March 2024. The landlord provided a tenant allowance for leasehold improvements of $0.2 million that was accounted for as a lease incentive. The Company's remaining contractual obligation under this lease is approximately $0.1 million as of December 31, 2023. In November 2019, UPI entered into a sublease for this office space, with a lease commencement date of January 1, 2020 and terminating at the end of the lease term in March 2024. The subtenants exercised their early access clause and moved into the premises at the end of November 2019. The remaining rental payments to be received over the lease term is approximately $0.1 million as of December 31, 2023. The Company accounts for the sublease as on operating lease in accordance with ASC 842.

- In November 2019, UPI entered into a new lease agreement for an office in Princeton, New Jersey, which the Company now uses as its headquarters. The lease commencement date was November 29, 2019 with an original lease term of 38 months, expiring January 31, 2023. In June 2022, the Company signed a lease extension for the Princeton office, extending the term of the lease through January 31, 2026. The Company's remaining contractual obligation under this lease is approximately $1.2 million as of December 31, 2023.

In addition, the Company has other operating office equipment and vehicle leases. The Company's operating leases may require minimum rent payments, contingent rent payments adjusted periodically for inflation, or rent payments equal to the greater of a minimum rent or contingent rent. The Company's leases do not contain any residual value guarantees or material restrictive covenants. The Company's leases expire at various dates from 2024 through 2026, with varying renewal and termination options.

The components of lease cost for the year ended December 31, 2023 and 2022 were as follows (in thousands):

		Year Ended December 31, 2023		Year Ended December 31, 2022
Operating lease cost	$	934	$	975
Sublease income		(224)		(224)
Variable lease cost		73		65
	$	783	$	816

The amounts recognized as of December 31, 2023 and 2022 were as follows (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022

Right-of-use assets	$ 1,671	$ 2,452
Long-term lease liabilities	844	1,586
Other current liabilities	819	941

As of December 31, 2023, no impairment losses have been recognized.

Supplemental information related to leases for the periods reported is as follows (in thousands, except for lease term and discount rate amounts):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	1,169	1,195
Right-of-use assets obtained in exchange for new operating lease liabilities	122	2,165
Weighted-average remaining lease term of operating leases (in years)	1.92	2.73
Weighted-average discount rate of operating leases	10.21%	10.25%

As of December 31, 2023, maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
2024	$ 938
2025	825
2026	58
Total future minimum lease payments	$ 1,821
Less: Interest	(158)
Present value of lease liabilities	$ 1,663

As of December 31, 2022, maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
2023	$ 1,146
2024	904
2025	788
2026	49
Total future minimum lease payments	$ 2,887
Less: Interest	(360)
Present value of lease liabilities	$ 2,527

Subleases

As of December 31, 2023, undiscounted cash flows to be received under the Company's operating sublease on an annual basis were as follows (in thousands):

	Operating Leases
Years ending December 31,	
2024	$ 49
Total future minimum sublease payments	$ 49

As of December 31, 2022, undiscounted cash flows to be received under the Company's operating sublease on an annual basis was as follows (in thousands):

	Operating Leases
Years ending December 31,	
2023	$ 251
2024	49
Total future minimum sublease payments	$ 300

NOTE 12 – REVENUE FROM PRODUCT SALES

Net product sales consist of the following for the year ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Jelmyto	$ 82,713	$ 64,357

Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customer, chargebacks relating to differences between the wholesale acquisition cost and the contracted price offered to the end consumer, chargebacks relating to 340B drug pricing programs and other government sponsored programs, Medicaid drug rebate programs, the Company's copay assistance program, and Medicare refunds for discarded drug, which are estimated based on the Company's historical experience. Reserves related to items that are contractually able to be net settled are recognized as contra accounts receivable while other remaining reserves are recognized within other current liabilities on the consolidated balance sheets. The following table shows the activity with respect to sales reserves for the year ended December 31, 2023 and 2022, in thousands:

	Reserves related to government sponsored programs	Other reserves	Total accrued sales reserves
Balance as of December 31, 2021	$ 373	$ 941	$ 1,314
Changes during 2022			
Accruals	6,967	6,463	13,430
Utilizations	(6,750)	(6,557)	(13,307)
Balance as of December 31, 2022	$ 590	$ 847	$ 1,437
Changes during 2023			

Accruals	11,110	12,258	23,368
Utilizations	(10,638)	(8,196)	(18,834)
Balance as of December 31, 2023	$ 1,062	$ 4,909	$ 5,971

NOTE 13 – LICENSE AND COLLABORATION AGREEMENTS

Agenus Agreement

In November 2019, the Company entered into a license agreement with Agenus Inc. ("Agenus"), pursuant to which Agenus granted to the Company an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary monoclonal antibody of Agenus known as AGEN1884 (zalifrelimab), an anti-CTLA-4 antagonist, for the treatment of cancers of the urinary tract via intravesical delivery. UGN-301 is a formulation of zalifrelimab administered using *RTGel* technology that is in Phase 1 clinical development for high-grade NMIBC.

MD Anderson Agreement

In January 2021, the Company announced that it entered into a three-year strategic research collaboration agreement with MD Anderson focusing on the sequential use of UGN-201 and UGN-301 as an investigational treatment for high-grade NMIBC. Pursuant to the agreement, the Company has made bi-annual payments totaling $2.0 million to MD Anderson to fund the collaboration, recognized evenly over the associated period through research and development expenses. In July 2022, the Company determined that it had achieved the objectives that it established when the agreement was initiated, and notified MD Anderson that it was exercising its right to conclude the collaboration in 2022 as the Company did not foresee initiating further development activities as part of the collaboration, although the Company will continue to collaborate on existing joint projects. As a result of this notification, the Company is not responsible for any further fixed bi-annual funding payments in 2023, although the Company will be responsible for costs related to existing joint projects to the extent they exceed the payments already made to MD Anderson.

NOTE 14 – EMPLOYEE RIGHTS UPON RETIREMENT

In Israel, the Company is required by law to make severance payments upon dismissal of an employee or upon termination of employment in certain other circumstances.

The Company operates a number of post-employment defined contribution plans. A defined contribution plan is a program that benefits an employee after termination of employment, under which the Company regularly makes fixed payments to a separate and independent entity so that the Company has no legal or constructive obligation to pay additional contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods. The fund assets are not included in the Company's financial position.

The Company operates pension and severance compensation plans subject to Section 14 of the Israeli Severance Pay Law, 5723-1963. The plans are funded through payments to insurance companies or pension funds administered by trustees. In accordance with its terms, the plans meet the definition of a defined contribution plan, as defined above.

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NOTE 15 – SHAREHOLDERS' EQUITY

The Company had 100.0 million ordinary shares authorized for issuance as of December 31, 2023 and 2022. The Company had 32.5 million and 23.1 million ordinary shares issued and outstanding as of December 31, 2023 and 2022, respectively. Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors (the "Board"). Since its inception, the Board has not declared any dividends.

On July 26, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and other accredited investors (the "Purchasers"), pursuant to which the Company agreed to sell and issue to the Purchasers 7,300,380 ordinary shares of the Company ("Shares") and 5,278,776 of pre-funded warrants to purchase ordinary shares of the Company at a purchase price of $9.54 per Share or $9.539 for each ordinary share underlying a pre-funded warrant, in a private placement transaction that closed on July 28, 2023 and August 9, 2023 (the "Private Placement") for aggregate gross proceeds of $120.0 million, before deducting fees to placement agents and financial advisors and before other expenses paid by the Company. Each pre-funded warrant has an exercise price of $0.001 per ordinary share, subject to customary adjustments, became exercisable upon original issuance and will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation. The aggregate fee paid by the Company to placement agents and financial advisors was $3.6 million, plus the reimbursement of certain expenses.

Resales of the Shares and the ordinary shares issuable upon exercise of the pre-funded warrants were registered pursuant to the Company's registration statement on Form S-3 (File No. 333-274423) filed with the U.S. Securities and Exchange Commission ("SEC") on September 8, 2023, which was declared effective on September 15, 2023.

On December 20, 2023, the Company issued 1,599,733 ordinary shares through a cashless conversion of 1,599,840 pre-funded warrants for the purchase of ordinary shares of the Company.

Monograph Capital Partners I, L.P. ("Monograph"), a life sciences venture firm that is affiliated with Fred Cohen, M.D., a director of the Company, purchased 1,572,327 of the Shares in the Private Placement, for an aggregate purchase price of $15.0 million. Dr. Cohen is the Chair and Chief Investment Officer of Monograph.

NOTE 16 – SHARE-BASED COMPENSATION

In October 2010, the Board approved a share option plan (the "2010 Plan") for grants to Company employees, consultants, directors, and other service providers. Subsequently, in March 2017, the Board adopted the 2017 Equity Incentive Plan (the "2017 Plan" and, together with the 2010 Plan, the "Plans"), which was approved by the shareholders in April 2017. The 2017 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance share awards, performance cash awards, and other forms of share awards to the Company's employees, directors and consultants.

The grant of options to Israeli employees under the Plans is subject to the terms stipulated by Section 102 of the Israeli Income Tax Ordinance ("Section 102"). The option grants are subject to the track chosen by the Company, either the "regular income" track or the "capital gains" track, as set out in Section 102. The Company registered the Plans under the capital gains track, which offers more favorable tax rates to the employees. As a result, and pursuant to the terms of Section 102, the Company is not allowed to claim as an expense for tax purposes the amounts credited to the employees in respect of options granted to them under the Plans, including amounts recorded as salary benefits in the Company's accounts, with the exception of the work-income benefit component, if any, determined on grant date. For non-employees and for non-Israeli employees, the Plans is subject to Section 3(i) of the Israeli Income Tax Ordinance.

Employees are typically granted stock options and/or restricted stock units ("RSUs"), upon commencement of employment. Also, eligible employees may receive an annual grant of options or RSUs. Non-employee members of the Board typically receive a grant of stock options upon initial appointment to the Board, and/or stock options annually. The term of any option granted under the Plans cannot exceed 10 years. Options shall not have an exercise price less than 100% of the fair market value of the Company's ordinary shares on the grant date, and generally vest over a period of three years. If the individual possesses more than 10% of the combined voting power of all classes of equity of the Company, the exercise price shall not be less than 110% of the fair market value of an ordinary share on the date of grant.

The Company's RSU and option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including a termination in connection with a change in control. RSUs generally vest in a 33% increment upon the first anniversary of grant, and in either equal quarterly or annual amounts for the two years following the one-year anniversary of the grant date. Options generally vest in a 33% increment upon the first anniversary of the grant date, and in either equal quarterly or annual amounts for the two years following the one-year anniversary of the grant date.

The expected volatility is based on a mix of the Company's historical volatility, and the historical volatility of comparable companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted. The expected term is the length of time until the expected dates of exercising the options and is estimated for employees using the simplified method due to insufficient specific historical information of employees' exercise behavior, and for non-employees, and directors using the contractual term.

On January 31, 2023, the Board approved a performance stock unit ("PSU") award of 100,000 shares under the 2017 Plan to the Company's Chief Executive Officer, subject to shareholder approval. Vesting of these PSUs will depend upon obtaining regulatory approval for the Company's lead product candidate UGN-102 in the three years following the grant. The PSU award was approved by the Company's shareholders at the 2023 Annual Shareholders' Meeting on September 7, 2023.

The maximum number of ordinary shares that was initially authorized for issuance under the 2017 Plan was 1,400,000. On January 1, 2018, the share reserve increased by 250,167 to 1,650,167 shares. On October 12, 2018, the Company increased the number of ordinary shares authorized for issuance under the

2017 Plan by 1,900,000 to 3,550,167 shares. On June 8, 2020, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 400,000 to 3,950,167 shares. On June 7, 2021, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 400,000 to 4,350,167 shares. On June 8, 2022, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 400,000 to 4,750,167 shares. On September 7, 2023, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 450,000 to 5,200,167 shares.

In May 2019, the Company adopted the UroGen Pharma Ltd. 2019 Inducement Plan (the "Inducement Plan"). Under the Inducement Plan, the Company is authorized to issue up to 900,000 ordinary shares pursuant to inducement awards. The only persons eligible to receive grants under the Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1, including individuals who were not previously an employee or director of the Company or are following a bona fide period of non-employment, in each case as an inducement material to such individual's agreement to enter into employment with the Company. In December 2021, the Board approved a 300,000 increase in the share reserve of the Inducement Plan to 1,200,000 shares.

As of December 31, 2023, 3,784,480 ordinary shares are subject to outstanding awards under the Company's share-based compensation plans, and 1,009,614 ordinary shares remain available for future awards.

Options granted:

Set forth below are grants made by the Company as of December 31, 2023. The majority of options vest over three years and expire on the tenth anniversary of the date of grant.

a) During 2023, the Company granted 530,000 options with exercise prices ranging from $8.84 to $17.94 per share.

b) During 2022, the Company granted 410,064 options with exercise prices ranging from $5.19 to $11.88 per share.

The fair value of options granted during 2023 and 2022 was $4.3 million and $2.2 million, respectively.

The total unrecognized compensation cost of options as of December 31, 2023 was $4.4 million, which is expected to be recognized over a weighted average period of 1.7 years.

The fair value of options granted was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	2023	2022
Value of ordinary shares	8.84417.944	5.19911.888
Dividend yield	0%	0%
Expected volatility	67.21%-81.00%	72.35%-81.00%
Risk-free interest rate	3.47%-4.42%	1.69%-4.14%
Expected term (in years)	6.0-10 years	6.0-10 years

The expected volatility is based on a mix of the Company's historical volatility and the historical volatility of comparable companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted. The expected term is the length of time until the expected dates of exercising the options and is estimated for employees using the simplified method due to insufficient specific historical information of employees' exercise behavior, and for non-employees, and directors using the contractual term.

The following table summarizes the number of employee and non-employee options outstanding under the Plan for the years ended December 31, 2023 and 2022, and related information:

	Number of options	Weighted Average price per share
Outstanding as of December 31, 2021	2,969,557	$ 27.70
Granted	410,064	7.82
Forfeited	(496,417)	27.97
Exercised	(292,665)	5.16
Outstanding as of December 31, 2022	2,590,539	$ 27.05
Granted	530,000	11.75
Forfeited	(268,316)	27.42
Exercised	(166,427)	5.25
Outstanding as of December 31, 2023	2,685,796	$ 25.35
Vested and expected to vest, December 31, 2023	2,685,796	$ 25.35
Exercisable, December 31, 2023	1,831,743	$ 6.10

UROGEN PHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

The intrinsic value of stock options exercised was $0.7 million and $0.8 million for the years ended December 31, 2023 and 2022, respectively.

The following table summarizes the outstanding and exercisable options as of December 31, 2023:

	Options outstanding		Options exercisable	
Exercise price per share	Number of options outstanding at end of year	Weighted average remaining contractual life	Number of options exercisable at end of year	Weighted average remaining contractual life
$ 0.00 - 10.00	386,064	13.00	152,018	12.22
$ 10.01 - 20.00	920,000	8.27	372,496	7.11
$ 20.01 - 30.00	455,300	6.11	382,797	5.92
$ 30.01 - 40.00	201,000	4.83	201,000	4.83
$ 40.01 - 50.00	637,432	4.78	637,432	4.78
$ 50.01 - 59.23	86,000	4.43	86,000	4.43
	2,685,796		1,831,743	

The aggregate intrinsic value of the total vested and exercisable options as of December 31, 2023 is $1.6 million.

The following table summarizes information about RSU activity as of December 31, 2023:

	Outstanding Restricted Stock Units
Outstanding as of December 31, 2021	753,274
Granted	445,980
Vested and released	(374,293)
Forfeited	(134,006)
Outstanding as of December 31, 2022	690,955
Granted	854,249
Vested and released	(293,626)
Forfeited	(152,894)
Outstanding as of December 31, 2023	1,098,684

The fair value of RSUs granted during 2023 and 2022 was $10.4 million and $3.2 million, respectively. The total unrecognized compensation cost of RSUs as of December 31, 2023 is $9.2 million with a weighted average recognition period of 1.86 years.

The following table illustrates the effect of share-based compensation on the Statements of Operations:

	Year ended December 31,	
	2023	2022
Research and development expenses	$ 1,905	$ 2,626
Selling, general and administrative expenses	7,439	7,954
Total share-based compensation expense	$ 9,343	$ 10,580

NOTE 17 – INCOME TAXES

The Company is taxed under Israeli tax laws:

Corporate tax rate

The applicable Israeli tax rate relevant to the Company for 2022 and thereafter is 23%.

For financial reporting purposes, the expense for current income taxes consists of the following (in thousands):

	2023	2022
Current taxes:		
U.S. Federal	$ 2,937	$ 584
U.S. State	983	1,171
Total current taxes	$ 3,920	$ 1,755

Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company and its subsidiary deferred tax assets are as follows (in thousands):

	December 31,	
	2023	2022
In respect of:		
Net operating loss carryforward	$ 103,566	$ 96,434
Research and development expenses	22,451	17,949
Stock-based compensation	11,953	11,485
Interest expense	1,345	-
In-process research and development	1,102	1,489
Right-of-use asset	(276)	(434)
Lease Liabilities	283	461
Accrued expenses	2,310	1,769
Depreciation of fixed assets	(45)	(113)
Other	875	561
Less—valuation allowance	(143,566)	(129,601)
Net deferred tax assets	$ —	$ —

The change in valuation allowance for the years ended December 31, 2023 and 2022 were as follows (in thousands):

	2023	2022
Balance at the beginning of the year	$ (129,601)	$ (100,619)
Changes during the year	(13,965)	(28,982)
Balance at the end of the year	$ (143,566)	$ (129,601)

The main reconciling items between the statutory tax rates of the Company and the effective rate are nondeductible expenses related to financing on the prepaid forward obligation and share-based compensation, the provision for a full valuation allowance in respect of tax benefits from carryforward tax losses due to the uncertainty of the realization of such tax benefits, utilization of tax credits and expense related to uncertain tax positions. A reconciliation of the Company's statutory tax rate to effective tax is as follows (in thousands, except statutory rate):

	December 31,	
	2023	2022
Pretax loss	$ (98,324)	$ (108,028)
Statutory rate	23%	23%
Income tax expense/(benefit) at statutory rate	(22,615)	(24,847)
Additional tax (tax saving) in respect of:		
Non-deductible expenses	5,704	1,052
R&D and orphan drug credits	(1,197)	(3,586)
Different tax rate of foreign subsidiaries	(689)	(263)
Uncertain tax positions	176	176
Change in valuation allowance(1)	22,898	28,982
Other	(358)	241
Income tax expense	$ 3,920	$ 1,755

(1) In the course of preparing the 2022 tax returns, adjustments were made for certain nondeductible amounts, reducing net operating loss carryforward and reflected as a change in valuation allowance of approximately $8.9 million in the current year.

Pretax loss for December 31, 2023 and 2022 includes pretax loss from foreign (United States) jurisdictions of $17.9 million and $13.3 million, respectively.

The Internal Revenue Code contains provisions that may limit our use of federal net operating loss carryforwards if significant changes occur in the constructive stock ownership of UroGen Pharma Inc. In the event it has had an "ownership change" within the meaning of Section 382 of the Code, utilization of its net operating loss carryforwards could be restricted under Section 382 of the Code and similar state provisions. Such limitations could result in the expiration of the net operating carryforwards incurred before 2018 before their utilization.

Losses for tax purposes carried forward to future years

As of December 31, 2023 and 2022, the Company had approximately $452.0 million and $419.1 million of carryforward tax losses, prior to tax effecting, respectively, available to reduce future taxable income without limitation of use.

Uncertain tax positions

A reconciliation of the beginning and ending amount of uncertain tax positions is as follows (in thousands):

	2023	2022
Uncertain tax positions at the beginning of the year	$ 3,018	$ 2,842
Gross increases — tax positions in current period	—	—
Gross increases — tax positions in prior period	176	176
Uncertain tax positions at the end of the year	$ 3,194	$ 3,018

The balances of uncertain tax positions as of December 31, 2023 would affect the Company's effective tax rate if recognized.

The Company has recorded a liability for uncertain tax positions of $3.2 million as of December 31, 2023 for tax positions relating to transfer pricing between affiliated entities. The Company recognizes interest accrued and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2023, the Company's liability for uncertain tax positions includes $1.2 million of accrued interest and penalties.

The Company operates on a global basis and is subject to tax laws and regulations in the United States and Israel. The estimate of the Company's tax liabilities relating to uncertain tax positions requires management to assess uncertainties and to make judgments about the application of complex tax laws and regulations, expectations regarding the outcome of tax authority examinations, as well as the ultimate measurement of potential liabilities.

The uncertain tax positions are reviewed quarterly and adjusted as events occur that could affect potential liabilities for additional taxes, including lapsing of applicable statutes of limitations, correspondence with tax authorities, proposed assessments by tax authorities, identification of new issues, and issuance of new legislation or regulations. The Company believes that adequate amounts of tax have been provided in income tax expense for any adjustments that may result from its uncertain tax positions. Based upon the information currently available, the Company does not reasonably expect changes in its existing uncertain tax positions in the next 12 months and has recorded the gross uncertain tax positions as a long-term liability.

The Company has received final tax assessments up to and including its 2017 tax year.

NOTE 18 – RELATED PARTIES

See Note 15 for discussion regarding an affiliated investor in the Private Placement for the year ended December 31, 2023. There were no related party transactions for the year ended December 31, 2022.

NOTE 19 – COMMITMENTS AND CONTINGENCIES

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of December 31, 2023 and 2022. The Company does not anticipate recognizing any significant losses relating to these arrangements.

On February 25, 2024, we received a Paragraph IV Certification Notice Letter from Teva, providing notification that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of *Jelmyto*. In the Notice Letter, Teva alleges that two of the patents listed in the FDA Orange Book for *Jelmyto*, U.S. Patent Numbers 9,040,074 and 9,950,069 each of which expires in January 2031, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission. If we are unable to maintain patent protection for *Jelmyto*, *Jelmyto* will be subject to immediate competition from generic entrants after regulatory exclusivity expires in April 2027.

Leases

See Note 11 for further discussion regarding lease commitments.

NOTE 20 – SUBSEQUENT EVENTS

In February 2024, the Company sold 1,400,468 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $26.6 million. The net proceeds to the Company after deducting sales commissions to Cowen were approximately $25.9 million. Following such sale, the remaining capacity under the ATM Sales Agreement is approximately $56.8 million.

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million is mandatory and required to be drawn by September 30, 2024, subject to satisfaction of customary conditions. The fourth tranche of $75.0 million may be drawn at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0M tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) satisfaction of customary conditions.

All outstanding loans with Pharmakon accrue interest using a benchmark rate of 3-month SOFR plus 7.25% plus an additional adjustment of 0.26161%. All outstanding principal will be required to be repaid in four equal quarterly installments commencing in the second quarter of 2026, with a one-year extension upon FDA approval of an NDA for UGN-102. All outstanding loans with Pharmakon can be prepaid in whole at the Company's discretion, at any time, subject to prepayment premiums, make-whole amounts and fees.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2023.

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Trading Plans

On December 26, 2023, our Chief Medical Officer, Mark Schoenberg, entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, to sell up to 30,000 ordinary shares. The trading plan expires on April 10, 2025.

Amended and Restated Loan Agreement

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million is mandatory and required to be drawn by September 30, 2024, subject to satisfaction of customary conditions. The fourth tranche of $75.0 million may be drawn at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0M tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) satisfaction of customary conditions.

All outstanding loans with Pharmakon accrue interest using a benchmark rate of 3-month SOFR plus 7.25% plus an additional adjustment of 0.26161%. All outstanding principal will be required to be repaid in four equal quarterly installments commencing in the second quarter of 2026, with a one-year extension upon FDA approval of an NDA for UGN-102. All outstanding loans with Pharmakon can be prepaid in whole at the Company's discretion, at any time, subject to prepayment premiums, make-whole amounts and fees.

Notice of 2024 Annual Meeting Date and Related Deadlines

As of the date of this Annual Report, we intend to hold our 2024 Annual meeting of Shareholders (the "2024 Annual Meeting of Shareholders") on or about August 7, 2024. This date is more than 30 days before the one-year anniversary of our 2023 annual meeting of shareholders, which was held on September 7, 2023.

Under Section 66(b) of the Israeli Companies Law, 5759-1999, as amended from time to time, and the regulations promulgated thereunder (collectively, the "Companies Law"), shareholders who hold, in the aggregate, at least 1% of the voting power in the Company may submit a request to include an item to the agenda within seven days following the Company's notice of convening a shareholders' general meeting at which directors are to be elected and certain other

proposals are to be considered (or within three days of the Company's notice in other instances), *provided* the requested item is appropriate for presentation at a general meeting and for consideration by the shareholders.

In addition to the eligibility requirements under the Companies Law, our articles of association specify additional procedural requirements for shareholder proposals. Under our articles of association, in the event that the date of the annual general meeting is advanced more than 30 days prior to the anniversary of the preceding year's annual general meeting, notice by the proposing shareholder, in order to be timely, must be received no earlier than the close of business 120 days prior to such annual general meeting, April 9, 2024, and no later than the close of business 90 days prior to such annual general meeting, May 9, 2024.

In addition, shareholder proposals may be submitted for inclusion in a proxy statement under Rule 14a-8 under the Exchange Act. Under Rule 14a-8 of the Exchange Act, to be eligible for inclusion in our proxy materials for the 2024 Annual Meeting of Shareholders, shareholder proposals must be received by us a reasonable time before we begin to print and send our proxy materials. We have determined that April 13, 2024, which is the date disclosed in our definitive proxy statement on Schedule 14A for our 2023 annual meeting of shareholders, remains a reasonable time before we expect to begin to print and distribute our proxy materials for our 2024 Annual Meeting, and that any shareholder proposals must be received on or before the close of business on that day. In addition, Rule 14a-8 proposals must otherwise comply with the requirements of the rule. Additional requirements regarding shareholder proposals submitted for inclusion in our proxy materials for an annual general meeting of shareholders can be found in the articles of association, which is available as an exhibit to this Annual Report. Proposals should be addressed to: UroGen Pharma Ltd., 400 Alexander Park Drive, 4th Floor, Princeton, New Jersey 08540.

In addition to satisfying the foregoing requirements under our articles of association, to comply with the universal proxy rules, shareholders who intend to solicit proxies in support of director nominees other than our board of directors' nominees must provide notice that sets forth any additional information required by Rule 14a-19 promulgated under the Exchange Act.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be set forth in an amendment to this Annual Report on Form 10-K to be filed with the SEC by April 29, 2024 (the "Form 10-K Amendment").

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Corporate Code of Ethics and Conduct. The Corporate Code of Ethics and Conduct is available on our website at *http://www.urogen.com* under the Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Shareholders may request a free copy of the Corporate Code of Ethics and Conduct from c/o UroGen Pharma Ltd., 400 Alexander Park Dr., Princeton, NJ 08540.

Item 11. Executive Compensation

The information required by this item will be set forth in the Form 10-K Amendment.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be set forth in the Form 10-K Amendment.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be set forth in the Form 10-K Amendment.

Item 14. Principal Accountant Fees and Services

The information required by this item will be set forth in the Form 10-K Amendment.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Part II, Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits.

Exhibit Number	Exhibit Description
3.1	Articles of Association of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Report on Form 6-K, filed with the SEC on May 18, 2017).
4.1	Reference is made to Exhibit 3.1.
4.2	Description of the Registrant's Ordinary Shares (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 2, 2020).
4.3	Form of July 2023 Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 27, 2023).
10.1*	Form of Officer Indemnity and Exculpation Agreement (incorporated by reference to Exhibit 99.2 to the Registrant's Report Form 6-K, filed with the SEC on July 13, 2018).
10.2*	Amended and Restated 2010 Israeli Share Option Plan (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 20-F, filed with the SEC on March 15, 2018).
10.3*	2017 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2023).
10.4*	2017 Israeli Equity Incentive Sub Plan to the 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form F-1, filed with the SEC on April 7, 2017).
10.5	Form of Stock Option Grant Notice and Stock Option Agreement under the UroGen Pharma Ltd. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2023).
10.6	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the UroGen Pharma Ltd. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2023).
10.7	Amendment to Form of Restricted Stock Unit Grant Notice under the UroGen Pharma Ltd. 2017 Equity Incentive Plan.
10.8	Form of Performance-Based Restricted Stock Unit Grant Notice and Performance-Based Restricted Stock Unit Award Agreement under the UroGen Pharma Ltd. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2023).
10.9*	UroGen Pharma Ltd. 2019 Inducement Plan, as amended (incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 21, 2022).
10.10	Form of Stock Option Grant Notice and Stock Option Agreement under the UroGen Pharma Ltd. 2019 Inducement Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2019).
10.11	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the UroGen Pharma Ltd. 2019 Inducement Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2019).
10.12	Amendment to Form of Restricted Stock Unit Grant Notice under the UroGen Pharma Ltd. 2019 Inducement Plan.
10.13*	Amended and Restated Compensation Policy for Officer Holders (incorporated by reference to Exhibit 10.8 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 24, 2023).
10.14*	Employment Agreement by and between the Registrant and Elizabeth Barrett, dated as of January 3, 2019 (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K, filed with the SEC on February 28, 2019).

10.15*	Amendment 1 to Employment Agreement by and between the Registrant and Elizabeth Barrett, dated as of January 26, 2021 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2021).
10.16*	Omnibus Amendment to Equity Awards by and between the Registrant and Elizabeth Barrett, dated as of January 19, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2021).
10.17*	Performance-Based Restricted Stock Unit Grant Notice by and between the Registrant and Elizabeth Barrett, dated as of November 13, 2023 (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2023).
10.18*	Amended Restricted Stock Unit Grant Notice by and between the Registrant and Elizabeth Barrett, dated as of December 20, 2023.
10.19*	Employment Agreement by and between the Registrant and Mark Schoenberg, dated as of December 5, 2017 (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K, filed with the SEC on February 28, 2019).
10.20*	Amendment 1 to Employment Agreement by and between the Registrant and Mark Schoenberg, dated as of January 26, 2021 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2021).
10.21*	Amendment 2 to Employment Agreement by and between the Registrant and Mark Schoenberg, dated as of March 15, 2021 (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2021).
10.22*	Employment Agreement between the Registrant and Jason Smith, dated August 12, 2020 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2020).
10.23*	Amendment 1 to Employment Agreement between the Registrant and Jason Smith, dated January 26, 2021 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2021).
10.24*	Employment Agreement between the Company and Dong Kim, dated March 20, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 21, 2022).
10.25†	License Agreement, dated November 8, 2019, by and between the Registrant and Agenus Inc. (incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 2, 2020).
10.26	Lease Agreement, dated November 4, 2019, by and between the Registrant and Witman Properties, L.L.C. and Alexander Road at Davanne, L.L.C. (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 2, 2020).
10.27	Amendment to Lease Agreement, dated June 8, 2022, by and between the Registrant and Witman Properties, L.L.C. and Alexander Road at Davanne, L.L.C. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2022).
10.28†**	Manufacturing and Supply Agreement, dated May 26, 2020, by and between the Registrant and Isotopia Molecular Imaging Ltd. (the "Isotopia Agreement") and the extension to the Isotopia Agreement, dated August 25, 2022, by and between the Registrant and Isotopia Molecular Imaging Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2022).
10.29†**	Manufacturing and Supply Agreement - Amendment No. 2, dated May 19, 2023, by and between the Registrant and Isotopia Molecular Imaging Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023).
10.30†**	Manufacturing & Supply Agreement, dated as of April 24, 2020 and amended as of March 2, 2022, by and between UroGen Pharma Ltd. and Cenexi-Laboratoires Thissen s.a. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2022).
10.31†**	Amendment 2 to Manufacturing & Supply Agreement, dated as of December 28, 2023 by and between UroGen Pharma Ltd. and Cenexi-Laboratoires Thissen s.a.
10.32†**	License and Supply Agreement, dated as of January 16, 2024, by and between UroGen Pharma Ltd. and Medac Gesellschaft für klinische Spezialpräparate m.b.H.
10.33	Loan Agreement, dated as of March 7, 2022, by and among UroGen Pharma Ltd. (the "Company"), UroGen Pharma, Inc., as the borrower, and certain direct and indirect subsidiaries of the Company party thereto from time to time, as guarantors, BPCR Limited Partnership, as a lender, BioPharma Credit Investments V (Master) LP, as a lender, and BioPharma Credit PLC, as collateral agent for the lenders (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 10, 2022).
10.34	Amendment to Loan Agreement, dated June 29, 2023, by and among the Company, UroGen Pharma, Inc., as the borrower, and certain direct and indirect subsidiaries of the Company party thereto from time to time, as guarantors, BPCR Limited Partnership, as a lender, BioPharma Credit Investments V (Master) LP, as a lender, and BioPharma Credit PLC, as collateral agent for the lenders (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023).
10.35	Amended and Restated Loan Agreement, dated as of March 13, 2024, by and among UroGen Pharma, Inc., as the borrower, and a credit party, Urogen Pharma Ltd. as Parent, and a Credit Party, the other guarantors signatory hereto or otherwise party hereto from time to time as additional Credit Parties, BioPharma Credit PLC as collateral agent, BPCR Limited Partnership as a lender and BioPharma Credit Investments V (Master) LP as a lender.
21.1	Subsidiary of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on

	March 24, 2023).
23.1	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm.
24.1	Power of Attorney (see signature page hereto).
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive and Financial Officers Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97	UroGen Pharma Ltd. Incentive Compensation Recoupment Policy.
101	The following financial information from the Annual Report on Form 10-K of UroGen Pharma Ltd. for the year ended December 31, 2023, formatted in Inline XBRL (extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Changes in Shareholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.
104	The cover page to this Annual Report on Form 10-K has been formatted in Inline XBRL

* Management contract or compensatory plan.
† Certain information in this exhibit has been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is the type of information that the registrant treats as private or confidential.
** Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

UROGEN PHARMA LTD.

March 14, 2024

By: /s/ Elizabeth Barrett
Elizabeth Barrett
President and Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

We, the undersigned directors and officers of UroGen Pharma Ltd., hereby severally constitute and appoint Elizabeth Barrett and Don Kim, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Elizabeth Barrett Elizabeth Barrett	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 14, 2024
/s/ Don Kim Don Kim	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 14, 2024
/s/ Arie Belldegrun Arie Belldegrun, M.D.	Chair	March 14, 2024
/s/ Cynthia Butitta Cynthia Butitta	Director	March 14, 2024
/s/ Fred E. Cohen Fred E. Cohen, M.D., D.Phil.	Director	March 14, 2024
/s/ Leana S. Wen Leana S. Wen, M.D., M.Sc.	Director	March 14, 2024
/s/ Stuart Holden Stuart Holden, M.D.	Director	March 14, 2024
/s/ James Robinson Jr. James Robinson Jr.	Director	March 14, 2024
/s/ Dan Wildman Dan Wildman	Director	March 14, 2024

UroGen Pharma Ltd.

Restricted Stock Unit Grant Notice
(2017 Equity Incentive Plan)

UroGen Pharma Ltd. (the "***Company***"), pursuant to its 2017 Equity Incentive Plan (the "***Plan***"), hereby awards to Participant a Restricted Stock Unit Award for the number of the Company's Ordinary Shares ("***Restricted Stock Units***" or "***RSUs***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this "***Restricted Stock Unit Grant Notice***"), and in the Plan and the Restricted Stock Unit Award Agreement (the "***Award Agreement***"), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this Restricted Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Participant:	
SSN:	
Date of Grant:	
Vesting Commencement Date:	
Number of Restricted Stock Units:	

Vesting Schedule: The Award shall vest over a period of three years as follows: (i) 1/3rd of the RSUs will vest on the first (1st) anniversary of the Vesting Commencement Date, and (ii) 1/3rd of the RSUs will vest annually thereafter over the remaining two (2) years, subject to Grantee's Continuous Service (as defined in the 2017 Plan) as of each such date.

Issuance Schedule: Subject to any Capitalization Adjustment, one Ordinary Share (or its cash equivalent, at the discretion of the Company) will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Sell to Cover the Withholding Obligation: Participant appoints and authorizes the Company's registered broker-dealer agent ("Agent") to (i) sell on the open market at the then prevailing market price(s), on Participant's behalf, as soon as practicable on or after the date on which the Ordinary Shares are delivered to Participant pursuant to Section 6 of the Award Agreement in connection with the vesting of the Restricted Stock Units, the number of Ordinary Shares sufficient to generate proceeds to cover (A) the satisfaction of the Withholding Obligation arising from the vesting of those Restricted Stock Units and (B) all applicable fees and commissions, if any, due to, or required to be collected by, the Agent with respect thereto; (ii) remit directly to the Company and/or any affiliate of the Company the proceeds necessary to satisfy the Withholding Obligation; (iii) retain the amount required to cover all applicable fees and commissions, if any, due to, or required to be collected by, the Agent, relating directly to the sale of the Ordinary Shares; and (iv) remit any remaining funds to Participant. Participant authorizes the Company and the Agent to cooperate and share information with one another to determine the number of Ordinary Shares that must be sold to satisfy the Withholding Obligation.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Ordinary Shares pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award, with the exception, if applicable, of (i) restricted stock unit awards or options previously granted and delivered to Participant, (ii) the written employment agreement, offer letter or other written agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (iii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

UroGen Pharma Ltd. **Participant**

By: _____ _____
Signature Signature

Title: Chief Executive Officer Date: _____

Date: _____

Attachments: Award Agreement and 2017 Equity Incentive Plan

UroGen Pharma Ltd.
Restricted Stock Unit Grant Notice
(2019 Inducement Plan)

UroGen Pharma Ltd. (the "***Company***"), pursuant to its 2019 Inducement Plan (the "***Plan***"), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company's Ordinary Shares ("***Restricted Stock Units***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this "***Restricted Stock Unit Grant Notice***") and in the Plan and the Restricted Stock Unit Award Agreement (the "***Award Agreement***"), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in the Award and the Plan, the terms of the Plan shall control.

Participant:
SSN (last 4 digits)
Date of Grant:
Vesting Commencement Date:
Number of Restricted Stock Units:

Vesting Schedule: The RSUs shall vest over a period of three (3) years as follows: one-third (1/3) of the RSUs will vest on the first (1st) anniversary of the Vesting Start Date, and one-third (1/3) of the RSUs will vest annually thereafter for the remaining two (2) years, subject to Grantee's Continuous Service (as defined in the 2019 Plan) as of each such date.

Issuance Schedule: Subject to any Capitalization Adjustment, one Ordinary Share will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Sell to Cover the Withholding Obligation: Participant appoints and authorizes the Company's registered broker-dealer agent ("Agent") to (i) sell on the open market at the then prevailing market price(s), on Participant's behalf, as soon as practicable on or after the date on which the Ordinary Shares are delivered to Participant pursuant to Section 6 of the Award Agreement in connection with the vesting of the Restricted Stock Units, the number of Ordinary Shares sufficient to generate proceeds to cover (A) the satisfaction of the Withholding Obligation arising from the vesting of those Restricted Stock Units and (B) all applicable fees and commissions, if any, due to, or required to be collected by, the Agent with respect thereto; (ii) remit directly to the Company and/or any affiliate of the Company the proceeds necessary to satisfy the Withholding Obligation; (iii) retain the amount required to cover all applicable fees and commissions, if any, due to, or required to be collected by, the Agent, relating directly to the sale of the Ordinary Shares; and (iv) remit any remaining funds to Participant. Participant authorizes the Company and the Agent to cooperate and share information with one another to determine the number of Ordinary Shares that must be sold to satisfy the Withholding Obligation.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of Ordinary Shares pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award with the exception, if applicable, of (i) the written employment agreement, offer letter or other written agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

UroGen Pharma Ltd.

By: _____ _____
Signature Signature

Title: Chief Executive Officer Date: _____

Date: _____

Attachments: Award Agreement and 2019 Inducement Plan

UroGen Pharma Ltd.

amended Restricted Stock Unit Grant Notice (2017 Equity Incentive Plan)

UroGen Pharma Ltd. (the "***Company***"), pursuant to its 2017 Equity Incentive Plan (the "***Plan***"), hereby awards to Participant a Restricted Stock Unit Award for the number of the Company's Ordinary Shares ("***Restricted Stock Units***" or "***RSUs***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this amended notice of grant (this "***Restricted Stock Unit Grant Notice***"), and in the Plan and the Restricted Stock Unit Award Agreement (the "***Award Agreement***"), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this amended Restricted Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Participant:	**Liz Barrett**
SSN:	
Date of Grant:	**January 31, 2021**
Vesting Commencement Date:	**January 31, 2021**
Number of Restricted Stock Units:	**40,000**

Vesting Schedule: The Award shall vest over a period of three years as follows: (i) 2/3rds of the RSUs have vested pursuant to Participant's original Restricted Stock Unit Notice, Award and Award Agreement, and (ii) 1/3rd of the RSUs will vest on July 30, 2024, subject to Participant's Continuous Service through each such vesting date.

Issuance Schedule: Subject to any Capitalization Adjustment, one Ordinary Share (or its cash equivalent, at the discretion of the Company) will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Ordinary Shares pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award, with the exception, if applicable, of (i) restricted stock unit awards or options previously granted and delivered to Participant, (ii) the written employment agreement, offer letter or other written agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (iii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

UroGen Pharma Ltd.	**Participant (Liz barrett)**
By: /s/ Don Kim	/s/ Liz Barrett
Signature	Signature
Title: Chief Financial Officer	Title: CEO
Date: 12/20/2023	Date: 12/20/2023

Attachments: Award Agreement and 2017 Equity Incentive Plan

UroGen Pharma Ltd.

AMENDED RESTRICTED STOCK UNIT GRANT NOTICE (2017 EQUITY INCENTIVE PLAN)

UroGen Pharma Ltd. (the "***Company***"), pursuant to its 2017 Equity Incentive Plan (the "***Plan***"), hereby awards to Participant a Restricted Stock Unit Award for the number of the Company's Ordinary Shares ("***Restricted Stock Units***" or "***RSUs***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this amended notice of grant (this "***Restricted Stock Unit Grant Notice***"), and in the Plan and the Restricted Stock Unit Award Agreement (the "***Award Agreement***"), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this Restricted Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Participant:	**Elizabeth Barrett**

SSN:
Date of Grant: **January 31, 2023**
Vesting Commencement Date: **January 31, 2023**
Number of Restricted Stock Units: **75,000**

Vesting Schedule: The Award shall vest over a period of three years as follows: (i) 1/3rd of the RSUs will vest on July 30, 2024, and (ii) 1/3rd of the RSUs will vest annually thereafter over the remaining two (2) years subject to Grantee's Continuous Service (as defined in the 2017 Plan) as of each such date.

Issuance Schedule: Subject to any Capitalization Adjustment, one Ordinary Share (or its cash equivalent, at the discretion of the Company) will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Ordinary Shares pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award, with the exception, if applicable, of (i) restricted stock unit awards or options previously granted and delivered to Participant, (ii) the written employment agreement, offer letter or other written agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (iii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

UROGEN PHARMA LTD.	PARTICIPANT (LIZ BARRETT)
By: /s/ Don Kim Signature	/s/ Liz Barrett Signature
Title: Chief Financial Officer	Title: CEO
Date: 12/20/2023	Date: 12/20/2023

Attachments: Award Agreement and 2017 Equity Incentive Plan

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED BECAUSE THE REGISTRANT HAS DETERMINED THE INFORMATION IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Amendment #2 to Manufacturing and Supply Agreement

This Amendment #2 to the Manufacturing & Supply Agreement ("Amendment #2"), effective as off its date of last signature ("Amendment #2 Effective Date"), is by and between **UroGen Pharma Ltd.**, a company organized and existing under the laws of the State of Israel having an address at 9 HaTaasia St., Ra'anana 4365007, Israel ("Customer") and **Cenexi-Laboratoires Thissen S.A.**, a company incorporated in Belgium,having its registered office at 2-4-6, Rue de la Papyrée, B-1420 Braine-l'Alleud, also acting hereunder on behalf of its Affiliates ("Manufacturer").

WHEREAS, Customer and Manufacturer entered into a certain Manufacturing and Supply Agreement dated April 24, 2020 (the "Agreement") regarding the manufacturing by Manufacturer and the purchase by Customer of UGN-101;

WHEREAS, an amendment to the Agreement (the "Amendment #1") has been signed by and between Customer and Manufacturer, effective as March 2nd, 2022 regarding, among other terms, good faith discussions between the Parties regarding certain equipment investments by Customer, refurbishment of a workshop at Manufacturer's premises, and dedication of certain manufacturing capacity by Manufacturer; and

WHEREAS, following conclusive clinical trials and applicable regulatory approvals, UROGEN plans to launch UGN-102, for a new therapeutic indication. As a result, the Parties anticipate that volumes of Contract Products manufactured by Manufacturer pursuant to the Agreement will increase from 2025.

WHEREAS, as further set forth herein, the Parties have agreed to:

- revise the MAQ Forecast levels (Exhibit 7 to the Agreement, modified by Amendment #1); and
- the terms and conditions of the planned purchase of the equipment (Exhibit 9 under Amendment #1) with regard to the amount, schedule, ownership, use, maintenance costs and status of the equipment in the event of termination of the Agreement.

NOW THEREFORE, in consideration of the above, and for good and valuable consideration the receipt and sufficiency of which the parties acknowledge, Customer and Manufacturer agree to amend the Agreement as follows:

ARTICLE N. 1 Equipment Investments

The following new Section 12.8 is added to the Agreement, immediately following section 12.7 and before article 13:

"Section 12.8: Equipment Investments

12.8.1 Purchase of Dedicated Equipment. Manufacturer shall use best efforts to purchase, install, validate and qualify the dedicated equipment described on Exhibit 10 for the execution of the Agreement (the "Dedicated Equipment"). Manufacturer shall ensure that the Dedicated Equipment meets the technical specifications which will be described in the "Technical Specifications".

12.8.2 Installation of Dedicated Equipment. Manufacturer shall install the Dedicated Equipment at the premises of Manufacturer, in accordance with the Technical Specifications and all applicable laws, rules and regulations.

12.8.3 Refurbishment of Manufacturer's Premises. Manufacturer shall perform the necessary refurbishment work on its premises in order to install the Dedicated Equipment in accordance with the refurbishment plan set forth on Exhibit 10 (such activities collectively, the "Refurbishment Activities") and in accordance with the budget set forth in Exhibit 10. Manufacturer shall use best efforts to perform the Refurbishment Activities in a diligent manner consistent with Exhibit 10 and all applicable laws, rules and regulations. For sake of clarity, the refurbishment of Manufacturer's Premises and the Dedicated Equipment will be purchased and installed according the current Manufacturer's knowledge on the process and Technical Specifications of the Product.

12.8.4 Validation and Qualification of Dedicated Equipment. Manufacturer shall ensure that all Dedicated Equipment is validated and qualified in accordance with the Technical Specifications and Customer's instructions and as is required to use such Dedicated Equipment to manufacture Contract Products in accordance with all applicable laws, rules and regulations, including cGMP and the Quality Agreement (the "Qualification Activities"). Manufacturer will be responsible for all costs and expenses associated with the Qualification Activities and any associated engineering support related thereto.

12.8.5 Customer's Financial Contribution. As Customer's sole financial contribution for the purchase, installation, validation and qualification of the Dedicated Equipment as set forth in this Agreement, and the performance of the Refurbishment Activities, Customer shall pay Manufacturer's documented internal and out-of-pocket costs for the purchase, delivery and installation of the Dedication Equipment and the performance of the Refurbishment Activities, up to a maximum sum of [***]€ (the "Dedicated Equipment Fees" and such maximum amount, the "Maximum Dedicated Equipment Fees"). All internal costs shall be expensed in accordance with the budget agreed upon on Exhibit 10. In no event shall Customer be responsible for more than the Maximum Dedicated Equipment Fees pursuant to this Section 12.8 unless Customer agrees in writing to increase the Maximum Dedicated Equipment Fees amount. Manufacturer shall be responsible for all internal and out-of-pocket costs required to perform the purchase, delivery and installation of the Dedicated Equipment and the performance of the Refurbishment Activities in excess of the Maximum Dedicated Equipment Fees (as such amount may be amended in accordance with the foregoing sentence).

12.8.6 Invoicing and Payment. Manufacturer shall invoice Customer for the anticipated Dedicated Equipment Fees in accordance with the invoicing and payment schedule set forth on Exhibit 10 and subject to the maximum Dedicated Equipment Fees set forth in Section 12.8.5 above. On a quarterly basis, Manufacturer will provide Customer with documentation for the actual Dedicated Equipment Fees incurred by Manufacturer (with reasonable supporting

documentation). In the event the actual Dedicated Equipment Fees are less than the anticipated Dedicated Equipment Fees paid by Customer for such time period, Manufacturer will credit such overpayment against the next Dedicated Equipment Fee payment owed to Manufacturer and upon completion of the installation of the Dedicated Equipment and performance of the Refurbishment Activities (or earlier upon termination of this Agreement in accordance with the termination provisions included in the Agreement), Manufacturer shall promptly refund Customer any anticipated Dedicated Equipment Fees paid that exceed the actual Dedicated Equipment Fees incurred by Manufacturer. Without limiting the generality of the foregoing, Manufacturer will provide Customer with a copy of the invoices for the purchase of the Dedicated Equipment and for the refurbishment of the premises, in order to enable control and follow-up between the costs actually incurred and the estimated costs.

12.8.7 Capital Equipment Plan. The operational procedures and timeframes for the acquisition, installation and qualification of the Dedicated Equipment and for the refurbishment of the premises in which it will be installed are defined in Exhibit 10. Manufacturer shall use best efforts to perform its obligations under this Section 12.8 with respect to the purchase, installation and qualification of the Dedicated Equipment.

12.8.8 Dedicated Equipment. Manufacturer shall exclusively use the Dedicated Equipment in the manufacture of Contract Products for Customer pursuant to this Agreement. Manufacturer shall not use the Dedicated Equipment for any other purpose, including to manufacture products for itself or any third party without the prior written consent of Customer.

12.8.9 Ownership of Dedicated Equipment; Insurance; Maintenance. Manufacturer will be the sole owner of the Dedicated Equipment. Manufacturer will be responsible for obtaining and maintaining during the Term of the Agreement proper insurance coverage for the Dedicated Equipment and Manufacturer will provide evidence of such insurance to Customer upon Customer's request. Manufacturer shall be responsible for any losses, damage, theft, or other impairment of the Dedicated Equipment. Manufacturer shall use best efforts to regularly and timely maintain all Dedicated Equipment in good working condition. Manufacturer shall be responsible, at its own cost, for any maintenance or repairs required to properly maintain the Dedicated Equipment in accordance with industry standard.

12.8.10 Except as set forth below in this Section 12.8.10 or as expressly set forth under Section 12.8.6, upon termination of the Agreement in accordance with the termination provisions included in the Agreement, under no circumstances will Manufacturer be obliged to reimburse Customer for the Dedicated Equipment Fees. Notwithstanding the foregoing, in the event of termination of the Contract, Manufacturer shall pay to Customer a partial reimbursement for the Dedicated Equipment Fees based on the amortised value of the Dedicated Equipment at such time (the "Amortized Value"), which Amortized Value shall be calculated in accordance with the depreciation plan set out in Exhibit 11 to this Amendment #2. In no circumstances shall the Amortized Value be less than zero.

12.8.11 Negotiation of Amended Exhibit 10. Manufacturer will use diligent efforts to prepare a more detailed draft of Exhibit 10 for Customer's review and approval by [***] that includes the following:

(a) a technical description of the Dedicated Equipment (including Technical Specifications);

(b) a detailed plan for the acquisition and installation of the Dedicated Equipment and the performance of the Refurbishment Activities; and

(c) a detailed plan for the validation and qualification for the Dedicated Equipment;

(d) a detailed budget (including rate for internal costs) for the Dedicated Equipment Fees (the "Dedicated Equipment Fees Budget"), provided that such Dedicated Equipment Fees Budget complies with the Maximum Dedicated Equipment Fees; and

(e) a detailed timeline for performance of (i) the purchase and installation of the Dedicated Equipment, (ii) the performance of the Qualification Activities; and (iii) the performance of the Refurbishment Activities (the "Project Timeline"), provided that such overall Project Timeline shall not exceed the time period set forth on Exhibit 10 as of the Amendment #2 Effective Date.

Customer and Manufacturer will negotiate in good faith and use diligent efforts to finalize and execute such amended Exhibit 10 by [***].

ARTICLE N. 2 Term

Section 18.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

18.1 The Agreement will be effective as of the Effective Date and, unless earlier terminated as set forth in this Agreement, shall remain in full force and effect until April 1, 2027 (the "Initial Term"), and thereafter will automatically be renewed for consecutive 24 (twenty-four) month periods (the Initial Term and any renewal term(s) together referred to as the "Term"), unless either Party provides the other Party with written notice of non-renewal at least 18 (eighteen) months prior to the expiration of the then current Term.

ARTICLE N. 3 Exhibits

3.1 The Parties have decided to update applicable MAQ Forecast set in Exhibit 7 of the Agreement, amended by Amendment #1. Exhibit 7 of the Agreement is deleted in its entirety and replaced with Exhibit 7 to this Amendment #2.

3.2 A new Exhibit 10 is attached as Exhibit 10 to this Amendment #2.

3.3 A new Exhibit 11 is attached as Exhibit 11 to this Amendment #2.

ARTICLE N. 4 Final provisions

Except as amended above, all other terms and conditions of the Agreement shall remain the same and in full force and effect. Capitalized terms used herein which are not defined shall have the respective meanings ascribed to them in the Agreement. The Agreement as modified by Amendment #1 and this Amendment #2, constitute the entire agreement between the Parties with respect to the subject matter hereof. All references to the term "Agreement" in the Agreement shall be deemed to include all of the terms and conditions of Amendment #1 and this Amendment #2.

This Amendment #2 may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN

Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Amendment #1.

IN WITNESS WHEREOF, Customer and Manufacturer have executed this Amendment #2 as of the Amendment #2 Effective Date set forth above.

UroGen Pharma Ltd.	Cenexi Laboratories Thissen S.A.
Name: Marina Konorty	Name: Jim McPherson Cenexi
Title: EVP R&D and Technical Operation	Title: President and CEO Cenexi
Date: 12/28/2023	Date: 12/28/2023
Signature: /s/Marina Konorty	Signature: /s/Jim McPherson Cenexi

Exhibits:

- Updated Exhibit 7: updated Prices and MAQ
- Exhibit 10: Dedicated Equipment Description; Installation & Refurbishment Plan; Qualification Plan; Timeline and Budget for Dedicated Equipment Fees
- Exhibit 11: Amortisation plan for the Dedicated Equipment

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED BECAUSE THE REGISTRANT HAS DETERMINED THE INFORMATION IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

LICENSE and SUPPLY AGREEMENT

This License and Supply Agreement (the "**Agreement**") shall enter into force upon the latter date of signature of the Agreement (the "**Effective Date**") by and

between

Medac Gesellschaft für klinische Spezialpräparate m.b.H., a company registered under the laws of Germany having its registered office at Theaterstr. 6, 22880 Wedel, Germany

-"**medac**"-

and

UroGen Pharma Ltd, a company organized and existing under the laws of the State of Israel having an address at 9 HaTaassiya St., Ra'anana 4365405, Israel

-"**UroGen**"-

hereinafter individually and collectively referred to respectively as "a Party" and "the Parties".

BACKGROUND

WHEREAS, UroGen and medac entered into the Development Agreement dated as August 18, 2019, as amended by a certain Addendum 1 dated as of September 14, 2020, and as may be amended from time-to-time by the Parties pursuant to the terms of the Development Agreement (collectively referred to herein as the "**Development Agreement**"); and

WHEREAS, UroGen and medac are currently negotiating a Quality Agreement which shall cover manufacturing standards according to Applicable Laws and cGMP for supply of commercial material (collectively referred to herein as the "**Quality Agreement**"); and

WHEREAS, medac is a pharmaceutical company and Manufacturer of the Product as well as owns or otherwise controls the Licensed Patents and Licensed Know-How relating to the Product; and

WHEREAS, the Product has several potential benefits over the lyophilized mitomycin currently sourced and used by UroGen, including but not limited to a simpler reconstitution process and improved supply reliability because of a high batch size and a short manufacturing process; and

WHEREAS, medac is willing to grant to UroGen an exclusive license for the Licensed Patents as listed in Exhibit A to Develop, Commercialize, and Exploit the Product as a part of the Combined Product in the Field in the Territory, on the terms and conditions set forth herein and UroGen is willing to accept such License; and**WHEREAS**, UroGen is willing to purchase the Product exclusively from medac on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree on the following Agreement:

SECTION 1   - DEFINITIONS

1.1. As of the Effective Date and during the Term of the Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Section 1.

1.2. "Affiliate" shall mean any company or business entity controlled by, controlling or under common control with a Party to this Agreement. For this purpose, "control" shall mean the direct or indirect ownership of more than 50% (fifty percent) of the voting stock of a company, or in the absence of ownership of more than 50% (fifty percent) of the voting stock of that company, the power, directly or indirectly, to direct or cause the direction of the management and policies of such company. For the sake of clarity holding, parent, sister and daughter companies are regarded to be Affiliates.

1.3. "Applicable Law" means all applicable laws, rules, regulations and standards that are in force from time to time during the Term, whether the same are regional, national or international, all as applicable to each Party's rights and obligations pursuant to this Agreement.

1.4. "Authorized Third Party" means an Affiliate, person or entity under subcontract to medac for any of the services or deliverables under this Agreement that have been outsourced or delegated by medac, including but not limited to laboratory testing or Manufacturing, and which are listed in the Quality Agreement.

1.5. "Best Efforts" shall mean, with respect to a given obligation, the efforts that a reasonable person in the promisor's position would use so as to perform that obligation as expeditiously as possible.

1.6. "Best Knowledge" shall mean any existing fact or circumstance in connection with the preparation, negotiation or execution of this Agreement which a Party or its representatives had actual knowledge of or which was specifically referred to in any document (whether printed or electronic) to which such Party had access in the ordinary course of business or in the ordinary fulfilment of his, her or its duties.

1.7. "Bulk Product" means Product which has completed all processing stages up to, but not including, final packaging and is therefore unlabeled.

1.8. "Business Day" means a day other than a Saturday, Sunday, a public holiday in Germany, [***], Israel or the US, or a day on which banking institutions in the State of New York, USA, Hamburg, Germany, Wedel, Germany, [***] or Tel Aviv, Israel are authorized or obligated by Law or executive order to close, or as otherwise agreed by the Parties.

1.9. "**cGMP**" means current European Good Manufacturing Practice Guidelines for Medicinal Products and U.S. FDA Good Manufacturing Practices.

1.10. "Combined Product(s)" means a pharmaceutical product that includes the Product and a Reverse Thermal Gel that is designed to be used in the Field.

1.11. "Commercialize" means any and all activities directed to the promotion, marketing, distribution or sale (and offer for sale or import or export for sale or use) of a Combined Product after the relevant Marketing Authorization approval, when required, has been obtained. "Commercializing" and "Commercialization" have corresponding meanings.

1.12. "Commercially Reasonable Efforts" means a level of effort and resources comparable to the efforts and resources commonly used in the pharmaceutical and biotechnology industry by companies with resources and expertise similar to those of UroGen for products of similar market potential to Product, taking into account: (a) issues of efficacy, safety and expected and actual approved labelling, (b) the expected and actual competitiveness of alternative products being sold in the Territory, (c) the expected and actual exclusivity position; (d) the expected and actual reimbursement, profitability, market potential and return on investment.

1.13. "Competing Product" means any product that a.) contains a Gel as defined by IUPAC Compendium of Chemical Terminology, 3rd ed. International Union of Pure and Applied Chemistry, 2006 and a lyophilized formulation of Compound and b.) has a marketing authorization for the use in the Field.

1.14. "Compound" means Mitomycin C drug substance, CAS No.: 50-07-7.

1.15. "Confidential Information" shall have the meaning set forth in Section 15.1.

1.16. "Control" **or** "**Controlled**" means with respect to any Know-How or Patents or other Intellectual Property right, the legal authority or right (whether by ownership, license or otherwise other than by a license, sublicense or other rights granted pursuant to this Agreement) of a Party to grant a license of such Know-How, Patent or other Intellectual Property right to another Person, without breaching the terms of any agreement with, or misappropriating the proprietary or trade secret information of, or requiring the consent of, a Third Party.

1.17. "Cover", "**Covering**" **or** "**Covered**" means, with respect to a given product, technology, process or method, in a given country and a given Patent in the Territory, that, in the absence of ownership of or a license granted under such Patent containing a Valid Claim, the manufacture, use, offer for sale, sale or importation of such product in such country would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue without modification).

1.18. "Development" means, in relation to this Agreement, clinical trial Phase 3 and post approval studies of the Combined Product by UroGen, directed to obtaining and maintaining a Marketing Authorization for a Combined Product. "Develop" and "Developing" have corresponding meanings.

1.19. "Date of Dispatch" means the day the Product is released by medac's Affiliates for the pickup by UroGen.

1.20. "EMA" means the European Medicines Agency and any successor or replacement agency.

1.21. "Exploit" means to Commercialize, import, export, use, distribute and register. "**Exploitation**" means the act of Exploiting a product.

1.22. "FD&C Act" means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

1.23. "FDA" means the US Food and Drug Administration, and any successor or replacement agency.

1.24. "Field" means the treatment of urothelial carcinoma, including but not limited to low-grade intermediate risk non-muscle-invasive bladder cancer and low-grade upper tract urothelial cancer.

1.25. "Governmental Authority" means any supranational, multinational, federal, state, local, municipal, or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal), in each case, having jurisdiction over the applicable subject matter.

1.26. "Government Official" means (i) any Person employed by or acting on behalf of a Governmental Authority; (ii) any political party, party official or candidate; (iii) any Person who holds or performs the duties of an appointment, office or position created by custom or convention; and (iv) any Person who qualifies as a government official under Applicable Law.

1.27. "Improvements" shall mean all developments, inventions, modifications, new uses or new applications of, or extensions to, the Know-how, the Product or the Combined Product.

1.28. "Intellectual Property" or "**IP**" means all works of authorship including exclusive exploitation rights, and any and all rights under Patents, utility models, trade secrets, Know-How, copyrights, trademarks and other industrial or intangible property rights of a similar nature and moral rights of the respective Party; all rights pursuant to grants and/or registrations worldwide in connection with the foregoing and all other rights with respect thereto; all rights under applications for any such grant or registration, all rights of priority under international conventions to make such applications and the right to control their prosecution, and all rights under amendments, continuations, divisions and

continuations-in-part of such application; and all rights under corrections, reissues, patents of addition, extensions and renewals of any such grant, registration and/or right.

1.29. "**Know-How**" means all technology, scientific, technical and business information and other proprietary rights and information which is not publicly available, commercially valuable and being kept confidential including any invention, discovery, development, data, diagrams, documentation, formulations, information, instructions, processes, manufacturing, method, technique, material (including any chemical or biological material), means, non-clinical, clinical, safety and quality control data and information (including trial designs and protocols), specifications, techniques, technology, result, or other know-how, whether or not patentable.

1.30. "**Licensed Know-How**" means the Know-How that (a) is Controlled by medac or any of its Affiliates as of the Effective Date or that comes into the Control of medac or any of its Affiliates at any time during the Term and (b) is needed for the Exploitation of Combined Product.

1.31. "**Licensed Patents**" means Patents listed in Exhibit A, that (a) are Controlled by medac or any of its Affiliates as of the Effective Date or that come into the Control of medac or any of its Affiliates at any time during the Term and (b) that are related to or necessary for the Exploitation of the Combined Product. Exhibit A can be amended from time to time on mutual agreement by the Parties in case further Patents are needed for the scope of this Agreement. For clarity, the Licensed Patents shall include any medac Invention Patents if necessary for the activities of UroGen permitted by this Agreement.

1.32. "**Manufacture**" means all activities related to the manufacturing of the Product, or any ingredient thereof, including manufacturing for clinical use or commercial sale; in-process and Bulk Product testing; release of Bulk Product; quality-assurance activities related to manufacturing and release; ongoing stability tests and storage before release; distribution of the Product to kit packaging; and the related controls and regulatory activities related to any of the foregoing; *provided*, *however*, that for purposes of clarity "Manufacture" shall include lyophilization.

1.33. "**Manufacturing Batch Record**" means a detailed, step-by-step description of the entire production process for a specific drug. The Manufacturing Batch Record ("MBR") explains exactly how the product is produced, indicating specific types and quantities of components and raw materials, processing parameters, in-process quality controls, environmental controls, etc. An executed Batch Record documents the production events, quality charts, environmental monitoring records and inspection reports for the entire production process for a specific batch.

1.34. "**Marketing Authorization**" means the approval issued by the relevant authority to sell a Combined Product in a country of the Territory, including, in the US, the NDA as approved by the FDA.

1.35. "**medac Indemnitee**" has the meaning set forth in Section 14.3.

1.36. "**medac Invention**" means any Improvement relating to (a) the Product including but not limited to the composition or method of making the Product, (b) methods of using the Product other than either as part of a Combined Product or together with any UroGen Formulation; and (c) medac's lyophilization process described in U.S. Patent No. [***] conceived and reduced to practice by medac.

1.37. "**Mitomycin medac**" means any lyophilisate that is Manufactured by medac or its Affiliates on medac's manufacturing order comprising the Compound and Urea and Manufactured according to any patents listed in Exhibit A with the exclusion of Product.

1.38. "**NDA**" means a new drug application for a drug filed in accordance with 21 C.F.R. Part 314.

1.39. "**Party**" means medac or UroGen; "**Parties**" means medac and UroGen.

1.40. "**Patents**" means (a) all patents and patent applications (provisional and non-provisional) anywhere in the world, including PCT applications, (b) all divisionals, continuations, continuations in-part thereof, or any other patent application claiming priority, or entitled to claim priority, directly or indirectly to (i) any such patents or patent applications or (ii) any patent or patent application from which such patents or patent applications claim, or is entitled to claim, direct or indirect priority, and (c) all patents issuing on any of the foregoing anywhere in the world (including from PCT applications), together with all registrations, reissues, re-examinations, patents of addition, utility models or designs, renewals, supplemental protection certificates, or extensions of any of the foregoing and counterparts thereof anywhere in the world.

1.41. "**PCT**" means the Patent Cooperation Treaty or the international patent system.

1.42. "**Person**" means any individual or any partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

1.43. "**Price**" shall have the meaning as set forth in Exhibit B.

1.44. "**Pricing Approval**" means the approval, agreement, determination or decision from a Governmental Authority establishing the price and/or reimbursement for a Combined Product for sale in a given country of the Territory or regulatory jurisdiction, as required by Applicable Law in such country of the Territory or other regulatory jurisdiction prior to the sale of the Combined Product in such country of the Territory or regulatory jurisdiction.

1.45. "**Product**" means a pharmaceutical lyophilized product as a specific formulation in a vial containing the mixture of 80 mg of the Compound and 640 mg Urea in an 80 mL vial wherein the Product is Manufactured according to medac's lyophilization process, including but not limited to the process claimed by U.S. Patent No. [***] and Patents listed in Exhibit A.

1.46. "**Product Complaint**" means any written, verbal or electronic expression of dissatisfaction regarding any Product or Combined Product sold by or on behalf of UroGen (or any of its Affiliates) in the Territory, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

1.47. "**Product Specifications**" means the specifications of the Product and all components as defined in the Quality Agreement.

1.48. "**Quality Agreement**" means the agreement to be signed separately by the Parties, detailing the pharmaceutical responsibilities of each Party

related to the Product and all components thereof including, among others, Starting Material and primary packaging material, manufacturing directions, instructions, protocols, reports, quality control, testing, release and shipment of Product.

1.49. **"Registration Dossier"** means the NDA when referring to the US and the US FDA, or the equivalent registration dossier for other territories prepared by UroGen for the purpose of obtaining a Marketing Authorization.

1.50. **"Regulatory Authority"** means any national, supranational, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity (including the FDA and the EMA and any other agencies in any country) regulating or otherwise exercising authority with respect to the Exploitation of pharmaceutical products.

1.51. **"Regulatory Materials"** means all U.S.A. and non-U.S.A. regulatory applications, filings, submissions and approvals (including all drug master files, investigational new drug applications, NDAs, and foreign counterparts thereof, and all Regulatory Approvals,) for the Combined Product (including manufacturing approvals, technical, medical, and scientific licenses, and pre-clinical study, clinical trial and non-clinical study authorization applications or notifications), all amendments, supplements, supporting files, data, studies, and reports relating thereto (in hard or electronic form) and all technical and other information contained therein, and all material correspondence with the FDA and other Regulatory Authorities relating to the foregoing, that, in each case, are in the possession of and controlled by, or held by or for UroGen or its Affiliates, whether generated, filed or held by or for UroGen or its Affiliates.

1.52. **"Reverse Thermal Gel"** means any thermo-sensitive hydrogels that are in liquid form at low temperatures and solidify at human body temperatures, as described in, but in no way limited to, U.S. Patent Nos. 9,040,074 and related Patents.

1.53. **"SEC"** means the U.S. Securities and Exchange Commission.

1.54. **"Starting Material"** means any substance used in the manufacturing of the Product excluding Compound.

1.55. **"Territory"** means the entire world.

1.56. **"Third Party"** means any person who is not a Party or an Affiliate of a Party.

1.57. **"Transition Period"** means the [***] period commencing on the date of UroGen's receipt of a Marketing Authorization for a Combined Product in the first country of the Territory.

1.58. **"Urea"** means Carbamide, CAS Number 57-13-6.

1.59. **"UroGen Formulation"** means a Reverse Thermal Gel developed or controlled by UroGen.

1.60. **"UroGen Invention"** means any Improvement relating to the Combined Product or UroGen Formulation excluding any method of making the Product and excluding any method of using the Product alone and not as part of Combined Product.

1.61. **"Valid Claim"** means, with respect to a particular country, a claim of a Patent that (a) is issued or, as to a claim in a pending patent application, has been pending for a period of [***] or fewer from its first office action, (b) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal, and (c) has not expired or been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. For clarity, any pending claim in an application in any country that has not been granted within [***] from its first office action shall not be included as a Valid Claim unless and until, and solely if, (x) such claim is granted while the relevant Product is covered by another issued Valid Claim in the same country and (y) the provisions of (b) and (c) above are satisfied.

SECTION 2 -   LICENSE GRANT

2.1. License Grant to UroGen. Subject to the terms and conditions of this Agreement, medac hereby grants to UroGen as of the Effective Date an exclusive license, including the right to sublicense in accordance with Section 2.3 of this Agreement, under the Licensed Know-How and Licensed Patents to Exploit the Product as an integrated part of a Combined Product in the Territory. No further license rights are granted by medac to Urogen by this Agreement, save as expressly set out in this Section.

2.2. Mitomycin medac Use Restriction. medac agrees that while the license granted in Section 2.1 remains exclusive, medac will not Manufacture or Exploit Mitomycin medac as part of a Competing Product in the Territory. Without limiting the above, the Parties agree that medac retains the unlimited right in the Territory to manufacture, use, supply, sell, license and distribute Mitomycin medac so long as Mitomycin medac is not an integrated part of a Competing Product. The rights with respect to the use and Exploitation of Mitomycin medac alone or in combination with a product which is not a Competing Product (e.g., Mitomycin medac in aqueous solutions), the use of Licensed Know-How and Licensed Patents outside the scope of licenses according to Section 2.1 shall remain with medac. Furthermore, medac reserves all rights to use the Know-How, Licensed Know-How and Licensed Patents for all other purposes including but not limited to the Manufacturing of Mitomycin medac in the Territory.

2.3. Sublicenses. UroGen shall have the right to grant sublicenses to any sublicensee under all of its rights under the licenses granted pursuant to Section 2.1 at any time during the Term in any part of the Territory; *provided however*, that with respect to each such sublicense, UroGen shall (i) notify medac in writing at least [***] in advance of the grant; (ii) provide medac with a full copy of a draft sublicense agreement and shall impose obligations on the sublicensee at least equivalent to those set out in this Agreement; and (iii) obtain medac's prior written consent of the sublicense giving the full name and address of such sublicensee, which consent shall not be unreasonably withheld and/or delayed. For clarification and subject to Section 6.4, the license rights according to Section 2.1 and the sublicence rights according to this Section do not include any right to grant any license and/or sublicenses to Manufacture the Product. UroGen shall remain fully responsible and liable for all acts and omissions of the sublicensee(s) as though they were acts and omissions of UroGen. No Affiliate of UroGen shall have any right to grant sublicenses under the licenses granted to UroGen pursuant to Section 2.1. UroGen shall ensure that any sublicenses and any of its sublicense agreements shall terminate upon expiration or termination of this Agreement.

2.4. Performance by Affiliates. The Parties recognize that each may perform some or all of its obligations under this Agreement through its Affiliates, vendors, agents, representatives *provided, however*, that each Party shall remain responsible for and be guarantor of the performance by its Affiliates, vendors, agents, representatives and shall cause its Affiliates, vendors, agents, representatives to comply with the provisions of this Agreement in connection with such performance.

SECTION 3 -   DEVELOPMENT COMMENCEMENT AND MARKETING AUTHORIZATION SUBMISSION IN THE UNITED STATES

3.1. **Timeline for Development in the United States.** UroGen shall use Best Efforts to initiate clinical study treatment (defined as the administration of the first scheduled dose of an investigational Combined Product) in an enrolled and consented patient no later than [***].

3.2. **Timeline for NDA submission in the United States.** Following the completion of the Development of a Combined Product, yielding positive results on study endpoints that meet the predefined success criteria as defined in study protocol(s) and otherwise satisfy applicable evidence standards and UroGen's own criteria for advancing an investigational Combined Product to Commercialization in the United States, UroGen shall use Best Efforts to submit a Marketing Authorization application to the U.S. Food and Drug Administration (FDA) for the Combined Product within [***].

SECTION 4 -   REGULATORY

4.1. General Responsibilities; Ownership of Regulatory Approvals. UroGen shall be responsible for the preparation, submission, and expense for all Regulatory Materials necessary or desirable for obtaining and maintaining Regulatory Approvals for the Combined Product(s) (including Product and UroGen Formulation contained therein to the extent separate Regulatory Approvals are required for them) in the Field in the Territory. All Regulatory Approvals for the Combined Product(s) in the Territory shall be in the name of UroGen or its sublicensees, and UroGen or its sublicensees shall own all right, title and interest in and to all such Regulatory Approvals and all related Regulatory Materials. At UroGen's reasonable request, medac shall use Commercially Reasonable Efforts to provide reasonable and timely assistance for information and documents regarding the Product, subject to potential extra costs and expense which are to be borne solely by UroGen. Following UroGen's reasonable request, Medac shall without undue delay notify UroGen in advance of the estimated extra costs and shall not incur such costs unless approved, in advance and in writing, by UroGen.

4.2. Select Registration Dossier Section review prior to submission. UroGen shall send to medac, on a rolling basis commencing no later than [***] prior any first submission of a Registration Dossier in a country of the Territory, the Module 3 Quality (according to current FDA and ICH guidelines) of the Combined Product(s) Registration Dossier relating to the Product. Medac shall have the right to review the Product related Module 3 Quality. Medac has the right to propose changes and correct errors to the Product related Module 3 Quality. All valid error corrections identified by medac shall be implemented by UroGen, while other proposed changes may be implemented at UroGen's discretion. Later changes to the Product relating Module 3 Quality parts of the Combined Product(s) shall be handled as defined in the Quality Agreement.

4.3. Pricing Approvals. To the extent that a given country or regulatory jurisdiction in the Territory requires Pricing Approval for sale of the Combined Product(s) in the Field in such country or regulatory jurisdiction, UroGen or its sublicensees shall (to the extent permitted by Applicable Laws) be solely responsible for (and shall use Commercially Reasonable Efforts toward) obtaining and maintaining Pricing Approvals in all such countries and regulatory jurisdictions in the Territory, in its own name or that of its sublicensee.

4.4. Regulatory Communications. The Parties shall provide timely and good faith cooperation in communicating with any Regulatory Authority having jurisdiction regarding the Product or the Combined Product(s). Any routine correspondence with any Regulatory Authority concerning

the Combined Product(s) and/or Product to the extent part of or intended to be part of a Combined Product(s) shall be the sole responsibility of UroGen; *provided, however*, that, at UroGen's request, medac will provide timely information and assistance to UroGen with respect to Regulatory Authority communications relating to the Product subject to potential actual extra costs incurred; *further provided,* that medac shall without undue delay notify UroGen in advance of the estimated extra costs and shall not incur such costs unless approved, in advance and in writing, by UroGen.

4.5. Each Party shall immediately inform the other Party (but no later than [***]) of notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority which (i) raises any material concerns regarding the safety or efficacy of the Combined Product(s); (ii) indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product or the Combined Product(s); or (iii) is reasonably likely to lead to a recall, market withdrawal or market notification with respect to the Product or the Combined Product(s). UroGen shall be solely responsible for responding to any such communications relating to the Product and the Combined Product(s), and the Parties shall reasonably cooperate with and assist each other in complying with regulatory obligations, including by medac providing to UroGen, within [***] after UroGen's request, any information and documentation which is in medac's possession as may be necessary or reasonably helpful for UroGen to prepare a response to an inquiry from a Regulatory Authority in the Territory with respect to the Product.

4.6. In addition to its obligations under this Agreement, each Party shall disclose to the other Party within [***] of receipt all material information pertaining to actions taken by Regulatory Authorities in connection with the Product or the Combined Product(s) including any notice, audit notice, notice of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Product or the Combined Product(s). The details are to be agreed in a separate Quality Agreement.

4.7. In case of any inconsistencies between the Quality Agreement and this Agreement regarding quality issues, the Quality Agreement shall be decisive. Otherwise, this Agreement shall prevail.

4.8. Within [***] of the Effective Date, UroGen shall provide medac with a non-binding long-term forecast showing the planned countries in which UroGen plans to seek a Marketing Authorization for the Product as part of the Combined Product for [***] and shall update this information at the beginning of each calendar year (the "Regulatory Roadmap"). This Regulatory Roadmap does not constitute firm Product development orders but serves for medac's long-term planning purposes only. In case countries are listed on the Regulatory Roadmap that require additional Product development, the Parties agree mutually and in good faith to discuss the necessary Product development activities and Product development timelines. medac shall without undue delay notify UroGen in advance of the estimated extra Product development costs and shall not incur such costs unless approved, in advance and in writing, by UroGen.

SECTION 5 -   PHARMACOVIGILANCE, ADVERSE EVENT REPORTING; SAFETY DATA EXCHANGE AND MEDICAL INQUIRIES

5.1. Starting from the date on which UroGen receives Marketing Authorization for a Combined Product in the Territory, UroGen or its sublicensees shall fulfil the local legal requirements for pharmacovigilance for the Combined Product in the Territory and is responsible to assure full compliance with the respective pharmacovigilance obligations under Applicable Laws.

SECTION 6 -   COMMERCIALIZATION AND SUPPLY

6.1. Commercialization in the Field in the Territory. During the Term, UroGen shall be solely and exclusively responsible for Exploiting the Combined Product(s) in the Territory for use in the Field. For clarity, UroGen or its Affiliates has the sole and exclusive authority and discretion to Commercialize Combined Product(s) for use in the Field in the Territory.

6.2. medac as Supplier of Product. medac agrees to manufacture and supply UroGen's requirements of Product for UroGen's Exploitation of the Combined Product(s) in accordance with this Agreement.

6.3. Exclusive Purchase of the Product. As part consideration for the rights granted by medac to UroGen under Section 2.1 of this Agreement, UroGen agrees to purchase the Product for its Combined Product(s) during the Term of this Agreement exclusively from medac. For clarity, UroGen retains the unlimited right to source from a party other than medac any lyophilized Compound, for use in any UroGen product including any UroGen combined products, that: a) includes mannitol as an excipient; and b) is not manufactured according to the patents listed in Exhibit A.

6.4. Manufacturing Site(s). medac will initially Manufacture the Product at its Affiliate, [***], in [***] (the "**[***] Site**"). The Parties agree that the Product, may also be established at a second Affiliate of medac [***][***]). In the event that medac is unable to deliver UroGen's supply requirements of Product from [***] Site for a continuous period of [***] (an "**[***] Supply Disruption**"), the following shall apply:

a) Should there be a [***] Supply Disruption, medac shall initiate a transfer of production to [***] Site in order to meet UroGen's supply requirements of Product. The transfer process shall commence immediately upon the identification of a [***] Supply Disruption, and medac shall use commercially reasonable efforts to ensure that the transfer to [***] Site is completed in a timely manner so as to minimize any disruption to the supply of Product to UroGen; b) Only in the case where there are concurrent supply disruptions at both [***] Site and [***] Site, whereby medac cannot meet UroGen's supply requirements for a continuous period of [***] (a "**Supply Disruption**"), UroGen shall have the right to qualify an alternative manufacturer and purchase Product from such manufacturer ("**Alternative Manufacturer**") until medac can again demonstrate its ability to satisfy UroGen's requirements for Product. Any Alternative Manufacturer must be approved in advance by medac, whereas such approval shall not be unreasonably withheld or delayed. The establishment of the Product including but not limited to transfer of the technology and Know-How for the manufacturing of the Product at the Alternative Manufacturer will be paid by UroGen in both cases (a) and (b). Parties agree that medac shall not be liable and responsible for any acts and omissions of the Alternative Manufacturer. UroGen shall ensure any Alternative Manufacturer agree in writing to comply with the terms and conditions of this Agreement that are applicable to UroGen's activities. UroGen shall remain fully liable for the performance of such Alternative Manufacturer in accordance with this Agreement.

The Parties agree that the establishment of the Product at the [***] Site is a transfer project and that the costs for such transfer project will be fully paid by UroGen in case UroGen initiates the transfer project. In case medac itself initiates the transfer project in the absence of an [***] Supply Disruption, medac shall notify UroGen in advance of such transfer project and the costs of such project shall be paid

by medac, unless the Parties mutually agree in writing to share such costs. For clarity, to the extent PPQ batches of Product manufactured at the [***] Site are acceptable for use by UroGen for Combined Product, the cost for such PPQ Product batches shall be borne by UroGen at the Price set forth in this Agreement.

Upon first commercial sale and all further sales of a Product manufactured by an Alternative Manufacturer as part of a Combined Product, UroGen will pay medac [***] of such Product. Upon request, UroGen will provide medac with sufficient evidence of the amount of Product manufactured by Alternative Manufacturer. Upon written request of medac and not more than [***], UroGen shall allow medac, or an independent accounting firm selected by medac to have access during normal business hours, at a mutually agreed date, to records or UroGen as may be reasonably necessary to verify the accuracy of the reported amounts. Such record verification shall concern the [***] prior to the date of such request.

6.5. Technology Transfer; Qualification of Additional Manufacturer. In the event of a Supply Disruption, upon UroGen's request, medac shall transfer the technology and Know-How that medac uses for the manufacture of the Product to UroGen or a Third Party manufacturer of UroGen's choosing and shall cooperate with UroGen and, if applicable, such Third Party, in the qualification of UroGen or such Third Party, as applicable, as a manufacturer of the Product.

6.6. Use of Contractors for the Combined Product(s). UroGen shall have the right, upon reasonable prior written notice to medac, to package, label, release and distribute the Combined Product(s) directly or indirectly through any Third Party(ies) acting as contractors; *provided however*, that UroGen remains responsible for the performance of its contractors and such actions do not in any way diminish, reduce or eliminate any of UroGen's obligations under this Agreement. In exercising its rights under this Section 6.6, UroGen shall not be required to obtain medac's prior written consent; *provided, however*, that UroGen shall ensure that its contractors are bound by terms and conditions to those of this Agreement and guarantee its contractors' performance under this Agreement.

SECTION 7 -   FORECAST / ORDERS / TERMS OF DELIVERY

7.1. UroGen has provided medac as Exhibit C with an Initial Non-Binding [***] Forecast showing the expected requirements of Products for [***] and will update this information [***] at a to be defined timepoint. This long-term forecast does not constitute firm orders but serves for medac's long term planning purposes only.

7.2. UroGen shall advise medac of its estimated needs of the Product for rolling [***] (the "Forecast") and update it on a [***] basis. The first [***] of the Forecast are considered as binding. The remaining [***] of the Forecast are considered non-binding but are allowed to fluctuate on the [***] bucket level only as per definition in Section 7.3. The first Forecast shall be submitted [***] prior to first commercial delivery of Product.

7.3. UroGen may deviate from each Forecast for [***] through [***] by no greater than [***] percent ([***]%) in total on each of the individual [***] buckets. Medac shall strive to deliver a requested increase, up to such [***] percent ([***]%) of the original quantity as per the individual [***] buckets [***]. UroGen may deviate from each Forecast for [***] through [***] by no greater than [***] percent ([***]%) in total on each of the individual [***] buckets. Medac shall strive to deliver a requested increase, up to such [***] percent ([***]%) of the original quantity as per the individual [***] buckets [***] to [***]. For the increase of the Forecast beyond the above-mentioned flexibilities medac is not obligated to deliver such exceeding amount. The Parties will discuss in such case how to achieve this goal. In case the Forecast [***] through [***] is reduced by UroGen by more than the specified percentage points, UroGen will reimburse medac for expenses already incurred for example but not limited to expenses incurred for staffing models that were built to service the demand, expenses incurred for materials bought by medac or its Affiliates specifically for the Manufacture of Product that cannot be used otherwise or penalties arising out of supply contracts with suppliers of medac or its Affiliates.

7.4. medac is responsible for ensuring the availability of the Product based on UroGen's Forecast(s). medac shall provide the Product to UroGen as Bulk Product (see also Section 7.9). Further packaging, storage and transport details will be defined in the Quality Agreement.

7.5. UroGen shall source from [***] and deliver to medac the Compound for the exclusive use for the Manufacturing of Product ("**UroGen-Supplied Compound**") in compliance with the current valid specifications, accompanying documentation reasonably required for Medac to perform the Manufacturing of Product as well as reference standards free of charge (DDP, INCOTERMS 2020) to medac's Affiliate [***] [***]. UroGen-Supplied Compound will remain the property of UroGen following delivery to medac's Affiliate. Medac shall ensure that the Affiliate handles and stores all UroGen-Supplied Compound in accordance with cGMP, the Quality Agreement, the Registration Dossier, and the Marketing Authorization and shall be responsible for any loss, damage, or theft of such UroGen-Supplied Compound. Following mutual written agreement of the Parties, medac shall assume sole responsibility for identifying and sourcing a second supplier of Compound for the use in the Manufacturing of Product. medac shall use commercially reasonable efforts to establish the second supplier of Compound for the manufacture of the Product, subject to potential extra costs source and expense related to the establishment of a second Compound and that are to be borne solely by UroGen. Following UroGen's reasonable request, Medac shall without undue delay notify UroGen in advance of such estimated extra costs and shall not incur such costs unless approved, in advance and in writing, by UroGen.

7.6. Except in cases of force majeure excusing UroGen's performance under the Agreement, in the event UroGen fails to deliver the UroGen-Supplied Compound to medac in sufficient quantities to satisfy UroGen's requirements for Product, medac shall not be responsible for any delay in supply of the Product. UroGen's failure to deliver sufficient quantities of UroGen-Supplied Compound to medac in a timely manner for its Product requirements shall not be considered as a Supply Disruption (as defined in Section 6.4) at either the [***] Site or the [***] Site.

7.7. The Date of Dispatch shall be within [***] unless otherwise agreed by the Parties after the day of manufacturing (day of manufacturing is defined as the day the Compound is added to the compounding vessel).

7.8. UroGen must place its firm orders at least [***] in advance. Each order shall contain the exact quantity, type of the Product and the delivery date. Orders must be placed in batch size (see Exhibit B). Only full batches can be ordered. Medac must confirm the orders within [***] after receipt of the orders in writing.

7.9. Commencing [***] following the Transition Period, UroGen hereby agrees to order at least [***] full batches of Product per [***] (the "Minimum Order Quantity"). In case UroGen orders less than [***] full batches in a [***] UroGen shall pay medac a compensation fee ("Compensation") equal to [***], minus any costs of Starting Material or packaging material not used. The Compensation shall be due and payable within [***] from the end of the [***] in which the Minimum Order Quantity was not met.

7.10. Both Parties agree that the responsibility for obtaining the Compound leads to two different scenarios with regards to the assessment of whether medac delivers the Product or provides a service (production of the Product). In the scenario in which UroGen is responsible for the procurement of the Compound for the production, medac provides a service to UroGen. In the scenario in which medac is responsible for the procurement of the Compound, medac delivers the Product.

7.11. According to Incoterms 2020 FCA, UroGen is responsible for transportation from medac's Affiliate [***].

7.12. Medac shall inform UroGen about the yield [***] before the Date of Dispatch. Produced or delivered quantity may vary up to [***] percent from the theoretical maximum batch size (see Exhibit B). The Parties will agree after production of [***] commercial batches on common yields that can be expected from a manufacturing run.

7.13. If a delay occurs, medac will inform UroGen giving the new Date of Dispatch. In such a case, medac will use Commercially Reasonable Efforts to provide the batch as soon as possible.

7.14. The place of performance is currently [***].

SECTION 8 -   AUDITS AND QUALITY

8.1. No later than [***], the Parties shall negotiate in good faith and enter into a separate written Quality Agreement for the commercial supply of Product. In case of any inconsistencies between the Quality Agreement and this Agreement regarding quality issues, the Quality Agreement shall control, and for inconsistencies related to non-quality issues, this Agreement shall control.

8.2. medac was qualified by UroGen in [***] as an approved supplier.

8.3. UroGen has the right to inspect the facilities of medac and together with medac the medac Affiliates responsible for Manufacturing of Product, including but not limited to the [***] Site and, if established under this Agreement, the [***] Site. These audits shall be arranged between the Parties without disturbing the operational processes as far as possible, and according to further details in the Quality Agreement.

8.4. The Parties shall allow and support any regulatory monitoring activity (e.g. inspections by authorities).

8.5. UroGen shall bear the reasonable and necessary costs of medac arising from the performance of regulatory authority audits that are specific to the Product. This obligation does not extend to facility requirements stemming from the GMP certification inspections unless agreed to in advance by UroGen.

8.6. medac agrees to maintain a quality assurance system including regular self-inspections and qualification of suppliers according to the standard operating procedures of medac and cGMP regulations. UroGen is responsible for the qualification of materials delivered by UroGen to medac or medacs' affiliates including UroGen-Supplied Compound. Details will be defined in the separate Quality Agreement between the Parties.

8.7. UroGen has the right to disclose relevant qualification documentation of medac to national/international authorities after prior notification to and confirmation by medac (email is sufficient).

8.8. The Manufacture and testing of the Product by medac and its Authorized Third Parties must comply with the information contained in the Registration Dossier. UroGen shall make available the corresponding parts of the Registration Dossier to medac. The manufacturing instructions and testing instructions prepared by medac according to the manufacturing directions and testing directions are the property of UroGen. Details will be defined in the separate Quality Agreement between the Parties. All originals and copies of the manufacturing instructions and testing instructions will be handed over by medac and its Authorized Third Parties to UroGen immediately after the termination of this Agreement. Medac undertakes to keep the entire documentation including the manufacturing instructions and test instructions up to date and to implement and document any changes to such instructions agreed upon by the Parties in writing during the Term of this Agreement.

8.9. The Product shall be manufactured by medac and its Authorized Third Parties according to the Product Specifications and the manufacturing instructions both approved by UroGen as well as the Batch Manufacturing Record.

8.10. Deviation and out-of-specification results management will be performed according to the Quality Agreement.

8.11. medac or its Affiliates will make a report with relevant data on the circumstances of such deviation, including without limitation explanations on the cause for such deviation, the batches affected by the deviation and possible measures to maintain or re-establish the appropriate quality of the Product ("**Investigation Report**"). Details will be defined in the separate Quality Agreement between the Parties. The costs for such Investigation Reports will be borne by medac. For clarification the Parties expressly agree that in case the deviation or out-of-specification result is caused by UroGen-Supplied Compound the costs will be borne by UroGen.

8.12. As of the Effective Date, the Parties agree that the [***] Site has not been inspected by the FDA and has not received FDA approval as a manufacturing site for Product. The Parties agree that the FDA may request a preapproval inspection of the [***] Site in connection with a Marketing Authorization application made by UroGen for a Combined Product in the United States. In the event that the [***] Site fails an FDA preapproval inspection, UroGen and medac agree to meet, discuss, and align in good faith upon a remediation plan for the [***] Site and the timelines for such plan. medac shall have sole responsibility for executing the remediation plan and for the costs of the remediation plan. In the event such remediation plan is unsuccessful and medac does not secure FDA approval for the [***] Site in a timely manner consistent with the Remediation Plan, medac shall establish the Product at an alternative Affiliate of medac, such as the [***] Site. If this transfer to a medac Affiliate cannot be achieved in a timely manner and may delay FDA approval of a Marketing Authorization for a Combined Product, UroGen shall have the right to contract with an Alternative Manufacturer, with appropriate support from medac for such transfer as described in Clauses 6.4. and 6.5 of the Agreement accordingly. For clarity, medac and its Affiliates are not liable to UroGen and are not subject to any claim of indemnification for failing any FDA preapproval inspection or for the inability to resolve the preapproval inspections issue with the FDA.

SECTION 9 -   PAYMENTS FOR RIGHTS AND LICENSES

9.1. No Payments for rights and licenses. The Parties acknowledge and agree that the rights and licenses granted to UroGen under this Agreement are granted without any obligation of UroGen to make financial payments to medac and shall be considered to be fully paid and royalty free subject to further provisions set forth in this Agreement including but not limited to the exclusive Product supply set forth in section 6.3 “Exclusive Purchase of Product” and section 6.4 “Manufacturing Site(s)”.

SECTION 10 -   PAYMENTS

10.1. UroGen shall pay the Price, plus VAT, if applicable, for the supply of the Product or the supply of the service. All payments must be made in Euro.

10.2. The Price may be renegotiated on [***] basis upon request of one of the Parties. Average fluctuations of outside factors that may influence the cost price, such as changes in exchange rates, inflation, labor and public utilities, volumes ordered by UroGen, change in economic market conditions shall be taken into consideration by the Parties in the process of renegotiating the Price. Variation should remain between +/- [***]%. In special hardship cases that lead to variations larger than +/- [***]%, the Parties will negotiate in good faith.

10.3. Payment shall be due [***] after receipt of a proper and uncontested invoice.

10.4. The Prices for the manufacturing of Product (Compound provided by UroGen) as well as additional services are set forth in Exhibit B. The Prices for the manufacturing of the Product (Compound provided by medac) will be added as an additional Exhibit at a later stage. The Prices include Starting Material, Manufacturing, all quality assurance measures related to Product batch release, packaging and preparation for shipment of Product according to the requirements defined in this Agreement and the Quality Agreement. Upon delivery of the Product, medac shall invoice UroGen for the applicable Bulk Product batch fee.

SECTION 11 -   QUALITY, DEFECTS, RECALLS

11.1. Medac confirms that the Product will be Manufactured according to cGMP and that Product shall meet the Product Specifications for the registered shelf life of the Product.

11.2. UroGen shall instruct its packaging contractor to perform incoming verification of delivery of the Product within [***] of arrival at the contractor’s facility. Such verification (a non-inclusive list, introduced for example only) may include for example shipping documentation, amount of shipping containers, any external damage to shipping containers, random sampling of bulk vials and verification of appearance, size and closure type, and of batch number printed on vial closure. In the event that the Product does not conform to shipping documentation or does not pass the verification, UroGen shall inform medac in writing within [***] from notification by its packaging contractor. Failure or delay without prior notification to medac and agreement by medac, shall mean acceptance of the delivered Product.

11.3. UroGen must inform medac within [***] in case it discovers any hidden or latent defects at any time during the shelf life of the Product. If there is a disagreement between the Parties as to the compliance of the Product with specifications, warranties and legal requirements, a sample may be sent to an independent laboratory for final evaluation, which shall be binding for both Parties. The independent laboratory shall be selected by both Parties jointly. In case the Parties do not agree upon an independent laboratory, such shall be chosen by the Chamber of Commerce in Hamburg, Germany. If the independent laboratory finds the Product to conform to the specifications, warranties and legal requirements UroGen, shall bear the costs of the laboratory and the Chamber of Commerce. Otherwise, the costs shall be borne by medac.

11.4. If a Party considers it necessary to withdraw or recall Product from the market, or if a Regulatory Authority requires such withdrawal or recall from a Party, the respective Party must immediately advise the other Party of such intention or request, and both Parties shall without delay discuss such withdrawal or recall. The procedure for any recall with respect to the Product, and the Parties’ respective responsibilities with respect thereto, shall be as set forth in the Quality Agreement.

11.5. If any such recall of Product is solely attributable to the non-compliance of UroGen with this Agreement or the terms of the Quality Agreement, then UroGen shall bear the full costs and expenses of any recall. If any such recall is solely attributable to medac’s non-compliance to this Agreement or the terms of the Quality Agreement, then medac shall bear the full cost and expense of any such recall. Such recall actions include: (a) Notification of known or the public notification of unknown possessors of Products; (b) Costs for transportation, including packaging, insurance, storage and customs costs of Products from the possessor to Purchaser, or to the next suitable location, where (i) the Product defects can be corrected, or (ii) the Products can be disposed of, destroyed, stored temporarily or exchanged; (c) Return of the repaired or exchanged Products; (d) Disposal or destruction of the Products; (e) Separation of the Products that are affected; (f) Inspection of the Products which verifiably belong to a production series that contains defective Products, whereby the inspection can take place at the location of the possessor or at a close-by suitable location; (g) Travel expenses that are required in connection with the aforementioned measures. If both medac and UroGen share responsibility for the cause of a recall, the cost and expense thereof shall be shared in proportion to each Party’s contribution to the recall, as mutually agreed in writing. If there is an unresolved disagreement between the Parties as to their respective contribution to the cause of any recall, then an independent expert shall determine, by a preponderance of evidence, each Party’s proportionate fault, if any, for the cause of the Product recall.

11.6. In the event that a Party recommends initiating a batch recall or that the Regulatory Authority requires such batch recall, the Parties shall cooperate in good faith to determine the measures that should be taken. The Parties shall immediately seek to determine the cause of the defect in the batch. The Parties will support each other and provide any necessary assistance in the handling of any Product return, quality complaint, and batch recalls (responsibilities are further defined in the Quality Agreement).

11.7. The Parties agree to inform each other as soon as practicable of any quality claims regarding the Product arising from a Third Party or Regulatory Authority and provide each other reasonable support. To the extent that they are related to Product, UroGen will inform medac of any quality claims related to Combined Product.

11.8. If UroGen rejects Product and the non-conformance is determined, based on evidence provided by UroGen, to have arisen from a medac Manufacturing defect (“**Defective Product**”) and UroGen has previously paid for the Defective Product, medac will promptly, at UroGen’s election, either: (i) refund all amounts paid by UroGen to medac for the Defective Product; or (ii) replace the Defective Product and all materials required for the Manufacture of the replacement Products with conforming Products without UroGen being liable for medac’s invoice price for such replacement Product and medac shall use Commercially Reasonable Efforts to Manufacture and deliver such

conforming Products as soon as possible and no later than [***] after UroGen's election under this Section 11.8. Notwithstanding the foregoing, medac shall not be liable for the Defective Product, if the non-conformance is determined to have arisen from the UroGen-Supplied Compound.

11.9. Planned changes to the Product, the Manufacturing process or the specifications will be communicated in writing in advance (the details will be set forth in the Quality Agreement). Planned changes will be at the sole discretion of medac; *provided, however*, that medac shall obtain UroGen's advance written consent for such changes, which shall not be unreasonably withheld. In the event planned changes to the Product require prior approval from a Regulatory Authority, medac and UroGen shall develop a mutually agreed plan to ensure ongoing supply of Product and/or minimize any potential impact to supply of Product. In the event that UroGen wants to change any Product Specification or Product related specification, UroGen shall submit such request to medac in writing. medac will use Commercially Reasonable Efforts to make such changes in the timeframe requested by UroGen unless such changes are technically or economically prohibitive. The costs arising out of UroGen-requested changes will be borne solely by UroGen; provided however, that if a change relates to Mitomycin medac or the Manufacture equipment, the Parties will agree in writing as to the share of costs that will be paid by each Party.

SECTION 12 -   INTELLECTUAL PROPERTY AND TRADEMARKS

12.1. Ownership of Intellectual Property.

12.1.1. General. In case of any inconsistencies between this Agreement and the Development Agreement regarding Intellectual Property issues, the provisions of this Agreement shall prevail. Except as expressly set forth otherwise in this Agreement, (i) Licensed Patents and/or Licensed Know-How are not assigned or transferred to UroGen, (ii) medac, regardless of inventorship, shall solely own, and shall have the sole right to apply for, Patents Covering any medac Invention ("**medac Invention Patents**"), and (iii) UroGen, regardless of inventorship, shall solely own, and it alone shall have the right to apply for, Patents Covering any UroGen Invention ("**UroGen Invention Patents**"). Any invention made in the performance of activities under this Agreement that is neither a medac Invention nor a UroGen Invention shall be owned by the Party whose employees or representatives made such invention and if such invention was made jointly by employees or representatives of both medac and UroGen, such inventions ("**Joint Inventions**") and any Patents claiming such Joint Invention ("**Joint Invention Patents**") shall be jointly owned by medac and UroGen (or their designated Affiliates).

UroGen shall and hereby does assign to medac (and shall cause its Affiliates and sublicensees and subcontractors to assign as long such entities are involved in any activities under this Agreement) all of its or their right, title and interest in and to any medac Inventions made by UroGen, its Affiliates or such sublicensees and subcontractors in the performance of UroGen's obligations under this Agreement. medac shall and hereby does assign (and do its utmost effort to cause its Affiliates to assign as long such entities are involved in any activities under this Agreement), any and all of its or their right, title and interest in and to any UroGen Inventions to UroGen, such that UroGen shall solely own such UroGen Inventions. Each Party shall promptly disclose to the other Party all Joint Inventions, as applicable, made by it during the Term.

12.1.2. Employees. (i) UroGen will require all of its and its employees as long such entities are involved in any activities under this Agreement and/or have access to any Confidential Information and (ii) medac will require all of its employees, to assign all inventions that are developed, made or conceived by such employees according to the ownership principles described in Section 12.1.1 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Each Party will also use its Commercially Reasonable Efforts to require any agents, independent contractors or sublicensees performing an activity pursuant to this Agreement to assign all inventions that are developed, made or conceived by such agents, independent contractors or sublicensees to medac and/or UroGen according to the ownership principles described in Section 12.1.1 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions.

12.2. Prosecution and Maintenance.

12.2.1. UroGen Invention Patents. UroGen shall have the sole right, but not the obligation, to prosecute and maintain the UroGen Invention Patents at UroGen's sole expense, using counsel of its own choosing.

12.2.2. Licensed Patent and medac Invention Patents. medac shall have the first right, but not the obligation, to prosecute and maintain the Licensed Patents and the medac Invention Patents solely owned by medac (other than the Joint Invention Patents) at medac's sole expense, using counsel of its own choosing. If medac declines to prosecute or maintain anywhere in the Territory of any Licensed Patent (other than the Joint Invention Patents) or of any medac Invention Patent solely owned by medac, in each case that are relevant to the Product, medac shall provide UroGen with [***] prior written notice to such effect, and medac shall have no responsibility with respect to the prosecution or maintenance of the Licensed Patents or medac Invention Patent solely owned by medac and no responsibility for any expenses incurred in connection with such Licensed Patents or medac Invention Patents solely owned by medac after the end of such [***] period. If UroGen gives written notice to medac before the end of such [***] period that UroGen elects to continue prosecution or maintenance of the applicable Licensed Patent or medac Invention Patents solely owned by medac, medac, upon UroGen's request, shall make reasonable efforts to timely execute such documents and perform such acts, at UroGen's expense, as may be reasonably necessary to permit UroGen to prosecute and maintain such applicable Licensed Patent or medac Invention Patent solely owned by medac at its sole expense. If UroGen does not give written notice to medac before the end of such [***] period that UroGen elects to continue prosecution or maintenance of such applicable Licensed Patent or medac Invention Patent solely owned by medac, medac shall be entitled to allow such Licensed Patent or medac Invention Patent solely owned by medac to become abandoned or lapse, as applicable.

12.2.3. Joint Invention Patents. The Parties will discuss in good faith and agree on how to file, prosecute, and maintain Joint Inventions Patents. The Parties will also discuss in good faith and agree on cost sharing and the selection of counsel, if needed. If a Party at any time declines to continue prosecution or maintenance anywhere in the Territory of any Joint Invention Patent ("**Declining Party**"), the Declining Party shall provide the other Party with [***] prior written notice, and thereafter the Declining Party shall have no responsibility with respect to the prosecution or maintenance of the applicable Joint Invention Patent and no responsibility for any expenses incurred in connection with such Joint Invention Patent after the end of such [***] period. If the other Party gives written notice to the Declining Party before the end of such [***] period that the other Party elects to continue prosecution or maintenance ("**Accepting Party**"), the Declining Party, upon the Accepting Party's request, shall make reasonable efforts to timely execute such documents and perform such acts as may be necessary to permit the Accepting Party to prosecute and maintain such

Joint Invention Patent at the Accepting Party's sole expense. For the avoidance of doubt, nothing herein shall be construed to give either Party the right to use the other Party's Confidential Information in prosecuting Joint Invention Patents without such Party's prior written consent.

12.2.4. Cooperation in Joint Invention Patents and Licenses. The Parties agree to cooperate in the preparation, filing, prosecution and maintenance of all Joint Invention Patents under this Section 12.2, including obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports concerning the invention disclosed in such Joint Invention Patent, obtaining execution of such other documents which are needed in the filing and prosecution of such Joint Invention Patent. Both Parties shall grant each other a worldwide, fully-paid-up, unlimited, irrevocable, perpetual, non-transferable and sublicensable right to use the Joint Invention Patents for all purposes, subject to the provisions in Section 12.2.3.

12.3. Third-Party Infringement of Licensed Patents in the Field and outside the Field.

12.3.1. Patent Notice. In the event medac becomes aware of (a) any suspected infringement of any Licensed Patents (an "**Infringement**") or (b) claims that any of the Licensed Patents are invalid or unenforceable or (c) claims that any Licensed Patents would not be infringed by the making, use, offer for sale, sale or import of a Competing Product in the Territory (each of clauses (b) and (c) a "**Patent Challenge**"), medac shall notify UroGen within [***] and provide UroGen with all details of such Infringement or Patent Challenge, as applicable. In the event UroGen becomes aware of any suspected Infringement or Patent Challenge of any Licensed Patents, UroGen shall notify medac within [***] and provide UroGen with all details of such suspected Infringement or Patent Challenge, as applicable.

12.3.2. Infringement of Licensed Patents in the Field. With respect to any Infringement of any Licensed Patents by a Competing Product in the Field in the Territory, medac shall have the first right, but not the obligation, through counsel of its choosing, to initiate an action at its sole cost and expense. In case the Infringement is caused by a Competing Product, medac shall allow Urogen a reasonable opportunity and reasonable time to review and comment regarding any such action and medac shall consider in good faith any reasonable comments offered by Urogen. Urogen shall have the option, but not the obligation, to join any such action relating to Competing Product with counsel of its own choosing at its sole cost and expense, provided that if joinder of UroGen in any such action is necessary in order to confer standing to enforce such Licensed Patent, then UroGen shall join such action upon medac's request and at medac's cost and expense (other than the cost and expense of any independent counsel retained by UroGen). If medac does not initiate an action with respect to any Infringement caused by a Competing Product (a) within [***] of learning of such Infringement or (b) medac earlier notifies Urogen in writing of its intent not to so initiate an action, then Urogen shall have the right, but not the obligation, to bring such an action based on an Infringement caused by a Competing Product at its sole cost and expense.

12.3.3. Cooperation; Award. In the event a Party is entitled to and brings an Infringement action in accordance with Section 12.3.2, the other Party shall cooperate fully, providing access to relevant documents and other evidence and making its employees available at reasonable business hours and joining in such action to the extent necessary to enable such action to be brought. If a Party pursues an action against such alleged Infringement according to Section 12.3.2, it shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken to preclude such Infringement. Any recoveries resulting from an enforcement action relating to a claim of Infringement shall be first applied against payment of the enforcing Party's costs and expenses in connection therewith and then the non-enforcing Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses shall be allocated [***] percent ([***]%) to the enforcing Party and [***] percent ([***]%) to the other Party.

12.3.4. Defense of Licensed Patents. With respect to any defense of any Licensed Patent (other than a Joint Invention Patent), medac shall have the right, but not the obligation, to defend any such Licensed Patent against such Patent Challenge in its sole discretion. If medac decides not to defend any Licensed Patent against a Patent Challenge, medac shall notify UroGen in writing within [***] of such decision and the Parties will discuss in good faith regarding how to proceed. *Provided, however*, that in such event, UroGen shall have the right to require that medac defend such Licensed Patent against such Patent Challenge at UroGen's expense.

12.3.5. Infringement of Licensed Patents Outside of the Field or in Relation to Other Products. With respect to any and all Infringement of any Licensed Patent (other than a Joint Invention Patent) anywhere outside the Field or in relation to any other product which is not a Competing Product, medac (or its designee) shall have the first right, but not the obligation, to bring an appropriate suit or other action against any Person engaged in such Infringement or defense of any such Licensed Patent in its sole discretion. If medac decides not to bring an action pursuant to this Section 12.3.5, medac shall notify UroGen in writing within [***] of such decision and the Parties will discuss in good faith regarding how to proceed.

12.3.6. Infringement and Defense of Joint Patents Within the Field or Outside of the Field. With respect to any and all alleged infringement or challenges asserting invalidity, unenforceability, or non-infringement of any Joint Invention Patent whether in or outside the Field, the Parties shall discuss and agree as to (i) whether any infringement action is to be initiated by one of the Parties or both Parties and (ii) which Party shall take the lead in enforcing or defending such Joint Invention Patent with respect to such Infringement or challenge.

12.3.7. Settlement. The Party that is entitled to pursue an action against an Infringement in accordance with this Section 12 - also shall have the right to control settlement of such claim and shall consult the other Party on a regular basis; *provided however*, that no settlement shall be entered into without the prior consent of the other Party, which consent shall not be unreasonably withheld if such settlement would not adversely affect or diminish the rights and benefits of the other Party under this Agreement, or impose any new obligations or adversely affect any obligations of the other Party under this Agreement.

12.4. Third Party Claims of Infringement.

12.4.1. Notification. If a Third Party asserts that a Patent or other Intellectual Property right owned or otherwise controlled by such Third Party is infringed by the Exploitation of the Combined Product in the Field in the Territory (an "**Infringement Claim**"), the Party first made aware of such a claim shall promptly provide the other Party written notice of such Infringement Claim along with a summary of facts, in reasonable detail, as understood by the Party related to such Infringement Claim.

12.4.2. Control. In the case of any Infringement Claim against UroGen (including any of its Affiliates or sublicensees) alone or against both UroGen and medac (including its Affiliates) due to UroGen's activities with the Combined Product, UroGen will have the right, but not the obligation, to control the defense of such Infringement Claim, including control over any related litigation, settlement, appeal or other disposition arising in connection therewith. medac will cooperate with UroGen and will have the right to consult with UroGen concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation in which medac is a party at medac's own expense. In the case of any Infringement Claim against medac alone due solely to UroGen's activities pursuant to the terms of this Agreement, UroGen will have the right to consult with medac concerning such Infringement Claim, and UroGen, upon request of medac, will reasonably cooperate with medac at Urogen's expense.

12.4.3. Settlement of Third-Party Claims of Infringement. The controlling party with respect to a particular claim pursuant to Section 12.4.1 shall have the right to control settlement of any claims pursuant to Section 12.4.1, provided that such controlling party shall not admit liability or Infringement on the part of the other Party or agree in any such settlement that would include an injunction against the other Party without obtaining the other Party's consent thereto.

12.5. Patent Marking. UroGen shall mark the Combined Product(s) marketed and sold by UroGen (or its Affiliate or distributor) hereunder with appropriate patent numbers or indicia at medac's request.

SECTION 13 -   REPRESENTATIONS, WARRANTIES AND COVENANTS

13.1. Mutual Representations and Warranties. Each Party hereby represents and warrants (as applicable) to the other Party as follows, as of the Effective Date:

13.1.1. Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full legal power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses by such Party granted by it hereunder.

13.1.2. Authority and Binding Agreement. (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, except as enforcement may be affected by bankruptcy, insolvency or other similar laws and by general principles of equity.

13.1.3. No Conflicts. The execution, delivery and performance by a Party of this Agreement and its compliance with the terms and conditions hereof does not and will not conflict with or result in a breach of or default under any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound.

13.2. Mutual Covenants. Each Party hereby represents and warrants (as applicable) to the other Party as follows:

13.2.1. Compliance with Applicable Laws. Each Party covenants to the other Party it shall comply with Applicable Laws, in the course of performing its obligations or exercising its rights pursuant to this Agreement.

13.2.2. Anti-Corruption. With respect to any Products, payments or services provided under this Agreement, such Party has not taken and will not during the Term take any action directly or indirectly to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official in order to gain an improper advantage, and has not accepted, and will not accept in the future such payment.

13.3. Additional UroGen Representations and Warranties. UroGen hereby represents and warrants to medac that it will Commercialize the Combined Product in accordance with its respective Marketing Authorizations and Applicable Laws. UroGen hereby represents and warrants to medac that it will use Licensed Patents and Licensed Know-How for the Combined Product in accordance with the terms of this Agreement.

13.4. Additional medac Representations and Warranties. medac hereby represents and warrants to UroGen that each of the warranties set out below is true and accurate in all respects and not misleading at the signature date and will, as of the Effective Date, be true and accurate and not misleading as if each warranty were repeated with reference to the facts and circumstances existing at the relevant time:

13.4.1. medac is the sole and exclusive owner of the Licensed Patents (other than any Joint Invention Patents included therein) except medac Invention Patents and Licensed Know-How for the Product, all of which is free and clear of any claims, liens, charges or encumbrances, and medac has obtained from all inventors of Licensed Patents and Licensed Know-How existing as of the Effective Date, agreements assigning to medac each such inventor's entire right, title and interest in and to all such Licensed Patents and Licensed Know-How, if applicable;

13.4.2. medac owns the right, power and authority to grant a license to the Licensed Know-How and Licensed Patents for the use of the Product as part of the Combined Product to UroGen and UroGen's Affiliates under this Agreement;

13.4.3. medac is not subject to any agreement or arrangement which limits the ownership or licensed rights of medac with respect to Licensed Know-How and Licensed Patents for the Product;

13.4.4. as of the Effective Date, Licensed Patents are currently in force as listed in Exhibit A or prosecution is currently ongoing; and

13.4.5. For the avoidance of doubt: medac does not warrant to UroGen that (i) the use and import of the Product and (ii) the use and the Commercialization of the Product as part of the Combined Product in the Territory will not infringe any patent or other intellectual property right granted to or enjoyed by any Third Party with respect to the Territory; therefore such use, import, distribution, promotion, marketing or sale shall be at the risk of UroGen.

13.5. Best Knowledge. Medac confirms to its Best Knowledge:

13.5.1. that it has not received in the past [***] written notice by any Regulatory Authority with regard to the Product;

13.5.2. the use, sale, offer for sale by medac (or its respective Affiliates), as applicable, of the Product as a part of Combined Product does not incorporate any Know-How of any Third Party as of the Effective Date.

13.5.3. there is currently no (a) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to the Best Knowledge of medac, threatened against medac regarding the Product or (b) judgment or settlement against or owed by medac, in each case in connection with the Licensed Patents or the Product or relating to the transactions contemplated by this Agreement as of the Effective Date;

13.5.4. medac has not received in writing any complaint, claim or notice, or threat of any complaint, claim or notice, (including any notification that a license under any patent is or may be required) alleging that the Product infringes or misappropriates any Patents or Know-How of any Third Party, and medac has not received a written request or demand for indemnification or defense from any Third Party in connection with the Product as of the Effective Date;

13.5.5. there are no inventorship challenges, no opposition or nullity proceedings or interferences pending, with respect to any Licensed Patents. medac, to the knowledge of medac, as Licensed Patents are concerned, is in compliance with Applicable Law; and

13.5.6. no Third Party is, as of the Effective Date, infringing or misappropriating any of the Licensed Patents or has any right granted by medac or its Affiliates to Develop or Commercialize the Product in the Field in the Territory.

13.6. medac Covenants. In addition to the covenants made by medac elsewhere in this Agreement, medac hereby covenants to UroGen that, from the Effective Date and until expiration or termination of this Agreement:

13.6.1. it shall not, and shall cause its Affiliates not to (a) license, sell, assign or otherwise transfer to any Person (other than UroGen or its Affiliates) any Licensed Patents or Licensed Know-How for use of the Product as part of the Combined Product (or agree to do any of the foregoing) or (b) incur or permit to exist, with respect to any Licensed Patents or Licensed Know-How for use of the Product as part of the Combined Product, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other binding obligation that is or would be inconsistent with the rights and licenses granted under the Licensed Patents or Licensed Know-How to UroGen for use of the Product as part of the Combined Product under this Agreement;

13.6.2. it will not (a) take any action that diminishes the rights under the Licensed Patents or Licensed Know-How for use of the Product as part of the Combined Product granted to UroGen under this Agreement or (b) fail to take any action that is reasonably necessary to avoid diminishing the rights under the Licensed Patents or Licensed Know-How for use of the Product as part of the Combined Product granted to UroGen under this Agreement;

13.6.3. it will (a) not enter into any Third Party agreement that materially affects (i) the rights granted to UroGen or its Affiliates for use of the Product as part of the Combined Product in the Field or (ii) medac's ability under reasonable effort to fully perform its material obligations hereunder; (b) under reasonable effort remain, and cause its Affiliates to remain, in compliance in all material respects under the Agreement with respective medac Third Party agreements (including Disclosed Third Party Agreements); and (c) furnish UroGen with copies of all notices received by medac or its Affiliates relating to any alleged breach or default by medac or its Affiliates under any medac Third Party agreement (including and Disclosed Third Party Agreement) within [***] after receipt thereof; and

13.6.4. it will maintain valid and enforceable agreements with all Persons acting by or on behalf of medac or its Affiliates under this Agreement which require such Persons to assign to medac their entire right, title and interest in and to all Licensed Patents and Licensed Know-How for the Product.

13.7. Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

13.8. No Other Representations or Warranties. Except as expressly stated in Section 13.1 through 13.7 of this Agreement, no representations or warranties whatsoever, whether express, implied, statutory, or otherwise including warranties of merchantability, fitness for a particular purpose, non-infringement, or non-misappropriation of third-party intellectual property rights, are made or given by or on behalf of a Party. Except as expressly stated in this Agreement, all representations and warranties, whether arising by operation of law or otherwise, are hereby expressly disclaimed by medac.

13.9. Except as expressly stated in this Section by medac nothing contained in this Agreement shall be construed as:

13.9.1. representation or warranty;

13.9.2. as to the validity of the Licensed Patents or the accuracy, safety, efficacy, or usefulness, for any purpose, of the matter claimed therein;

13.9.3. that the use of the Licensed Patents or Licensed Know-How will not infringe any intellectual rights or other proprietary rights of any other Person; or

13.9.4. an agreement by medac to bring or prosecute actions or suits against any Person for infringement, or conferring any right to any Person to bring or prosecute actions or suits against any Person for infringement;

13.9.5. an obligation by medac to furnish any technical information, copyrights, mask works or Licensed Know-How, or any tangible embodiments thereof.

SECTION 14 –   LIMITATION OF LIABILITY, LIMITATION OF DAMAGES, INDEMNIFICATION AND INSURANCE

14.1. Limitation on Liability and Damages.

14.1.1. Except with respect to liability arising from willful misconduct, or gross negligence by a Party, neither Party shall be liable under this Agreement for any special, indirect, incidental, consequential or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise, including loss of profits or revenue suffered by either Party or any of its Representatives. Nothing in this Agreement shall operate to exclude or restrict either Party's liability for any other form of liability which may not be excluded or limited by Applicable Laws.

14.1.2. In addition to the limitation of liability under Section 14.1.1. except with respect to liability arising from willful misconduct or gross negligence, medac's liability to UroGen for any claim for damages arising under the Agreement or the Quality Agreement (whether in contract, tort or otherwise) shall be limited to a maximum of [***] Euros ([***] €) per event and an aggregate amount not to exceed [***] Euros ([***] €) in total per calendar year (the "**Cap**"). Notwithstanding the foregoing, the exception for gross negligence set forth above in this Section 14.1.2 shall not apply to any claim that is based on medac or medac's Affiliates failing to timely deliver Product (including but not limited to any [***] Supply Disruption or Supply Disruption) under this Agreement due to medac's or its Affiliates' gross negligence with respect thereto, it being understood by the Parties that any such claim by UroGen shall be limited by the Cap.

For clarification the Parties expressly agree that the Cap includes damages according to 14.1.1 in cases of claims that are based on medac's or its Affiliates failing to timely deliver the Product (including but not limited to any [***] Supply Disruption or Supply Disruption) under this Agreement due to medac's or its Affiliates' gross negligence.

14.2. Indemnification by medac. Medac hereby agrees to save, indemnify, defend and hold UroGen, its Affiliates, and their respective directors, and employees (each a "**UroGen Indemnitee**") harmless from and against any and all liability, damages, expenses, Losses (including reasonable attorneys' fees and expenses) and cost that the Urogen Indemnitee may be required to pay to one or more Third Parties resulting from and arising in connection with any and all Third Party Claims resulting or otherwise arising from (i) any breach by medac of any of its representations or warranties set forth in Section 13 - of this Agreement, (ii) the gross negligence or willful misconduct by medac or its Affiliates or their respective officers, directors, employees, agents, consultants, vendors or sublicensees in performing any obligations under this Agreement or (iii) Manufacturing of the Product hereunder (including, for clarity, product liability claims brought against UroGen or its Affiliates related to defects of the Products) by medac or its Affiliates or their respective officers, directors, employees, agents, excluding any claim by a Third Party based on any Intellectual Property rights; *provided, however*, that in each case to the extent that such Third Party Claims arose or resulted from the gross negligence, recklessness, or willful misconduct of UroGen or any UroGen Indemnitee.

14.3. Indemnification by UroGen. UroGen hereby agrees to save, indemnify, defend and hold medac, its Affiliates, and their respective directors and employees (each a "**medac Indemnitee**") harmless from and against any and all liability, damages, expenses, Losses (including reasonable attorneys' fees and expenses) and cost that the medac Indemnitee may be required to pay to one or more Third Parties resulting from and arising in connection with any and all Third Party Claims resulting or otherwise arising from (i) any breach by UroGen of any of its representations or warranties set forth in Section 13 - of this Agreement or (ii) the gross negligence or willful misconduct by UroGen or its Affiliates or their respective officers, directors, employees, agents, consultants, vendors or sublicensees in performing any obligations under this Agreement or (iii) any breach of applicable Antitrust Law that arose or resulted from the Commercialization of Combined Product or (iv) infringement of any Third Party Intellectual Property due to the Commercialization of the Combined Product and any activity related therewith; *provided, however*, that in each case except to the extent that (i) such Losses are subject to indemnification by medac pursuant to Section 14.2, and (ii) that such Third Party Claim arose or resulted from the gross negligence, recklessness or willful misconduct by medac or any medac Indemnitee.

14.4. Indemnification Procedures.

14.4.1. Notice of Claim. All indemnification claims in respect of any UroGen Indemnitee or medac Indemnitee, as applicable, seeking indemnity under Section 14.2 or 14.3, as applicable (collectively, the "**Indemnitees**" and each an "**Indemnitee**") will be made solely by the corresponding Party (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party (the "**Indemnifying Party**") prompt written notice (an "**Indemnification Claim Notice**") of any Losses and any legal proceeding initiated by a Third Party against the Indemnified Party as to which the Indemnified Party intends to make a request for indemnification under Section 14.2 or 14.3, as applicable, but in no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice which materially prejudices the defense of such proceeding. Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). Together with the Indemnification Claim Notice, the Indemnified Party will furnish promptly to the Indemnifying Party copies of all notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim.

14.4.2. Control of Defense. At its option, the Indemnifying Party may assume the defense of any Third Party Claim subject to indemnification as provided for in Section 14.2 or 14.3, as applicable, by giving written notice to the Indemnified Party within [***] after the Indemnifying Party's receipt of an Indemnification Claim Notice. Upon assuming the defense of a Third Party Claim, the Indemnifying Party or its respective insurance company, if applicable, may appoint as lead counsel in the defense of the Third Party Claim any legal counsel it selects, and such Indemnifying Party shall thereafter continue to defend such Third Party Claim in good faith. Should the Indemnifying Party assume the defense of a Third Party Claim (and continue to defend such Third Party Claim in good faith), the Indemnifying Party will not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim, unless the Indemnifying Party has failed to assume the defense and employ counsel in accordance with this Section 14.4.

14.4.3. Right to Participate in Defense. Without limiting Section 14.4.2, any Indemnitee will be entitled to participate in the defense of a Third Party Claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnitee's own expense unless (i) the employment thereof has been

specifically authorized by the Indemnifying Party in writing, or (ii) the Indemnifying Party has failed to assume the defense (or continue to defend such Third Party Claim in good faith) and employ counsel in accordance with this Section 14.4, in which case the Indemnified Party will be allowed to control the defense.

14.4.4.Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnitee becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnitee in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its reasonable discretion, will deem appropriate (provided, however, that such terms shall include a complete and unconditional release of the Indemnified Party from all liability with respect thereto), and will transfer to the Indemnified Party all amounts which said Indemnified Party will be liable to pay prior to the time of the entry of judgment. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 14.4.2, the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, provided it obtains the prior written consent of the Indemnified Party (which consent will be at the Indemnified Party's reasonable discretion). The Indemnifying Party that has assumed the defense of (and continues to defend) the Third Party Claim in accordance with Section 14.4.2 will not be liable for any settlement or other disposition of a Loss by an Indemnitee that is reached without the written consent of such Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnitee will admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without first offering to the Indemnifying Party the opportunity to assume the defense of the Third Party Claim in accordance with Section 14.4.2.

14.4.5.Cooperation. If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will, and will cause each other Indemnitee to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection with such Third Party Claim. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses incurred in connection with such cooperation.

14.5.Expenses of the Indemnified Party. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim will be reimbursed on a calendar quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

14.6.Insurance and Product Liability. During the term of this Agreement, as well as for any additional period during which a Party may be held liable (whether by Applicable Law or pursuant to this Agreement), each Party shall maintain with a reputable insurance company general liability insurance, adequate to cover its indemnification obligations under this Section 14 -, in an amount not less than $[***] per event and $[***] in the aggregate per year (UroGen) and [***] Euro per event and €[***] in the aggregate per year (medac) and shall, at the other Party's request, provide a certificate of insurance. medac shall maintain product liability insurance covering the Products in an amount not less than €[***] Euro per occurrence and €[***] Euro in the aggregate per year. UroGen shall maintain a product liability insurance covering the in an amount of $[***] per occurrence and $[***] in the aggregate per year.

SECTION 15 -   CONFIDENTIALITY

15.1.Confidential Information. As used in this Agreement, the term "**Confidential Information**" means all information, whether it be written or oral, including all production schedules, lines of products, volumes of business, processes, new product developments, product designs, formulae, technical information, laboratory data, clinical data, patent information, Know-How, trade secrets, financial and strategic information, marketing and promotional information and data, and other material relating to any products, projects or processes of one Party (the "**Disclosing Party**") that is provided to, or otherwise obtained by, the other Party (the "**Receiving Party**") in connection with this Agreement including information exchanged prior to the date hereof in connection with the transactions set forth in this Agreement, including any information disclosed by either Party pursuant to the Development Agreement and any prior Mutual Non-Disclosure Agreement between the Parties. Notwithstanding the foregoing sentence, Confidential Information shall not include any information or materials that:

15.1.1.were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party, to the extent such Receiving Party has documentary evidence to that effect;

15.1.2.were generally available to the public or otherwise part of the public domain at the time of disclosure thereof to the Receiving Party;

15.1.3.became generally available to the public or otherwise part of the public domain after disclosure or development thereof, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;

15.1.4.were disclosed to a Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

15.1.5.were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party, to the extent such Receiving Party has documentary evidence to that effect.

15.2.Confidentiality Obligations. Each of UroGen and medac shall keep all Confidential Information received from or on behalf of the other Party with the same degree of care with which it maintains the confidentiality of its own Confidential Information, but in all cases no less

than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of this Agreement or disclose the same to any other Person other than to such of its and its Affiliates' directors, managers, employees, independent contractors, agents, consultants or sublicensees who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement; provided, however, that a Receiving Party shall advise any of its and its Affiliates' directors, managers, employees, independent contractors, agents, consultants or sublicensees who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure (including, in the case of a Third Party, by means of a written agreement with such Third Party having terms at least as protective as those contained in this Section 15 -) that all such directors, managers, employees, independent contractors, agents, consultants or sublicensees comply with such obligations. Upon expiration or termination of this Agreement, the Receiving Party shall destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the possession of the Receiving Party or its directors, managers, employees, independent contractors, agents, consultants or sublicensees, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes. Such archival copy shall be deemed to be the property of the Disclosing Party and shall continue to be subject to the provisions of this Section 15 -. It is understood that receipt of Confidential Information under this Agreement will not limit the Receiving Party from assigning its employees to any particular job or task in any way it may choose, subject to the terms and conditions of this Agreement.

15.3. Permitted Disclosure and Use. Notwithstanding Section 15.2, (i) either Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) comply with or enforce any of the provisions of this Agreement; or (b) comply with Applicable Law; and (ii) medac may disclose Confidential Information belonging to UroGen related to a Combined Product only to the extent such disclosure is reasonably necessary to obtain or maintain Regulatory Approval of a Product, as applicable, to the extent such disclosure is made to a Governmental Authority. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 15.3, such Party shall give reasonable advance written notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information, including seeking a protective order or other appropriate remedy.

15.4. Notification. The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information and will cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure.

15.5. Publicity. No press release shall be issued in connection with this transaction without the other Party's prior written consent, unless the issuing Party is otherwise required to issue such press release under Applicable Law or directive by any Governmental Authority. Except as otherwise provided in this Section 15.5, each Party shall maintain the confidentiality of all provisions of this Agreement, and without the prior written consent of the other Party, which consent shall not be unreasonably withheld, neither Party nor its respective Affiliates shall make any press release or other public announcement of or otherwise disclose the provisions of this Agreement to any Third Party, except for: (i) disclosure to those of its directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, potential strategic partners, advisors, agents and sublicensees whose duties reasonably require them to have access to this Agreement, provided that such directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, advisors, agents or sublicensees are required to maintain the confidentiality of this Agreement, (ii) disclosures required by Nasdaq regulation or any listing agreement with a national securities exchange, in which case the Disclosing Party shall provide the nondisclosing Party within at least [***] notice unless otherwise not practicable, but in any event no later than the time the disclosure required by such Nasdaq regulation or listing agreement is made, (iii) disclosures as may be required by Law, in which case the Disclosing Party shall provide the nondisclosing Party with prompt advance notice of such disclosure and cooperate with the nondisclosing Party to seek a protective order or other appropriate remedy, including a request for confidential treatment in the case of a filing with the Securities and Exchange Commission, and (iv) the report on Form 8-K, which may be filed by an UroGen or an Affiliate of UroGen setting forth the press release referred to above, and/or this Agreement in redacted form as provided in Section 15.6. A Party may publicly disclose without regard to the preceding requirements of this Section 15.5 any information that was previously publicly disclosed pursuant to this Section 15.5.

15.6. Redacted Agreement Filing. The Parties acknowledge that UroGen may be obligated to file a redacted copy of this Agreement with the SEC or other Governmental Authorities. UroGen shall be entitled to make such a required filing. In the event of any such filing, each Party shall (i) permit the other party to review and comment upon such request for confidential treatment at least [***] in advance of its submission to the SEC or such other Governmental Authorities, (ii) reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the then-current legal requirements governing redaction of information from agreements that must be publicly filed, (iii) promptly deliver to the other Party any written correspondence received by it from such Governmental Authority, if any, with respect to such confidential treatment request, and (v) if such Governmental Authority requests any changes to the redactions set forth in the redacted agreement, discuss such changes with the other Party and take the other Party's comments into consideration when deciding whether to agree to such changes. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

15.7. Publication. UroGen shall submit copies to medac of each proposed academic, scientific, medical and other publication or presentation that make specific reference to medac or that UroGen reasonably believes contains medac's Confidential Information at least [***] in advance of submitting such proposed publication or presentation to a publisher or other Third Party and medac shall have the right to review each such proposed publication or presentation and shall have the right to remove any of its Confidential Information prior to submission for publication or presentation; *provided however* UroGen shall have no obligation to submit to medac any publication or presentation regarding the Product unless there is specific reference to medac therein and, if so, medac shall have the right to review only those portions of the publication or presentation that contain such references. UroGen shall redact or otherwise modify the proposed publication or presentation to remove any such Confidential Information of medac.

15.8. Use of Names. Except as otherwise set forth in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other Party, which consent shall not be unreasonably withheld; *provided, however*, that either Party may use the name of the other Party in any document filed with any Regulatory Authority or Governmental Authority, including the FDA, EMEA and the Securities and Exchange Commission.

15.9. Survival. The obligations and prohibitions contained in Section 11 (Confidentiality) Section 16 - as they apply to Confidential Information shall survive the expiration or termination of this Agreement for a period of [***].

SECTION 16 -   TERM AND TERMINATION

16.1. Term for the United States. This Agreement shall become effective on the Effective Date of this Agreement and, unless earlier terminated pursuant to this Section 16 shall remain in effect for the United States until the expiration of the last to expire Licensed Patent (the "**U.S. Term**"). When there is one (1) year remaining in the Term, the Parties shall discuss, in good faith, an extension of the Agreement for the United States. For clarity, the licenses granted to UroGen in Section 2.1 and the exclusivity of supply provisions for the United States shall remain in full force and effect for the entirety of the U.S. Term.

16.2. Term for Countries Outside the United States. For countries in the Territory other than the United States, this Agreement shall become effective on the Effective Date of this Agreement and shall remain in effect for ten (10) years thereafter (**Ex-U.S. Initial Term**"). The Ex-U.S. Initial Term, on a country-by-country basis, shall automatically renew for successive two (2) year terms unless one Party provides written notice to the other Party at least one hundred eighty (180) calendar days in advance of the end of the then existing term that it does not wish to renew the term of this Agreement for such country.

16.3. If UroGen (a) does not initiate a clinical study as required by the terms in Section 3.1 -or (b) suspends the Development of the Combined Product for more than six (6) months after informing medac about such suspension of Development, or (c) does not submit a Marketing Authorization application as required as by the terms in Section 3.2 -or (d) fails to obtain a Marketing Authorization for the Combined Product in a country in the Territory more than eighteen months after submitting a Marketing Authorization application to the applicable Regulatory Authority, UroGen and medac shall meet and discuss in good faith UroGen's plan to resume Development or obtain a Marketing Authorization, and following such meeting UroGen may thereafter resume its Development activities or its efforts to obtain a Marketing Authorization in accordance with such plan. If after six (6) months following the good-faith discussion UroGen has failed to make material progress against such plan, medac shall have the right to terminate this Agreement with respect to (and only with respect to) such country upon [***] calendar days advance notice in writing to Urogen. Urogen shall inform medac about any temporary suspension of Development or the failure to obtain a Marketing Authorization in a country in the Territory without undue delay.

16.4. Notwithstanding the provisions of Section 16, in the event that a Marketing Authorization of the Combined Product in the United States has not been granted to UroGen by June 30, 2029, medac shall have the right to terminate this Agreement with immediate effect.

16.5. If a Marketing Authorization of the Combined Product in a country in the Territory was not granted, lapses or is otherwise withdrawn or cancelled, medac shall have the right to terminate this Agreement with respect to (and only with respect to) such country upon sixty calendar days (60) advance notice in writing to Urogen. Urogen shall inform medac as soon as reasonably practicable following the lapsing, withdrawal or cancellation of the Marketing Authorization in any country in the Territory.

16.6. If UroGen suspends Commercialization of the Product as a part of Combined Product in any country in the Territory for any reason other than a failure of medac to perform in accordance with this Agreement, Urogen will provide medac, in writing, the reasons for and the nature of the suspension to Commercialize the Product as part of the Combined Product in the country and the plan of action that Urogen intends to take, and has taken, to resume Commercialization of the Combined Product in such country. If UroGen fails to resume Commercialization of Product as part of Combined Product eighteen (18) months following such written communication, medac shall have the right to terminate this Agreement with respect to (and only with respect to) such country upon thirty (30) calendar days advance notice in writing to Urogen. Urogen shall inform medac about any suspension of Commercialization of the Product as part of Combined Product in a country in the Territory as soon as reasonably practicable.

16.7. Termination for Breach. Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement upon written notice to the other Party in the event that the other Party (the "**Breaching Party**") shall have materially breached the performance of any of its material obligations. The Breaching Party shall have [***] calendar days after receipt of such written notice to remedy such material breach. Should the Breaching Party fail to cure any such breach prior to the expiration of the [***] calendar day period, the non-breaching Party will have [***] days after expiration of the cure period to provide written notice of termination to the Breaching Party and this Agreement shall terminate upon the Breaching Party's receipt of such notice.

16.8. Event of Default. medac may terminate the Agreement for good cause with immediate effect in writing on a country-by-country basis, if UroGen loses a necessary approval for importing, marketing, or selling of the Combined Product(s) in the respective country.

16.9. Termination as a Result of Bankruptcy. Each Party shall have the right to terminate this Agreement upon written notice as a result of the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; *provided however*, that such termination shall be effective only if such proceeding is not dismissed within [***] calendar days after the filing thereof.

SECTION 17 -   EFFECTS OF EXPIRATION AND TERMINATION

17.1. Generally. Upon expiration or termination of this Agreement with respect to a country in the Territory (a) the Parties' rights and obligations under this Agreement shall terminate, and neither Party shall have any further rights or obligations under this Agreement from and after the Effective Date of termination, except as set forth in this Section 17 - with respect to such country; and (b) all rights and licenses under this Agreement shall immediately terminate with respect to such country, and all such rights with respect to such country shall revert back to medac.

17.2. Termination by medac for Breach or Insolvency. In the event that medac terminates this Agreement pursuant to Sections 16.7 (Termination for Breach) or 16.9 (Termination as a Result of Bankruptcy), UroGen and its Affiliates, sublicensees, and/or subcontractors shall have the right to sell remaining inventory of Product.

17.3. Survival. Notwithstanding anything to the contrary contained herein, the following provisions shall survive any expiration or termination of this Agreement: diligence obligations of Confidentiality, Indemnification, Liabilities, Applicable Laws, Quality, Effects of Expiration and Termination and Section 12.2.3., Section 12.3.4 and Section 12.4 - as long as Product is concerned - of Intellectual Property and Trademark. Except as set forth in this Section 17. or otherwise expressly set forth herein, upon termination or expiration of this Agreement all other rights and obligations of the Parties shall cease.

SECTION 18 -   DISPUTE RESOLUTION

18.1. Arising Between the Parties. With respect to all controversies, claims, or disputes arising out of, relating to, or in connection with this Agreement between the Parties, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within [***] Business Days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Chief Executive Officers of each of the Parties, or a designee from senior management with decision-making authority (the Chief Executive Officer or such designee, the "**Executive Officer**") for attempted resolution by good-faith negotiations within [***] Business Days after such notice is received.

18.2. Dispute Resolutions. If the Executive Officers are not able to resolve such dispute referred to them under Section 18.1 within such [***] day period, following receipt of the aforementioned dispute notice by the Party to be notified, then either Party shall have the right to pursue any legal or equitable remedy available to it under Swiss Law; *provided however*, that any litigation arising under this Agreement shall be submitted to the exclusive jurisdiction of the courts of Switzerland.

18.3. Injunctive Relief. Nothing herein may prevent either Party from seeking a preliminary injunction or temporary restraining order so as to prevent any Confidential Information from being disclosed in violation of this Agreement.

SECTION 19 -   MISCELLANEOUS

19.1. Entire Agreement; Amendment. This Agreement, including the Exhibits and Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized representative of each Party.

19.2. Force Majeure. A Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party makes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the foreseeable control of the Parties, that have not been caused or materially contributed to by that affected Party itself, including an act of God, war (excluded already started or foreseeable war), terrorist act, governmental lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of force majeure affecting such Party.

19.3. Notices. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 19.3, and shall be deemed to have been given for all purposes (i) when delivered, if hand-delivered or sent by facsimile on a Business Day, (ii) on the next Business Day if sent by a reputable international overnight courier service, or (iii) five (5) Business Days after mailing, if mailed by first-class certified or registered airmail, postage prepaid, return receipt requested. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below:

If to medac:	Medac Gesellschaft für klinische Spezialpräparate m.b.H Theaterstr. 6 22880 Wedel Germany Attention: Head of Third Party Business Email: [***] Fax: [***]
With a copy to:	Medac Gesellschaft für klinische Spezialpräparate m.b.H Theaterstr. 6 22880 Wedel Germany Attention: Legal Email: [***] Fax: [***]
If to UroGen	UroGen Pharma Ltd. 400 Alexander Park Drive Princeton, NJ 08540 Attention: Chief Business Officer Email: [***] Fax: [***]
With a copy to	UroGen Pharma Ltd. 400 Alexander Park Drive Princeton, NJ 08540 Attention: General Counsel Email: [***]

19.4. Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States of America or other countries which may be imposed upon or related to medac or UroGen from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity.

19.5. Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, (a) medac may

make an assignment of this Agreement to a successor to the business whether as a result of an agreement between medac and such successor by merger, sale of stock, sale of assets or other transaction as a result of which another Person or group obtains control of the board of directors or executive management of medac or its Affiliates (provided, however that medac will remain jointly and severally liable with, and will guarantee the performance of, the relevant Affiliate under this Agreement, and the relevant Affiliate assignee, will assume in writing all of medac's obligations under this Agreement) and (b) UroGen may make an assignment of this Agreement (i) to is Affiliates without having to obtain medac's consent (provided, however that the UroGen will remain jointly and severally liable with, and will guarantee the performance of, the relevant Affiliate under this Agreement, and the relevant Affiliate assignee, will assume in writing all of UroGen's obligations under this Agreement) or (ii) to a successor to the business of UroGen, whether as a result of an agreement between UroGen and such successor by merger, sale of stock, sale of assets or other transaction as a result of which another Person or group obtains control of the board of directors or executive management of Urogen without having to obtain medac's written consent, unless such successor either is a Competitor of medac or, within the [***] period prior to the effective date of such assignment, has been convicted by a court of competent jurisdiction of violating any laws prohibiting the use of child labor or protecting the human rights of its employees, in which case, medac's consent for such assignment shall be required as set forth in the first sentence of this Section 19.5. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 19.5 shall be null, void and of no legal effect. No assignment shall relieve any Party of responsibility for the performance of any obligation existing at the date of such assignment. For purposes of this Section 19.5, "**Competitor of medac**" shall mean a.) any Third Party that is manufacturing and supplying to one or more other Third Parties, mitomycin- drug product where the revenue obtained with mitomycin drug products, during the prior calendar year by such Third Party, constitutes at least [***] percent ([***]%) of the aggregate revenue obtained from sales of all products and provision of any services by such Third Party and its affiliates during such [***] or b.) any Third Party that is itself a marketing authorization holder for Compound comprising drug products in the European Union and / or European Free Trade Association..

19.6. Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to perform all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

19.7. Severability. If any one or more of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, such provision or provisions shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good-faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

19.8. No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

19.9. Independent Contractors. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

19.10. English Language; Governing Law. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. The Agreement shall be exclusively governed by and construed in accordance with the law of Switzerland. The UN Convention on Contracts for the International Sale of Goods (CISG) and Swiss Private International Law shall not apply. All disputes arising out of or in connection with this Agreement shall be subject to the exclusive jurisdiction of the courts of Zürich, Switzerland.

19.11. Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. The Parties acknowledge that either Party's electronic signature is the legally binding equivalent to a handwritten signature and neither Party shall raise any objection to the contrary.

[Remainder of Page Intentionally Blank; Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the date first written above.

UroGen Pharma Ltd.

/s/ Polly A. Murphy
Polly A. Murphy
Chief Business Officer

Medac Gesellschaft für klinische Spezialpräparate m.b.H.

[***]
[***]
Chief Executive Officer
[***]
[***]
Chief Business Development Officer
[***]
[***]
Head of Legal & Insurance
[***]
[***]
Head of Third Party Business / B2B
[***]
[***]
Manager Product Research and Development & API Expert

Exhibit A: Licensed Patents

Exhibit B: Product, Price

Exhibit C: Initial Non-Binding Five-Year Forecast

EXHIBIT 10.35

AMENDED AND RESTATED LOAN AGREEMENT

Dated as of March 13, 2024

among

UROGEN PHARMA, INC.

(as ***Borrower***, and a ***Credit Party***),

UROGEN PHARMA LTD.

(as ***Parent***, and a ***Credit Party***),

THE OTHER GUARANTORS SIGNATORY HERETO OR OTHERWISE PARTY HERETO FROM TIME TO TIME

(as additional ***Credit Parties***),

BIOPHARMA CREDIT PLC

(as ***Collateral Agent***),

BPCR LIMITED PARTNERSHIP

(as a ***Lender***)

and

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP

(as a ***Lender***)

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AMENDED AND RESTATED LOAN AGREEMENT

THIS AMENDED AND RESTATED LOAN AGREEMENT (this "**Agreement**"), dated as of March 13, 2024 (the "**Effective Date**") by and among UROGEN PHARMA, INC., a Delaware corporation (as "**Borrower**" and a Credit Party), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "**Parent**" and a Credit Party), the other Guarantors signatory hereto or otherwise party hereto from time to time, as additional Credit Parties, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales with company number 10443190 (as the "**Collateral Agent**"), BPCR LIMITED PARTNERSHIP, a limited partnership established under the laws of England and Wales with registration number LP020944 (as a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership acting by its general partner, BioPharma Credit Investments V GP LLC (as a "**Lender**"), provides the terms on which each Lender shall make, and Borrower shall repay, the Credit Extensions (as hereinafter defined). This Agreement amends and restates in its entirety, and replaces, the terms of (and obligations outstanding under) that certain Loan Agreement among Borrower, Lenders, the Collateral Agent and the other parties thereto, dated as of March 7, 2022 (the "**Prior Effective Date**") and amended by that certain First Amendment to Loan Agreement dated as of June 29, 2023 (the "**Prior Loan Agreement**"). The parties hereto agree that, effective on the Effective Date, the Prior Loan Agreement is amended and restated in its entirety to read as follows:

1 ACCOUNTING AND OTHER TERMS

Except as otherwise expressly provided herein, all accounting terms not otherwise defined in this Agreement shall have the meanings assigned to them in conformity with Applicable Accounting Standards. Calculations and determinations must be made following Applicable Accounting Standards. If at any time any change in Applicable Accounting Standards would affect the computation of any financial requirement set forth in any Loan Document (including for purposes of measuring compliance with any provision of Section 6), and either Borrower or the Collateral Agent shall so request, the Collateral Agent and Borrower shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in Applicable Accounting Standards; provided, that, until so amended, (x) such requirement shall continue to be computed in accordance with Applicable Accounting Standards prior to such change therein and (y) all financial statements, Compliance Certificates and similar documents provided, delivered or submitted hereunder shall be provided, delivered or submitted together with a reconciliation between the calculations and amounts set forth therein before and after giving effect to such change in Applicable Accounting Standards. Notwithstanding any other provision contained herein, all terms of an accounting or financial nature used herein shall be construed, and all computations of amounts referred to herein, including in Section 5 and Section 6 shall be made, without giving effect to any (a) election under ASC 825-10 (or any other Financial Accounting Standards Board Accounting Standards Codification ("**ASC**") or Financial Accounting Standard or Applicable Accounting Standard (including IFRS 9) having a similar result or effect) to value any Indebtedness or other liabilities of any Credit Party or any Subsidiary of any Credit Party at "fair value" and (b) any treatment of Indebtedness in respect of convertible debt instruments under ASC 470-20 (or any other ASC or Financial Accounting Standard or Applicable Accounting Standard having a similar result or effect) to value any such Indebtedness in a reduced or bifurcated manner as described therein, and such Indebtedness shall at all times be

valued at the full stated principal amount thereof. Notwithstanding anything to the contrary above or in the definition of "Capital Lease Obligations", all obligations of any Person that are or would have been treated as operating leases for purposes of Applicable Accounting Standards prior to the effectiveness of ASC 842 shall continue to be accounted for as operating leases for all purposes hereunder or under any other Loan Documents (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with ASC 842 (on a prospective or retroactive basis or otherwise) to be treated as Capital Leases. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "Dollars" or "$" are United States Dollars, unless otherwise noted.

For purposes of determining compliance with Section 5 and Section 6 with respect to the amount of any Indebtedness, Investment or other transaction in a currency other than Dollars, no Default or Event of Default shall be deemed to have occurred solely as a result of changes in rates of currency exchange occurring after the time such Indebtedness, Investment or other transaction is incurred, made or acquired (so long as such transaction, at the time incurred, made or acquired, was permitted hereunder).

The Collateral Agent does not warrant or accept responsibility for, and shall not have any liability with respect to (a) the continuation of, administration of, submission of, calculation of or any other matter related to the Term SOFR Reference Rate, Adjusted Term SOFR or Term SOFR, or any component definition thereof or rates referred to in the definition thereof, or any alternative, successor or replacement rate thereto (including any Benchmark Replacement), including whether the composition or characteristics of any such alternative, successor or replacement rate (including any Benchmark Replacement) will be similar to, or produce the same value or economic equivalence of, or have the same volume or liquidity as, the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR or any other Benchmark prior to its discontinuance or unavailability, or (b) the effect, implementation or composition of any Conforming Changes. The Collateral Agent and its affiliates or other related entities may engage in transactions that affect the calculation of the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR, any alternative, successor or replacement rate (including any Benchmark Replacement) or any relevant adjustments thereto, in each case, in a manner adverse to the Borrower. The Collateral Agent may select information sources or services in its reasonable discretion to ascertain the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR or any other Benchmark, in each case pursuant to the terms of this Agreement, and shall have no liability to Borrower, any Lender or any other Person for damages of any kind, including direct or indirect, special, punitive, incidental or consequential damages, costs, losses or expenses (whether in tort, contract or otherwise and whether at law or in equity), for any error or calculation of any such rate (or component thereof) provided by any such information source or service.

2 LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay

.

Borrower hereby unconditionally promises to pay each Lender the outstanding principal amount of the Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans

.

(a) Availability. Subject to the terms and conditions of this Agreement (including Sections 3.1, 3.2, 3.5, 3.6 and 3.7):

(i) Borrower agrees to request in accordance with Section 3.7, and each Lender severally agrees to make, a term loan to Borrower on the Tranche A Closing Date in an original principal amount equal to such Lender's Tranche A Commitment (individually or collectively, as the context dictates, the "**Tranche A Loan**");

(ii) At Borrower's option, Borrower may request in accordance with Section 3.7, and each Lender severally agrees to make, a term loan to Borrower on the Tranche B Closing Date in an original principal amount equal to such Lender's Tranche B Commitment (collectively, the "**Tranche B Loan**");

(iii) Borrower agrees to request in accordance with Section 3.7, and each Lender severally agrees to make, a term loan to Borrower on the Tranche C Closing Date in an original principal amount equal to such Lender's Tranche C Commitment (individually or collectively, as the context dictates, the "**Tranche C Loan**"); and

(iv) At Borrower's option, Borrower may request in accordance with Section 3.7, and each Lender severally agrees to make, a term loan to Borrower on the Tranche D Closing Date in an original principal amount equal to such Lender's Tranche D Commitment (collectively, the "**Tranche D Loan**").

After repayment or prepayment (in whole or in part), no Term Loan (or any portion thereof) may be re-borrowed.

(b) Repayment.

(i) With respect to any and all Term Loans, Borrower shall make four (4) equal quarterly payments of principal of each such Term Loan commencing on the Payment Date occurring in the second calendar quarter of 2026 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, however, that upon the satisfaction of the Tranche D Approval Condition, the quarterly payments of principal payable pursuant to this Section 2.2(b)(i) will instead commence on the Payment Date occurring in the second calendar quarter of 2027 and continuing quarterly thereafter through the Term Loan Maturity Date.

(ii) The Term Loans, including all unpaid principal thereunder (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any and all other outstanding amounts payable under the Loan Documents), are due and payable in full on the Term Loan Maturity Date.

(iii) The Term Loans may be prepaid only in accordance with Section 2.2(c), except as provided in Section 8.1.

(c) Prepayment of Term Loans.

(i) Borrower shall have the option, at any time after the Tranche A Closing Date, to prepay, in whole but not in part, outstanding principal amounts under the Term Loans advanced by Lenders under this Agreement; provided that (A) Borrower provides written notice to the Collateral Agent of its election (which shall be irrevocable unless the Collateral Agent otherwise consents in writing) to prepay all of the Term Loans at least three (3) Business Days prior to such prepayment, and (B) the prepayment of such principal amount shall be accompanied by any and all accrued and unpaid interest thereon through the date of prepayment, any and all amounts payable in connection with such prepayment pursuant to Section 2.2(e) and Section 2.2(f) (as applicable) and any and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4 and Section 2.7). The Collateral Agent will promptly notify each Lender of its receipt of such notice, and the amount of such Lender's Applicable Percentage of such prepayment. Notwithstanding anything in this Section 2.2(c)(i) to the contrary, Borrower may rescind any notice of prepayment under this Section 2.2(c)(i) if such prepayment would have resulted from a refinancing of the Term Loans or other contingent transaction, which refinancing or transaction shall not be consummated or shall otherwise be delayed (in which case, a new notice shall be required to be sent in connection with any subsequent prepayment).

(ii) Upon a Change in Control, Borrower shall promptly, and in any event no later than ten (10) days after the consummation of such Change in Control, notify the Collateral Agent in writing of the occurrence of a Change in Control, which notice shall include reasonable detail as to the nature, timing and other circumstances of such Change in Control (such notice, a "**Change in Control Notice**"). Borrower shall prepay in full all of the Term Loans advanced by Lenders under this Agreement, no later than three (3) Business Days after the delivery of such Change in Control Notice, in an amount equal to the sum of (A) all unpaid principal and any and all accrued and unpaid interest with respect to the Term Loans (such interest to be calculated based on Term SOFR for the Interest Period during which such Change in Control is consummated), and (B) any and all amounts payable with respect to the prepayment under this Section 2.2(c)(ii) pursuant to Section 2.2(e) and Section 2.2(f) (as applicable), together with any and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4 and Section 2.7). The Collateral Agent will promptly notify each Lender of its receipt of the Change in Control Notice, and the amount of such Lender's Applicable Percentage of such prepayment.

(iii) Prior to any prepayment, repurchase, redemption or similar action, of the Permitted Convertible Indebtedness in accordance with its terms (the "**Convertible Indebtedness Redemption**") (which occurs prior to the Term Loan Maturity Date), Borrower shall promptly, and in any event no later than fifteen (15) days prior to the consummation of such Convertible Indebtedness Redemption, notify the Collateral Agent in writing of the occurrence of such Convertible Indebtedness Redemption, which notice shall include reasonable detail as to the nature, timing and other circumstances of such Convertible Indebtedness Redemption (such notice, a "**Convertible Indebtedness Redemption Notice**"). Borrower shall prepay in full all of the Term Loans advanced by Lenders under this Agreement, no later than ten (10) days prior to the Convertible Indebtedness Redemption in an amount equal to the sum of (A) all unpaid principal and any and all accrued and unpaid interest with respect to the Term Loans (or such remaining outstanding portion thereof), and (B) any applicable amounts payable with respect to the prepayment under this Section 2.2(c)(iii) pursuant to Section 2.2(e) and Section 2.2(f) (as applicable) and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4 and Section 2.7). The Collateral Agent will promptly notify each Lender of its receipt of the Convertible Indebtedness Redemption Notice, and the amount of such Lender's Applicable Percentage of such prepayment. Notwithstanding the foregoing, none of the following shall be deemed to be a Convertible Indebtedness Redemption: (w) the conversion by holders of Permitted Convertible Indebtedness (including any cash payment upon conversion) or required payment of any interest with respect to any Permitted Convertible Indebtedness, in each case, in accordance with the terms of the indenture or other documentation governing such Permitted Convertible Indebtedness, (x) cash payments to redeem any Permitted Convertible Indebtedness; provided, however, that the closing price per share of Parent's publicly-traded common stock on the Trading Day immediately prior to the day on which Borrower delivers the redemption notice pursuant to the terms of the indenture governing such Permitted Convertible Indebtedness is a least 1.2 times the conversion price of such Permitted Convertible Indebtedness, (y) the exchange of existing Permitted Convertible Indebtedness for (1) new Permitted Convertible Indebtedness (the "**Refinancing Convertible Debt**") (or the cash proceeds from the issuance of such Refinancing Convertible Debt) to the extent such Refinancing Convertible Debt is permitted to be issued under the terms of this Agreement and to the extent that such new Refinancing Convertible Debt bears interest at a rate per annum not to exceed five percent (5.0%), (2) Equity Interests, (3) the cash proceeds, if any, received pursuant to the exercise, early unwind or termination of any Permitted Equity Derivative entered into in connection with such existing Permitted Convertible Indebtedness, or (4) cash in respect of accrued and unpaid interest on such exchanged existing Permitted Convertible Indebtedness, or (z) delivery of Equity Interests and cash in lieu of fractional shares or in respect of accrued and unpaid interest to any holder of Permitted Convertible Indebtedness to induce such holder to convert Permitted Convertible Indebtedness in accordance with the terms of the indenture governing such Permitted Convertible Indebtedness (any such transaction described in clause (w), (x), (y) or (z) above, a "**Permitted Transaction**" and collectively, the "**Permitted Transactions**").

(d) Prepayment Application. Any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) (together with the accompanying Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f) as applicable, and any due and unpaid Lender Expenses and Additional Consideration that is payable pursuant to Section 2.4 and Section 2.7) shall be paid to Lenders in accordance with their respective Applicable Percentages for application to the Obligations in the following order: (i) first, to due and unpaid Lender Expenses; (ii) second, to due and unpaid Additional Consideration, if any; (iii) third, to accrued and unpaid interest at the Default Rate incurred pursuant to Section 2.3(b), with respect to past due amounts, if any; (iv) fourth, without duplication of amounts paid pursuant to clause (iii) above, to accrued and unpaid interest at the Term Loan Rate; (v) fifth, to the Prepayment Premium; (vi) sixth, to the Makewhole Amount, if applicable; (vii) seventh, to the outstanding principal amount of the Tranche A Loan, the Tranche B Loan, the Tranche C Loan or the Tranche D Loan being prepaid, as applicable, provided, that, such prepayment shall be applied first to reduce the principal amount of the Tranche A Loan, then to reduce the principal of the Tranche B Loan, then to reduce the principal of the Tranche C Loan and finally, to reduce the principal of the Tranche D Loan, and (viii) eighth, to any remaining amounts then due and payable under this Agreement and the other Loan Documents.

(e) Makewhole Amount.

(i) Any prepayment of the Tranche A Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in each case occurring prior to the 2nd-year anniversary of the Tranche A Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Makewhole Amount; provided, however, that if the Tranche D Approval Condition is satisfied prior to the 2nd-year anniversary of the Tranche A Closing Date, then any such prepayment of the Tranche A Loan by Borrower occurring prior to the 3rd-year anniversary of the Tranche A Closing Date shall be accompanied by payment of an amount equal to the Tranche A Makewhole Amount; provided, further, that if the Tranche D Approval Condition is satisfied on or after the 2nd-year anniversary of the Tranche A Closing Date, then any prepayment of the Tranche A Loan occurring prior to the one-year anniversary of the

date on which the Tranche D Approval Condition is satisfied shall be accompanied by payment of an amount equal to the Tranche A Makewhole Amount.

(ii) Any prepayment of the Tranche B Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in each case occurring prior to the 2nd-year anniversary of the Tranche B Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Makewhole Amount; provided, however, that if the Tranche D Approval Condition is satisfied prior to the 2nd-year anniversary of the Tranche B Closing Date, then any such prepayment of the Tranche B Loan by Borrower occurring prior to the 3rd-year anniversary of the Tranche B Closing Date shall be accompanied by payment of an amount equal to the Tranche B Makewhole Amount; provided, further, that if the Tranche D Approval Condition is satisfied on or after the 2nd-year anniversary of the Tranche B Closing Date, then any prepayment of the Tranche B Loan occurring prior to the one-year anniversary of the date on which the Tranche D Approval Condition is satisfied shall be accompanied by payment of an amount equal to the Tranche B Makewhole Amount.

(iii) Any (A) prepayment of the Tranche C Loan by Borrower (i) pursuant to Section 2.2(c), or (ii) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in either case occurring prior to the 2nd-year anniversary of the Tranche C Closing Date, (B) without any duplication with sub-clause (C) below, prepayment of the Term Loans by Borrower (i) pursuant to Section 2.2(c), or (ii) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in either case, on or prior to September 30, 2024 where the Tranche C Loan has not yet been funded hereunder (including where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero) or (C) prepayment of the Term Loans by Borrower as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) upon the occurrence of an Event of Default under Section 7.2(c) (including where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero) shall, in any case of sub-clause (A) or (B) or (C) above, be accompanied by payment of an amount equal to the Tranche C Makewhole Amount. For the avoidance of doubt, no Tranche C Makewhole Amount shall be due and payable hereunder in the event the Tranche C Closing Date does not occur by September 30, 2024 and (x) each of the conditions precedent to each Lender's obligation to advance its Applicable Percentage of the Tranche C Loan has been satisfied (or waived in accordance with Section 11.5) prior to September 30, 2024 and (y) the failure of the Tranche C Closing Date to occur by September 30, 2024 is solely caused by the failure of Lenders to fund the Tranche C Loan by September 30, 2024 in accordance with Section 3.7.

(iv) Any prepayment of the Tranche D Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in each case occurring prior to the 2nd-year anniversary of the Tranche D Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche D Makewhole Amount. Notwithstanding anything herein to the contrary, the Tranche D Makewhole Amount shall not in any event be due and payable if the Tranche D Closing Date has not occurred.

(f) Prepayment Premium.

(i) Any prepayment of the Tranche A Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Prepayment Premium.

(ii) Any prepayment of the Tranche B Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Prepayment Premium.

(iii) Any (A) prepayment of the Tranche C Loan by Borrower (i) pursuant to Section 2.2(c), or (ii) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), (B) without any duplication with sub-clause (C) below, prepayment of the Term Loans by Borrower (i) pursuant to Section 2.2(c), or (ii) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in either case, on or prior to September 30, 2024 where the Tranche C Loan has not yet been funded hereunder (including where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero) or (C) prepayment of the Term Loans by Borrower as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) upon the occurrence of an Event of Default under Section 7.2(c) (including where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero) shall, in any case of sub-clause (A) or (B) or (C) above, be accompanied by payment of an amount equal to the Tranche C Prepayment Premium. For the avoidance of doubt, no Tranche C Prepayment Premium shall be due and payable hereunder in the event the Tranche C Closing Date does not occur by September 30, 2024 and (x) each of the conditions precedent to each Lender's obligation to advance its Applicable Percentage of the Tranche C Loan has been satisfied (or waived in accordance with Section 11.5) prior to September 30, 2024 and (y) the failure of the Tranche C Closing Date to occur by September 30, 2024 is solely caused by the failure of Lenders to fund the Tranche C Loan by September 30, 2024 in accordance with Section 3.7.

(iv) Any prepayment of the Tranche D Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall, in any such case, be accompanied by payment of an amount equal to the Tranche D Prepayment Premium. Notwithstanding anything herein to the contrary, the Tranche D Prepayment Premium shall not in any event be due and payable if the Tranche D Closing Date has not occurred.

For the avoidance of doubt, no Prepayment Premium shall be due and owing for any payment of principal of the Term Loans made on the Term Loan Maturity Date.

(g) Any Makewhole Amount, Prepayment Premium or Additional Consideration payable as a result of any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall be presumed to be the liquidated damages sustained by each applicable Lender as the result of the early redemption and repayment of such Term Loan Notes and Borrower agrees that it is reasonable under the circumstances currently existing. BORROWER EXPRESSLY WAIVES (TO THE FULLEST EXTENT IT MAY LAWFULLY DO SO) THE PROVISIONS OF ANY PRESENT OR FUTURE REQUIREMENTS OF LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF ANY MAKEWHOLE AMOUNT OR PREPAYMENT PREMIUM OR ADDITIONAL CONSIDERATION IN CONNECTION WITH ANY SUCH PREPAYMENT OR ACCELERATION OR OTHERWISE. Borrower expressly agrees that (to the fullest extent it may lawfully do so) that: (i) each Makewhole Amount and Prepayment Premium and Additional Consideration is reasonable and is the product of an arm's-length transaction among sophisticated business people, ably represented by counsel; (ii) each Makewhole Amount and Prepayment Premium and Additional Consideration shall be payable notwithstanding the then-prevailing market rates at the time payment thereof is made; (iii) there has been a course of conduct among

Lenders and Borrower giving specific consideration in this transaction for such agreement to pay each Makewhole Amount and Prepayment Premium and Additional Consideration; and (iv) Borrower shall be estopped hereafter from claiming differently than as agreed to in this Section 2.2(g) and Section 8.6. Borrower expressly acknowledges that its agreement to pay the Makewhole Amount and Prepayment Premium and Additional Consideration, as the case may be, to applicable Lenders as herein described is a material inducement to such Lenders to make any Credit Extension. Without affecting any of any Lender's rights or remedies hereunder or in respect hereof, if Borrower fails to pay the applicable Makewhole Amount or Prepayment Premium or Additional Consideration when due, then the amount thereof shall thereafter bear interest until paid in full at the Default Rate.

2.3 Payment of Interest on the Term Loans

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(a) Interest Rate.

(i) Subject to Section 2.3(b) below, the principal amount outstanding under each Term Loan shall accrue interest at a *per annum* rate equal to Adjusted Term SOFR for the Interest Period therefor *plus* the Applicable Margin (the "**Term Loan Rate**"), which interest shall be payable quarterly in arrears in accordance with this Section 2.3.

(ii) Interest shall accrue on each Term Loan commencing on, and including, the day on which such Term Loan is made, and shall accrue on such Term Loan, or any portion thereof, through and including the day on which such Term Loan or such portion is paid.

(iii) Interest is due and payable quarterly on each Interest Date, as calculated by the Collateral Agent (which calculations shall be deemed correct absent manifest error, provided that the Collateral Agent shall provide evidence of such calculation upon Borrower's written request), commencing on the Interest Date occurring in the calendar quarter immediately following the Tranche A Closing Date; provided, however, that if any such date is not a Business Day, the applicable interest shall be due and payable on the first Business Day immediately after such date.

(b) Default Rate. In the event Borrower fails to pay any of the Obligations when due (after giving effect to any applicable grace or cure period), or upon the commencement and during the continuance of an Insolvency Proceeding of Borrower, or upon the occurrence and during the continuance of any other Event of Default, immediately (and without notice or demand by any Lender or the Collateral Agent for payment thereof) to Borrower, such past due Obligations shall accrue interest at a rate per annum which is three percentage points (3.00%) above the rate that is otherwise applicable thereto (the "**Default Rate**"), and such interest shall be payable entirely in cash on demand of any Lender or the Collateral Agent. Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment of any Obligations and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of the Collateral Agent or any Lender.

(c) 360-Day Year. Interest payable under each Term Loan shall be computed on the basis of a year of 360 days and the actual number of days elapsed.

(d) Payments. Except as otherwise expressly provided herein, all Term Loan payments and any other payments hereunder by (or on behalf of) Borrower shall be made on the date specified herein to such bank account of each applicable Lender as such Lender (or the Collateral Agent) shall have designated in a written notice to Borrower delivered on or before the Tranche A Closing Date (which such notice may be updated by such Lender (or the Collateral Agent) by written notice to the Borrower from time to time after the Tranche A Closing Date). Except as otherwise expressly provided herein, interest is payable quarterly on each Interest Date. Payments of principal or interest received after 11:00 a.m. on such date are considered received at the opening of business on the next Business Day. When any payment is due on a day that is not a Business Day, such payment is due on the next Business Day thereafter and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest made hereunder and pursuant to any other Loan Document, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

(e) Conforming Changes. In connection with the use or administration of Term SOFR, the Collateral Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Loan Document. The Collateral Agent will promptly notify Borrower and Lenders of the effectiveness of any Conforming Changes in connection with the use or administration of Term SOFR.

(f) Benchmark Replacement Setting.

(i) Benchmark Replacement. Notwithstanding anything to the contrary herein or in any other Loan Document, if a Benchmark Transition Event and its related Benchmark Replacement Date have occurred prior any setting of the then-current Benchmark, then (x) if a Benchmark Replacement is determined in accordance with clause (a) of the definition of "Benchmark Replacement" for such Benchmark Replacement Date, such Benchmark Replacement will replace such Benchmark for all purposes hereunder and under any Loan Document in respect of such Benchmark setting and subsequent Benchmark settings without any amendment to, or further action or consent of any other party to, this Agreement or any other Loan Document and (y) if a Benchmark Replacement is determined in accordance with clause (b) of the definition of "Benchmark Replacement" for such Benchmark Replacement Date, such Benchmark Replacement will replace such Benchmark for all purposes hereunder and under any Loan Document in respect of any Benchmark setting at or after 5:00 p.m. (New York City time) on the fifth (5th) Business Day after the date notice of such Benchmark Replacement is provided to Borrower and the Lenders without any amendment to, or further action or consent of any other party to, this Agreement or any other Loan Document so long as the Collateral Agent has not received, by such time, written notice of objection to such Benchmark Replacement from Lenders comprising the Required Lenders. If the Benchmark Replacement is Daily Simple SOFR, all interest payments will be payable on a quarterly basis.

(ii) Conforming Changes. In connection with the implementation and administration of a Benchmark Replacement, the Collateral Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Loan Document.

(iii) Notices; Standards for Decisions and Determinations. The Collateral Agent will promptly notify Borrower and the Lenders of (A) the implementation of any Benchmark Replacement and (B) the effectiveness of any Conforming Changes in connection with the

use, administration, adoption or implementation of a Benchmark Replacement. The Collateral Agent will notify Borrower of (x) the removal or reinstatement of any tenor of a Benchmark pursuant to sub-clause (iv) below and (y) the commencement of any Benchmark Unavailability Period. Any determination, decision or election that may be made by the Collateral Agent or, if applicable, any Lender (or group of Lenders) pursuant to this Section 2.3(f), including any determination with respect to a tenor, rate or adjustment or of the occurrence or non-occurrence of an event, circumstance or date and any decision to take or refrain from taking any action, will be conclusive and binding absent manifest error and may be made in its or their sole discretion and without consent from any other party to this Agreement or any other Loan Document, except, in each case, as expressly required pursuant to this Section 2.3(f).

(iv) Unavailability of Tenor of Benchmark. Notwithstanding anything to the contrary herein or in any other Loan Document, at any time (including in connection with the implementation of a Benchmark Replacement), (A) if the then-current Benchmark is a term rate (including the Term SOFR Reference Rate) and either (1) any tenor for such Benchmark is not displayed on a screen or other information service that publishes such rate from time to time as selected by the Collateral Agent in its reasonable discretion or (2) the regulatory supervisor for the administrator of such Benchmark has provided a public statement or publication of information announcing that any tenor for such Benchmark is not or will not be representative, then the Collateral Agent may modify the definition of "Interest Period" (or any similar or analogous definition) for any Benchmark settings at or after such time to remove such unavailable or non-representative tenor and (B) if a tenor that was removed pursuant to sub-clause (A) above either (1) is subsequently displayed on a screen or information service for a Benchmark (including a Benchmark Replacement) or (2) is not, or is no longer, subject to an announcement that it is not or will not be representative for a Benchmark (including a Benchmark Replacement), then the Collateral Agent may modify the definition of "Interest Period" (or any similar or analogous definition) for all Benchmark settings at or after such time to reinstate such previously removed tenor.

2.4 Expenses

. Borrower shall pay to or reimburse (or pay directly on behalf of) the Collateral Agent and, as applicable, each Lender, all of such Person's reasonable and documented Lender Expenses incurred through and after the Prior Effective Date, promptly after receipt of a written demand therefor by such Lender or the Collateral Agent (with, in the case of any Lender, a copy of such demand to the Collateral Agent), setting forth in reasonable detail such Person's Lender Expenses.

2.5 Requirements of Law; Increased Costs

. In the event that any applicable Change in Law:

(a) Does or shall subject any Lender to any Tax of any kind whatsoever with respect to this Agreement or the Term Loans (except, in each case, Indemnified Taxes, Taxes described in clause (b) through (d) of the definition of Excluded Taxes, and Connection Income Taxes);

(b) Does or shall impose, modify or hold applicable any reserve, capital requirement, special deposit, compulsory loan, insurance charge or similar requirements against assets held by, or deposits or other liabilities in or for the account of, advances or loans by, or other credit extended by, or any other acquisition of funds by, any Lender; or

(c) Does or shall impose on any Lender any other condition (other than Taxes); and the result of any of the foregoing is to increase the cost to such Lender (as determined by such Lender in good faith using calculation methods customary in the industry) of making, renewing or maintaining the Term Loans or to reduce any amount receivable in respect thereof or to reduce the rate of return on the capital of such Lender or any Person controlling such Lender,

then, in any such case, such Lender shall promptly notify Borrower in writing of the event by reason of which it has incurred additional costs or has reduced amounts receivable or rate of return, and submit to Borrower a certificate as to such additional costs or has reduced amounts receivable or rate of return containing the calculation thereof in reasonable detail, which shall be conclusive in the absence of manifest error. Such Lender shall first, prior to Borrower being required to take any action under this Section 2.5, take commercially reasonable actions to mitigate the additional costs or reduced amounts receivable or rate of return, including assigning all of its rights and delegating and transferring all of its obligations hereunder to an existing Affiliate of such Lender that would not be subject to such, or would be subject to less, additional costs or reduced amounts receivable or rate of return, if any. Borrower shall promptly, and no later than thirty (30) days of its receipt of the certificate described above, pay to such Lender, subject to the terms of this Section 2.5, any undisputed additional amounts necessary to compensate such Lender for such additional cost or reduced amounts receivable or rate of return as reasonably determined by such Lender with respect to this Agreement or the Term Loans made hereunder. The provisions hereof shall survive the termination of this Agreement and the payment of the outstanding Term Loans and all other Obligations. Failure or delay on the part of any such Lender to demand compensation for any increased costs or reduction in amounts received or receivable or reduction in return on capital under this Section 2.5 shall not constitute a waiver of such Lender's right to demand such compensation; provided that Borrower shall not be under any obligation to compensate such Lender under this Section 2.5 with respect to increased costs or reductions with respect to any period prior to the date that is 180 days prior to the date of the delivery of the notice required pursuant to the foregoing provisions of this paragraph; provided, further, that if the Change in Law giving rise to such increased costs or reductions is retroactive, then the 180-day period referred to above shall be extended to include the period of retroactive effect thereof.

2.6 Taxes; Withholding, Etc.

(a) All sums payable by any Credit Party hereunder and under the other Loan Documents shall (except to the extent required by Requirements of Law) be paid free and clear of, and without any deduction or withholding on account of, any Tax imposed, levied, collected, withheld or assessed by any Governmental Authority. In addition, Borrower agrees to pay, and shall indemnify and hold each Lender harmless from, Other Taxes, and as soon as practicable after the date of paying Other Taxes to a Governmental Authority, Borrower shall furnish to each Lender (as applicable, with a copy to the Collateral Agent) the original or a certified copy of a receipt evidencing payment thereof or other evidence reasonably satisfactory to such Lender.

(b) If any Credit Party or any other Person ("**Withholding Agent**") is required by Requirements of Law to make any deduction or withholding on account of any Tax (as determined in the good faith discretion of such Withholding Agent) from any sum paid or payable by any Credit Party to any Lender under any of the Loan Documents: (i) such Withholding Agent shall notify such Lender in writing (with a copy to the Collateral Agent) of any such requirement or any change in any such requirement promptly after such Withholding Agent becomes aware of it; (ii) such Withholding Agent shall make any such withholding or deduction; (iii) such Withholding Agent shall pay any such Tax before the date on which penalties attach thereto, such payment to be made (if the liability to pay is imposed on any Credit Party) for its own account or (if that liability is imposed on such Lender, as the case may be) on behalf of and in the name of such Lender in accordance with Requirements of Law; (iv) if the Tax is an Indemnified Tax, the sum payable by such Credit Party in respect of which the relevant deduction, withholding or payment of Indemnified Tax is required shall be increased to the extent necessary to ensure that, after the making of that deduction, withholding or payment (including any deductions for Indemnified Taxes applicable to

additional sums payable under this Section 2.6(b)), such Lender receives on the due date a net sum equal to what it would have received had no such deduction, withholding or payment of Indemnified Tax been required or made; and (v) as soon as practicable after paying any sum from which it is required by Requirements of Law to make any deduction or withholding, Borrower shall (or shall cause such Withholding Agent, if not Borrower, to) deliver to such Lender (with a copy to the Collateral Agent) evidence reasonably satisfactory to such Lender of such deduction, withholding or payment and of the remittance thereof to the relevant taxing or other Governmental Authority.

(c) The Credit Parties shall jointly and severally indemnify each Lender for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 2.6(c)) paid by such Lender and any liability (including any reasonable expenses) arising therefrom or with respect thereto whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. Any indemnification payment pursuant to this Section 2.6(c) shall be made to the applicable Lender within twenty (20) days from written demand therefor.

(d) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to Borrower, at the time or times reasonably requested by Borrower, such properly completed and executed documentation reasonably requested by Borrower as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, such Lender, if reasonably requested by Borrower, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower as will enable Borrower to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Section 2.6(d)(i), (ii) or (iv) below) shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender. For avoidance of doubt, for the purposes of this Section 2.6(d), the term "Lender" shall include each applicable assignee. Without limiting the generality of the foregoing:

(i) If any Lender is organized under the laws of the United States, such Lender shall deliver, and shall cause each applicable assignee thereof to deliver, to Borrower two (2) executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax.

(ii) If any Lender is a Foreign Lender, such Lender shall deliver, and shall cause each applicable assignee thereof to deliver, to Borrower, on or about the date on which such Foreign Lender becomes a Lender under this Agreement, and at such other times as may be necessary in the determination of Borrower (in the reasonable exercise of its discretion), whichever of the following is applicable:

(1) in the case that such Lender is a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document (including any original issue discount), a properly completed and duly executed copy of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, a properly completed and duly executed copy of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

(2) a completed and duly executed copy of IRS Form W-8ECI;

(3) in the case that such Foreign Lender is claiming an exemption from U.S. federal withholding Tax pursuant to the "portfolio interest exemption" under Section 881(c) of the IRC, it shall provide Borrower with the applicable executed IRS Form W-8BEN-E or IRS Form W-8BEN, as applicable, and a certificate reasonably satisfactory to Borrower to the effect that any interest received by such Foreign Lender is not received by a "bank" on "extension of credit made pursuant to a loan agreement entered into in the ordinary course of its trade or business" within the meaning of 881(c)(3)(A) of the IRC, a "10 percent shareholder" of Borrower within the meaning of Section 871(h)(3)(B) of the IRC, or a "controlled foreign corporation" related to Borrower as described in Section 881(c)(3)(C) of the IRC, or

(4) to the extent that such Foreign Lender is not the beneficial owner, an executed copy of IRS Form W-8IMY, accompanied by a withholding statement and IRS Form W-8ECI, IRS Form W-8BEN-E (or W-8BEN, as applicable), IRS Form W-9 or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a certificate referenced in Section 2.6(d)(ii)(3) above on behalf of each such direct or indirect partner.

(iii) If any Lender is a Foreign Lender it shall, to the extent it is legally entitled to do so, deliver to Borrower (in such number of copies as shall be requested by the recipient) on or about the date on which it becomes a party to this Agreement (and from time to time thereafter upon the reasonable request of Borrower), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower to determine the withholding or deduction required to be made.

(iv) If a payment made to any Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the IRC, as applicable), such Lender shall deliver to Borrower at the time or times prescribed by law and at such time or times reasonably requested by Borrower such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the IRC) and such additional documentation reasonably requested by Borrower as may be necessary for Borrower to comply with their obligations under FATCA and to determine that Lender has complied with its obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

(v) Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or notify the Borrower in writing of its legal inability to do so.

(e) If any party hereto determines, in its discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this Section 2.6 (including by the payment of additional amounts pursuant to this Section 2.6), it shall pay to the indemnifying

party an amount equal to such refund (but only to the extent of indemnity payments made, or additional amounts paid, under this Section 2.6 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this clause (e) in the event that such indemnified party is required to repay such refund to such Governmental Authority and the requirement to repay such refund to such Governmental Authority is not due to the indemnified party's failure to timely provide complete and accurate Internal Revenue Service forms and other documentation required pursuant to Section 2.6(d) or Section 2.8. Notwithstanding anything to the contrary in this clause (e), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this clause (e) if the payment of such amount would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the indemnification payments or additional amounts giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such tax had never been paid. This clause (e) shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

(f) Tax Status of Borrower. Borrower is currently treated as a corporation for U.S. federal income tax purposes. Borrower shall provide the Required Lenders with a prior written notice as promptly as practicable, and in any event not less than ten (10) days, before taking any affirmative action (including making any election under Section 301.7701-3(c) of the Treasury Regulations (or any successor provision) by way of filing an IRS Form 8832) to change its U.S. entity tax classification.

(g) Tax Reporting Assistance. Borrower shall use reasonable efforts to assist any Lender (i) in the computation of accruals with respect to any "original issue discount" or "market discount" arising with respect to the Term Loans for U.S. federal income tax purposes, and (ii) with its compliance with any associated tax reporting or filing requirements of such Lender or its partners, members or beneficial owners.

2.7 Additional Consideration

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(a) As additional consideration for the obligation of each Lender to fund its Applicable Percentage of the Tranche A Loan and the Tranche B Loan and the funding of its Applicable Percentage of the Tranche A Loan and the Tranche B Loan pursuant to Section 2.2(a) and Section 3.7, on the Tranche A Closing Date, Borrower shall pay to each Lender an amount equal to the product of (i) the sum of such Lender's Tranche A Commitment and Tranche B Commitment, *multiplied by* (ii) 0.0175 (such product, the "**Tranche A/B Additional Consideration**"). Any and all Tranche A/B Additional Consideration shall be fully earned when paid and shall not be refundable for any reason whatsoever and shall be treated as original issue discount with respect to the Tranche A Loan for U.S. federal income tax purposes. The Tranche A/B Additional Consideration payable hereunder shall be due on the Tranche A Closing Date and shall be deducted from the proceeds of the Tranche A Loan to be advanced to Borrower pursuant to Section 2.2(a) and Section 3.7.

(b) As additional consideration for the obligation of each Lender to fund its Applicable Percentage of the Tranche C Loan and the funding of its Applicable Percentage of the Tranche C Loan pursuant to Section 2.2(a) and Section 3.7, on the Tranche C Closing Date, Borrower shall pay to each Lender an amount equal to the product of (i) the sum of such Lender's Tranche C Commitment, *multiplied by* (ii) 0.0175 (such product, the "**Tranche C Additional Consideration**"). Any and all Tranche C Additional Consideration shall be fully earned when paid and shall not be refundable for any reason whatsoever and shall be treated as original issue discount with respect to the Tranche C Loan for U.S. federal income tax purposes. The Tranche C Additional Consideration payable hereunder shall be due and payable on the Tranche C Closing Date and shall be deducted from the proceeds of the Tranche C Loan to be advanced to Borrower pursuant to Section 2.2(a) and Section 3.7; provided, however, that, (A) in the event of any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) on or prior to the Tranche C Closing Date (including where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero), or (B) in the event of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) upon the occurrence of an Event of Default under Section 7.2(c) (including where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero), in each case of sub-clause (A) and (B) above, the Tranche C Additional Consideration payable hereunder shall be due and payable upon the occurrence of any such event, without any notice, demand or other action by the Collateral Agent or any Lender, and shall be paid together with such prepayment (and in addition to the accompanying Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable). For the avoidance of doubt, no Tranche C Additional Consideration shall be due and payable hereunder in the event the Tranche C Closing Date does not occur by September 30, 2024 and (x) each of the conditions precedent to each Lender's obligation to advance its Applicable Percentage of the Tranche C Loan has been satisfied (or waived in accordance with Section 11.5) prior to September 30, 2024 and (y) the failure of the Tranche C Closing Date to occur by September 30, 2024 is solely caused by the failure of Lenders to fund the Tranche C Loan by September 30, 2024 in accordance with Section 3.7.

(c) As additional consideration for the obligation of each Lender to fund its Applicable Percentage of the Tranche D Loan and, if applicable, the funding of its Applicable Percentage of the Tranche D Loan pursuant to Section 2.2(a) and Section 3.7, on the Tranche D Closing Date, Borrower shall pay to each Lender an amount equal to the product of (i) the sum of such Lender's Tranche D Commitment, *multiplied by* (ii) 0.0175 (such product, the "**Tranche D Additional Consideration**"). Any and all Tranche D Additional Consideration shall be fully earned when paid and shall not be refundable for any reason whatsoever and shall be treated as original issue discount with respect to the Tranche D Loan for U.S. federal income tax purposes. The Tranche D Additional Consideration payable hereunder shall be due and payable on the Tranche D Closing Date and shall be deducted from the proceeds of the Tranche D Loan to be advanced to Borrower pursuant to Section 2.2(a) and Section 3.7; provided, however, that, (A) in the event (x) of any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) on or prior to August 29, 2025, and (y), as of the date of such prepayment or acceleration, the FDA has not formally declined to approve an NDA for UGN-102 (mitomycin), by or on behalf of Parent, for the introduction or delivery for introduction into interstate commerce of UGN-102 (mitomycin) in the United States, or (B) in the event of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) upon the occurrence of an Event of Default under Section 7.2(c) (including where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero), in each case of sub-clause (A) and (B) above, the Tranche D Additional Consideration payable hereunder shall be due and payable upon the occurrence of such event, without any notice, demand or other action by the Collateral Agent or any Lender, and shall be paid together with such prepayment (and in addition to any accompanying Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable).

2.8 Note Register; Term Loan Notes

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(a) Note Register. Borrower will maintain at all times at its principal executive office a register that identifies each beneficial owner that is entitled to a payment of principal and stated interest on each Term Loan (the "**Note Register**") and provides for the registration and transfer of Term

Loan Notes so that each Term Loan is at all times in "registered form" within the meaning of Section 163(f), 871(h)(2) and 881(c)(2) of the IRC and any related regulations (and any other relevant or successor provisions of the IRC or such regulations). Each Term Loan: (i) shall, pursuant to this clause (a), be registered as to both principal and any stated interest with Borrower or its agent, and (ii) may be transferred or exchanged by any Lender only by surrender of the old instrument at the principal executive office of Borrower (or at the place of payment named in the Term Loan Note, if any), accompanied, if so required by Borrower in the case of a Lender Transfer, by a written instrument of transfer in form reasonably satisfactory to Borrower duly executed by the holder thereof or by such holder's attorney duly authorized in writing, and Borrower will execute and deliver in exchange therefor a new Term Loan Note or Term Loan Notes, in such denomination(s) as may be requested by such holder, of like tenor and in the same aggregate outstanding principal amount as the aggregate outstanding principal amount of the Term Loan Note(s) so surrendered. Any Term Loan Note issued in exchange for any other Term Loan Note or upon transfer thereof shall carry the rights to unpaid interest and interest to accrue that were carried by the Term Loan Note so exchanged or transferred, and neither gain nor loss of interest shall result from any such transfer or exchange. The entries in the Note Register shall be conclusive and binding for all purposes, including as to the outstanding principal amount of the Term Loan Note and the payment of interest, principal and other sums due hereunder absent manifest error and Borrower, Lenders and any of their respective agents may treat the Person in whose name any Term Loan Note is registered as the sole and exclusive record and beneficial holder and owner of such Term Loan Note for all purposes whatsoever.

(b) Term Loan Notes. Each Lender shall issue to Borrower, and Borrower shall execute and deliver to each Lender to evidence such Lender's Term Loan, (i) on the Tranche A Closing Date, a Tranche A Note, (ii) on the Tranche B Closing Date, a Tranche B Note, (iii) on the Tranche C Closing Date, a Tranche C Note, and (iv) on the Tranche D Closing Date, a Tranche D Note. All amounts due under the Term Loan Notes shall be repayable as set forth in this Agreement and interest shall accrue on the principal amount of the Term Loans represented by the Term Loan Notes, in each case, in accordance with the terms of this Agreement. All Term Loan Notes shall rank for all purposes *pari passu* with each other.

3 CONDITIONS OF TERM LOANS

3.1 Conditions Precedent to Tranche A Loan

. Each Lender's obligation to advance its Applicable Percentage of the Tranche A Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt:

(i) on the Prior Effective Date, of copies of the Loan Agreement, the Disclosure Letter, the Perfection Certificate for Parent and its Subsidiaries and the Advance Request Form, in each case (x) dated as of the Prior Effective Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form and substance reasonably satisfactory to the Collateral Agent; and

(ii) on the Tranche A Closing Date, of copies of the other Loan Documents (including the schedules thereto), including the Tranche A Notes executed by Borrower and the Collateral Documents (but excluding any Control Agreements, Collateral Access Agreements and any other Loan Document described in Schedule 5.14 of the Disclosure Letter to be delivered after the Tranche A Closing Date) and, if and to the extent any update thereto is necessary between the Prior Effective Date and the Tranche A Closing Date, an updated Disclosure Letter or Perfection Certificate (provided, that in no event may the Disclosure Letter or the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)), in each case (x) dated as of the Tranche A Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form and substance reasonably satisfactory to the Collateral Agent;

(b) the Collateral Agent's receipt of (i) true, correct and complete copies of the Operating Documents of each of Parent and the other Credit Parties, and (ii) a Secretary's Certificate, dated the Tranche A Closing Date, certifying that the foregoing copies are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent);

(c) the Collateral Agent's receipt of a good standing certificate for each Credit Party (where applicable in the subject jurisdiction), certified (where available) by the Secretary of State (or the equivalent thereof) of the jurisdiction of incorporation, formation or organization of such Person as of a date no earlier than thirty (30) days prior to the Tranche A Closing Date;

(d) the Collateral Agent's receipt of a Secretary's Certificate in relation to each Credit Party, dated the Tranche A Closing Date, certifying that (i) attached as Exhibit A to such certificate is a true, correct, and complete copy of the Borrowing Resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Credit Party of the Loan Documents to which it is a party, (ii) the name(s) and title(s) of the officers of such Credit Party authorized to execute the Loan Documents to which such Credit Party is a party on behalf of such Credit Party together with a sample of the true signature(s) of such Credit Party(s), and (iii) that the Collateral Agent and each Lender may conclusively rely on such certificate with respect to the authority of such officers unless and until such Credit Party shall have delivered to the Collateral Agent a further certificate canceling or amending such prior certificate;

(e) each Credit Party shall have obtained all Governmental Approvals, if any, and all consents or approvals of other Persons, including the approval or consent of the equityholders of Borrower or Parent, if any, and the consent of RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2) required pursuant to Section 6.8 of the Pre-Paid Forward Contract, in each case that are necessary in connection with the transactions contemplated by the Loan Documents, and each of the foregoing shall be in full force and effect and in form and substance reasonably satisfactory to the Collateral Agent;

(f) the Collateral Agent's receipt on the Tranche A Closing Date of opinions of (i) Cooley LLP, counsel to Borrower and the other the Credit Parties, and (ii) Erdinast Ben Natan Toledano & Co. with Hamburger Evron, counsel to the Parent in each case in form and substance reasonably satisfactory to the Collateral Agent;

(g) (i) subject to Section 5.14, the Collateral Agent's receipt on the Tranche A Closing Date of (i) evidence that any products liability and general liability insurance policies maintained regarding any Collateral are in full force and effect and (ii) appropriate evidence showing the Collateral Agent, for the benefit of Lenders and the other Secured Parties, having been named as additional insured or loss payee, as applicable (such evidence to be in form and substance reasonably satisfactory to the Collateral Agent) with respect to any products liability and general liability insurance policies maintained in the United States regarding any Collateral;

(h) the Collateral Agent's receipt prior to the Prior Effective Date of all documentation and other information required by bank regulatory authorities under applicable "know-your-customer" and anti-money laundering rules and regulations, including the U.S.A. Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "**Patriot Act**");

(i) concurrent with the funding of the Tranche A Loan, payment of Lender Expenses then due as specified in Section 2.4 hereof for which Borrower has received an invoice at least one (1) Business Day prior, and payment of the Additional Consideration in accordance with Section 2.7, which such payments shall be deducted from the proceeds of the Tranche A Loan;

(j) the Collateral Agent's and each Lender's receipt of: (i) the RTW Intercreditor Agreement, executed and delivered by each of Parent and the RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2), (ii) subject to Section 5.14, a copy of the amendment to the Security Agreement/Debenture Unlimited in Amount, dated April 4, 2021, between Parent and RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2), acknowledging the creation of a first priority security interest in and Lien upon the Collateral in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties and providing that such security interest and Lien is senior in priority to any and all security interests and Liens in favor of RTW Investments ICAV thereunder, and (iii) subject to Section 5.14, evidence of the filing of such amended Security Agreement/Debenture Unlimited in Amount with the Israeli Registrar of Companies (such evidence to be in form and substance reasonably satisfactory to the Collateral Agent); and

(k) the Collateral Agent's receipt of a certificate, dated the Tranche A Closing Date and signed by a Responsible Officer of Parent, confirming: (i) there is no Adverse Proceeding pending or, to the Knowledge of Parent, threatened in writing, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter; (ii) satisfaction of the conditions precedent set forth in this Section 3.1 and in Section 3.5, Section 3.6 and Section 3.7 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent); and (iii) that the organizational structure and capital structure of Parent and each of its Subsidiaries is as described on Schedule 4.15 of the Disclosure Letter as at the Tranche A Closing Date.

3.2 Conditions Precedent to Tranche B Loan

. Each Lender's obligation to advance its Applicable Percentage of the Tranche B Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt, on the Tranche B Closing Date, of the Tranche B Note executed by Borrower, and, if and to the extent any update thereto is necessary between the Tranche A Closing Date and the Tranche B Closing Date, a Disclosure Letter or Perfection Certificate updated in reasonable detail (provided, that in no event may the Disclosure Letter or the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)), in each case (x) dated as of the Tranche B Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form reasonably satisfactory to the Collateral Agent;

(b) the Collateral Agent's receipt of a Secretary's Certificate in relation to each Credit Party, dated the Tranche B Closing Date, certifying (i) that attached as Exhibit A to such certificate is a true, correct, and complete copy of the Borrowing Resolutions then in full force and effect authorizing the Tranche B Loan or, alternatively, (ii) that the Borrowing Resolutions adopted as of the Tranche A Closing Date authorizing the Term Loans and previously delivered to the Collateral Agent pursuant to Section 3.1(d) have not been modified and remain in full force and effect;

(c) [RESERVED];

(d) concurrent with the funding of the Tranche B Loan, payment of Lender Expenses then due as specified in Section 2.4 hereof and for which an invoice has been received by Borrower at least (1) Business Day prior, and such payment shall be deducted from the proceeds of the Tranche B Loan;

(e) no prepayment of the principal amount of any Term Loan has been made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a); and

(f) the Collateral Agent's receipt of a certificate, dated the Tranche B Closing Date and signed by a Responsible Officer of Parent, confirming: (i) there is no Adverse Proceeding pending or, to the Knowledge of Parent, threatened in writing, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter delivered in accordance with Section 3.1(a)(i) or Section 3.2(a), as applicable; and (ii) satisfaction of the conditions precedent set forth in this Section 3.2 and in Section 3.5, Section 3.6 and Section 3.7 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent.

3.3 Conditions Precedent to Tranche C Loan

. Each Lender's obligation to advance its Applicable Percentage of the Tranche C Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt:

(i) on the Effective Date, of copies of this Amended and Restated Loan Agreement, an Israeli law-governed Fixed Charge Debenture (Unlimited in Amount), an Israeli law-governed Floating Charge Debenture (Unlimited in Amount), a Secretary's Certificate in relation to each Credit Party, certifying that attached as Exhibit A to such certificate is a true, correct, and complete copy of the Borrowing Resolutions then in full force and effect authorizing the transactions contemplated by this Amended and Restated Loan Agreement, including the Tranche C Loan and such Israeli law-governed debentures, and opinions of Erdinast Ben Natan Toledano & Co., counsel to the Parent, in each case (x) dated as of the Effective Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form and substance reasonably satisfactory to the Collateral Agent;

(ii) promptly, and in no event later than five (5) Business Days following the Effective Date, of copies of a Patent Security Agreement by and between Parent and the Collateral Agent, (x) dated as of the Effective Date, (y) executed (where applicable) and delivered by Parent, and (z) in form and substance reasonably satisfactory to the Collateral Agent; and

(iii) on the Tranche C Closing Date, of the Tranche C Note executed by Borrower, and, if and to the extent any update thereto is necessary between the Tranche B Closing Date and the Tranche C Closing Date, a Disclosure Letter or Perfection Certificate updated in reasonable detail (provided, that in no event may the Disclosure Letter or the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)), in each case (x) dated as of the Tranche C Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form reasonably satisfactory to the Collateral Agent;

(b) if the Operating Documents of any of Parent or the Credit Parties delivered to the Collateral Agent pursuant to Section 3.1(b) have subsequently been amended, restated, supplemented or otherwise modified, the Collateral Agent's receipt of (i) true, correct and complete copies of the Operating Documents of each such Credit Party, and (ii) a Secretary's Certificate, dated the Tranche C Closing Date, certifying that the foregoing copies are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent);

(c) the Collateral Agent's receipt of a good standing certificate for each Credit Party (where applicable in the subject jurisdiction), certified (where available) by the Secretary of State (or the equivalent thereof) of the jurisdiction of incorporation, formation or organization of such Person as of a date no earlier than thirty (30) days prior to the Tranche C Closing Date;

(d) concurrent with the funding of the Tranche C Loan, payment of Lender Expenses then due as specified in Section 2.4 hereof and for which an invoice has been received by Borrower at least (1) Business Day prior, and payment of the Tranche C Additional Consideration in accordance with Section 2.7, which such payments shall be deducted from the proceeds of the Tranche C Loan;

(e) no prepayment of the principal amount of any Term Loan has been made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a); and

(f) the Collateral Agent's receipt of a certificate, dated the Tranche C Closing Date and signed by a Responsible Officer of Parent, confirming: (i) there is no Adverse Proceeding pending or, to the Knowledge of Parent, threatened in writing, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter delivered in accordance with Section 3.1(a)(i) or Section 3.2(a) or Section 3.3(a), as applicable; and (ii) satisfaction of the conditions precedent set forth in this Section 3.3 and in Section 3.5, Section 3.6 and Section 3.7 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent.

3.4 Conditions Precedent to Tranche D Loan

. Each Lender's obligation to advance its Applicable Percentage of the Tranche D Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt, on the Tranche D Closing Date, of the Tranche D Note executed by Borrower, and, if and to the extent any update thereto is necessary between the Tranche C Closing Date and the Tranche D Closing Date, a Disclosure Letter or Perfection Certificate updated in reasonable detail (provided, that in no event may the Disclosure Letter or the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)), in each case (x) dated as of the Tranche D Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form reasonably satisfactory to the Collateral Agent;

(b) the Collateral Agent's receipt of a Secretary's Certificate in relation to each Credit Party, dated the Tranche D Closing Date, certifying that attached as Exhibit A to such certificate is a true, correct, and complete copy of the Borrowing Resolutions then in full force and effect authorizing the Tranche D Loan;

(c) the Tranche C Closing Date shall have occurred;

(d) the Tranche D Approval Condition shall have been satisfied;

(e) concurrent with the funding of the Tranche D Loan, payment of Lender Expenses then due as specified in Section 2.4 hereof and for which an invoice has been received by Borrower at least (1) Business Day prior, and payment of the Tranche D Additional Consideration in accordance with Section 2.7, which such payments shall be deducted from the proceeds of the Tranche D Loan;

(f) no prepayment of the principal amount of any Term Loan has been made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a); and

(g) the Collateral Agent's receipt of a certificate, dated the Tranche D Closing Date and signed by a Responsible Officer of Parent, confirming: (i) there is no Adverse Proceeding pending or, to the Knowledge of Parent, threatened in writing, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter delivered in accordance with Section 3.1(a)(i) or Section 3.2(a) or Section 3.3(a) or Section 3.4(a), as applicable; and (ii) satisfaction of the conditions precedent set forth in this Section 3.4 and in Section 3.5, Section 3.6 and Section 3.7 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent.

3.5 Additional Conditions Precedent to Term Loans

. The obligation of each Lender to advance its Applicable Percentage of each Term Loan is subject to the following additional conditions precedent:

(a) the representations and warranties made by the Credit Parties in Section 4 of this Agreement and in the other Loan Documents are true and correct in all material respects on the applicable Closing Date, unless any such representation or warranty is stated to relate to a specific earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (it being understood that any representation or warranty that is qualified as to "materiality," "Material Adverse Change," or similar language shall be true and correct in all respects (as so qualified), in each case, on the applicable Closing Date (both with and without giving effect to the Term Loans) or as of such earlier date, as applicable); and

(b) there shall not have occurred (i) any Material Adverse Change or (ii) any Default or Event of Default.

3.6 Covenant to Deliver

. The Credit Parties agree to deliver to the Collateral Agent or each Lender, as applicable, each item required to be delivered to Collateral Agent or each Lender, as applicable, under this Agreement as a condition precedent to any Credit Extension; provided, however, that any such items set forth on Schedule 5.14 of the Disclosure Letter shall be delivered to the Collateral Agent within the time period prescribed therefor on such schedule. The Credit Parties expressly agree that a Credit Extension made prior to the receipt by the Collateral Agent or any Lender, as applicable, of any such item shall not

constitute a waiver by the Collateral Agent or any Lender of the Credit Parties' obligation to deliver such item, and the making of any Credit Extension in the absence of any such item required to have been delivered by the date of such Credit Extension shall be in the applicable Lender's sole discretion.

3.7 Procedures for Borrowing

. Subject to the prior satisfaction of all other applicable conditions to the making of each Term Loan set forth in this Agreement, to obtain the Term Loans, Borrower shall deliver to the Collateral Agent and Lenders by electronic mail or facsimile a completed Advance Request Form for the Term Loans executed by a Responsible Officer of Borrower (which notice shall be irrevocable on and after the date on which such notice is given and Borrower shall be bound to make a borrowing in accordance therewith), in which case each Lender agrees, subject to the satisfaction of the applicable conditions precedent set forth in this Article 3, to advance an amount equal to its Applicable Percentage of the Tranche A Loan Amount, the Tranche B Loan Amount, the Tranche C Loan Amount and the Tranche D Loan Amount, as applicable, to Borrower on the applicable Closing Date, by wire transfer of same day funds in Dollars, to such account(s) in the United States as may be designated in writing to the Collateral Agent by Borrower at least two (2) Business Days prior to such Closing Date; provided, however, that, with respect to the Tranche B Loan, Borrower shall deliver to the Collateral Agent by electronic mail or facsimile such completed Advance Request Form no later than such date that is sixty (60) days prior to the Tranche B Closing Date; provided, further, that, with respect to the Tranche C Loan, Borrower shall deliver to the Collateral Agent by electronic mail or facsimile such completed Advance Request Form no later than such date that is thirty (30) days prior to the Tranche C Closing Date and in any event not later than August 30, 2024; provided, finally, that, with respect to the Tranche D Loan, Borrower shall deliver to the Collateral Agent by electronic mail or facsimile such completed Advance Request Form no later than such date that is sixty (60) days prior to the Tranche D Closing Date and in any event not later than June 30, 2025. Notwithstanding anything herein to the contrary, the parties hereto agree that (x) the delivery by Borrower to the Collateral Agent and Lenders by electronic mail or facsimile of a completed Advance Request Form for the Tranche C Loan no later than such date that is thirty (30) days prior to the Tranche C Closing Date is a condition precedent to each Lender's obligation to advance its Applicable Percentage of the Tranche C Loan hereunder and (y) Borrower's failure to deliver a completed Advance Request Form with respect to the Tranche C Loan by the date that is thirty (30) days prior to the Tranche C Closing Date will not, by itself, constitute an Event of Default hereunder.

4 REPRESENTATIONS AND WARRANTIES

In order to induce each Lender and the Collateral Agent to enter into this Agreement and for each Lender to make the Credit Extensions to be made on the applicable Closing Date, each Credit Party, jointly and severally with each other Credit Party, represents and warrants to each Lender and the Collateral Agent that the following statements are true and correct as of the Effective Date and on the applicable Closing Date on which each Term Loan is made (both with and without giving effect to the Term Loans) except as otherwise specified below:

4.1 Due Organization, Existence, Power and Authority

. Parent and each of its Subsidiaries (a) is duly incorporated, organized or formed, and validly existing and, where applicable, in good standing under the laws of its jurisdiction of incorporation, organization or formation identified on Schedule 4.15 of the Disclosure Letter, (b) has all requisite power and authority to (i) own, lease, license and operate its assets and properties and to carry on its business as currently conducted and (ii) execute and deliver the Loan Documents to which it is a party and to perform its obligations thereunder and otherwise carry out the transactions contemplated thereby, (c) is duly qualified and, where applicable, in good standing under the laws of each jurisdiction where its ownership, lease, license or operation of assets or properties or the conduct of its business requires such qualification, and (d) has all requisite Governmental Approvals to operate its business as currently conducted; except in each case referred to clauses (a) (other than with respect to Borrower and any other Credit Party), (b)(i), (c) or (d) above, to the extent that failure to do so could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.2 Equity Interests

. All of the outstanding Equity Interests in each Subsidiary of Parent, the Equity Interests in which are required to be pledged pursuant to the Collateral Documents, have been duly authorized and validly issued, are (where required by Requirements of Law to be) fully paid and, in the case of Equity Interests representing corporate interests, are non-assessable and, on the applicable Closing Date, all such Equity Interests owned directly by Parent or any other Credit Party are owned free and clear of all Liens except for Permitted Liens. Schedule 4.2 of the Disclosure Letter identifies each Person, the Equity Interests in which are required to be pledged on the Tranche A Closing Date (or the Tranche B Closing Date, if applicable) pursuant to the Collateral Documents.

4.3 Authorization; No Conflict

. Except as set forth on Schedule 4.3 of the Disclosure Letter, the execution, delivery and performance by each Credit Party of the Loan Documents to which it is a party, and the consummation of the transactions contemplated thereby, (a) have been duly authorized by all necessary corporate or other organizational action and (b) do not and will not (i) contravene the terms of any of such Credit Party's Operating Documents, (ii) conflict with or result in any breach or contravention of, or require any payment to be made under (A) any provision of any security issued by such Person or of any agreement, instrument or other undertaking to which such Credit Party is a party or affecting such Credit Party or the assets or properties of such Credit Party or any of its Subsidiaries or (B) any order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which such Credit Party or any of its properties or assets are subject, (iii) result in the creation of any Lien (other than under the Loan Documents) or (iv) violate any Requirements of Law, except, in the cases of clauses (b)(ii) and (b)(iv) above, to the extent that such conflict, breach, contravention, payment or violation could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.4 Government Consents; Third Party Consents

. Except as set forth on Schedule 4.4 of the Disclosure Letter, no Governmental Approval or other approval, consent, exemption or authorization, or other action by, or notice to, or filing with, any Governmental Authority or any other Person (including any counterparty to any Company IP Agreement or other Material Contract) is necessary or required in connection with (a) the execution, delivery or performance by, or enforcement against, any Credit Party of this Agreement or any other Loan Document, or for the consummation of the transactions contemplated hereby or thereby, (b) the grant by any Credit Party of the Liens granted by it pursuant to the Collateral Documents, (c) the perfection or maintenance of the Liens created under the Collateral Documents (including the priority thereof) or (d) the exercise by the Collateral Agent or any Lender of its rights under the Loan Documents or the remedies in respect of the Collateral pursuant to the Collateral Documents, except in each case of clause (a) through (d) above, for (i) filings necessary to perfect the Liens on the Collateral granted by the Credit Parties to the Collateral Agent for the benefit of Lenders and the other Secured Parties, (ii) the approvals, consents, exemptions, authorizations, actions, notices and filings which have been duly obtained, taken, given or made and are in full force and effect, (iii) filings under state or federal securities laws and (iv) those approvals, consents, exemptions, authorizations or other actions, notices or filings, the failure of which to obtain or make could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.5 Binding Obligation

. This Agreement has been duly executed and delivered by Borrower and each other Credit Party that is a party hereto and each other Loan Document has been duly executed and delivered by each Credit Party that is a party thereto, and in each case constitutes a legal, valid and binding obligation of Borrower or such Credit Party (as applicable), enforceable against Borrower or such Credit Party (as applicable) in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by general principles of equity.

4.6 Collateral

. In connection with this Agreement, Parent has delivered to the Collateral Agent a completed certificate signed by a Responsible Officer of Parent (the "**Perfection Certificate**"). Each Credit Party, jointly and severally, represents and warrants to the Collateral Agent and each Lender that:

(a) (i) its exact legal name is that indicated on the Perfection Certificate and on the signature page thereof; (ii) it is an organization of the type and is organized in the jurisdiction set forth in the Perfection Certificate; (iii) the Perfection Certificate accurately sets forth its organizational identification number or accurately states that it has none; (iv) the Perfection Certificate accurately sets forth as of the applicable Closing Date its place of business, or, if more than one, its chief executive office as well as its mailing address (if different than its chief executive office); (v) except as set forth in the Perfection Certificate, it (and each of its predecessors) has not, in the five (5) years prior to the applicable Closing Date, changed its jurisdiction of formation, organizational structure or type, or any organizational number assigned by its jurisdiction; and (vi) all other information set forth on the Perfection Certificate pertaining to it and each of its Subsidiaries is accurate and complete in all material respects as of the applicable Closing Date (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificate after the Effective Date to the extent expressly permitted by one or more provisions in this Agreement and the other Loan Documents to reflect changes since the Effective Date, provided that in no event may the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)). If any Credit Party is not now a Registered Organization but later becomes one, it shall promptly notify the Collateral Agent of such occurrence and provide the Collateral Agent with such Credit Party's organizational identification number. The Collateral Agent and each Lender hereby agree that the Perfection Certificate shall be deemed to be updated to reflect information provided in any notice delivered by any Credit Party to the Collateral Agent pursuant to Section 6.2.

(b) (i) it has good and valid title to, has the rights it purports to have in, and subject to Permitted Subsidiary Distribution Restrictions, Permitted Negative Pledges and the occurrence of the applicable Closing Date, the power to transfer each item of the Collateral upon which it purports to grant a Lien under any Collateral Document, free and clear of any and all Liens except Permitted Liens and except for such minor irregularities or defects in title as could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change and (ii) it has no deposit accounts maintained at a bank or other depository or financial institution which are not Excluded Accounts other than the deposit accounts described in the Perfection Certificate delivered to the Collateral Agent in connection herewith.

(c) a true, correct and complete list of each pending, registered, issued or in-licensed Patent, Copyright and Trademark that relates to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory and that, individually or when taken together with any other such Patents, Copyrights or Trademarks, is material to the business of Parent and its Subsidiaries, taken as a whole, which is owned or co-owned by or exclusively or nonexclusively in-licensed to any Credit Party or any of its Subsidiaries as of the Effective Date and on the applicable Closing Date (collectively, the "**Current Company IP**"), including its name/title, current owner or co-owners (including ownership interest), registration, patent or application number, and registration or application date, in each jurisdiction where issued or filed in the Territory, is set forth on Schedule 4.6(c) of the Disclosure Letter. Except as set forth on Schedule 4.6(c) of the Disclosure Letter: (i)(A) each item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries is valid, subsisting and, to the Knowledge of such Credit Party, is enforceable (or will be enforceable upon issuance) and no item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries has in any respect lapsed or expired, been cancelled, held unpatentable or invalidated, or become abandoned or unenforceable (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment), and, to the Knowledge of such Credit Party, no circumstance or grounds exist that would invalidate or reduce, in whole or in part, the validity, enforceability, subsistence or scope of any such Current Company IP, or the ownership or use of such Current Company IP, by any Credit Party or any of its Subsidiaries, and (B) no written notice has been received challenging the validity, patentability, enforceability, inventorship or ownership (other than from patent and trademark offices through the normal prosecution practices), or relating to any lapse, expiration, invalidation, cancellation, abandonment or unenforceability, of any item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment); and (ii) to the Knowledge of such Credit Party, (A) each item of Current Company IP that is exclusively or nonexclusively in-licensed from another Person is valid, subsisting and enforceable and no item of Current Company IP that is exclusively or nonexclusively in-licensed by a Credit Party or any of its Subsidiaries has in any respect lapsed or expired, been cancelled, held unpatentable or invalidated, or become abandoned or unenforceable (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment of licensor), and (B) no written notice has been received challenging the validity, patentability, enforceability, inventorship or ownership, or relating to any lapse, expiration, invalidation, cancellation, abandonment or unenforceability, of any item of Current Company IP that is exclusively or nonexclusively in-licensed by a Credit Party or any of its Subsidiaries (other than from patent and trademark offices through the licensor's normal prosecution practices). Each Credit Party or any of its Subsidiaries possesses valid title to the Current Company IP for which it is listed as the owner or co-owner, as applicable, on Schedule 4.6(c) of the Disclosure Letter. There are no Liens on any Current Company IP other than Permitted Liens. Except as set forth on Schedule 4.6(c) of the Disclosure Letter, (x) each Person who has or has had any rights in or to owned Current Company IP or any trade secrets owned by any Credit Party or any of its Subsidiaries, including each inventor named on the Patents within such owned Current Company IP filed by any Credit Party or any of its Subsidiaries has executed an agreement assigning his, her or its entire right, title and interest in and to such owned Current Company IP and such trade secrets, and the inventions, improvements, ideas, discoveries, writings, works of authorship, information and other intellectual property embodied, described or claimed therein, to the stated owner thereof, and (y) to the Knowledge of such Credit Party, no such Person has any contractual or other obligation that would preclude or conflict with such assignment or the exploitation of Product in the Territory or entitle such Person to ongoing payments. To the Knowledge of such Credit Party, there are no issued patents or pending patent applications, which, if issued, could reasonably be expected to materially adversely affect the exploitation of Product in the Territory.

(d) There are no maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is owned by or exclusively or nonexclusively licensed to any Credit Party or any of its Subsidiaries, nor have any applications or registrations therefor lapsed or become abandoned, been cancelled or expired (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment of the Credit Party, its Subsidiary and/or the licensor), in each case, except as would not reasonably be expected to result in a Material Adverse Change.

(e) There are no unpaid fees, royalties or indemnification payments under any Company IP Agreement that have become due, or are reasonably expected to become due or overdue except as would not reasonably be expected to result in a Material Adverse Change. Each Company IP Agreement is in full force and effect and, to the Knowledge of such Credit Party, is legal, valid, binding, and enforceable in accordance with its respective terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by equitable principles relating to enforceability. Neither Parent nor any of its Subsidiaries, as applicable, is in material breach of or material default under any Company IP Agreement to which it is a party or may otherwise be bound, and to the Knowledge of such Credit Party, no circumstances or grounds exist that would give rise to a claim of material breach or right of rescission, termination, non-renewal, revision, or amendment of any of the Company IP Agreements, including the execution, delivery and performance of this Agreement and the other Loan Documents.

(f) No payments by any Credit Party or any of its Subsidiaries are due to any other Person in respect of the Current Company IP, other than pursuant to the Company IP Agreements, the Pre-Paid Forward Contract, and those fees payable to patent offices in connection with the prosecution and maintenance of the Current Company IP and associated attorney fees.

(g) Except as noted on Schedule 4.6(g) of the Disclosure Letter, no Credit Party is a party to, nor is it bound by, any Excluded License or Restricted License.

(h) No Credit Party or any of its Subsidiaries has undertaken or omitted to undertake any acts, and, to the Knowledge of such Credit Party, no circumstance or grounds exist that would invalidate or reduce, in whole or in part, the enforceability or scope of (i) the Current Company IP in any manner that could reasonably be expected to materially adversely affect the exploitation of Product in the Territory, or (ii) any Credit Party's or Subsidiary's entitlement to own or license and exploit any Current Company IP in any manner other than with respect to Permitted Licenses and in-licenses and except as set forth on Schedule 4.6(h) of the Disclosure Letter.

(i) Except as set forth on Schedule 4.6(i) of the Disclosure Letter, to the Knowledge of such Credit Party, there is no product or other technology of any third party that could reasonably be expected to infringe a Patent within the Current Company IP.

(j) Except as set forth on Schedule 4.6(j) of the Disclosure Letter, in each case where an issued Patent within the Current Company IP that is material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory is owned or co-owned by any Credit Party or its Subsidiaries by assignment, the assignment has been duly recorded with the U.S. Patent and Trademark Office and foreign offices and agencies anywhere in the world in which foreign counterparts are registered, filed or issued.

(k) There are no pending or, to the Knowledge of such Credit Party, threatened (in writing) claims against Parent or any of its Subsidiaries alleging (i) that any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory infringes or violates (or in the past infringed or violated), or form a reasonable basis for a claim of infringement or violation of, any of the rights of any third parties in or to any Intellectual Property ("**Third Party IP**") or constitutes a misappropriation (or in the past constituted a misappropriation) of any Third Party IP, or (ii) that any Current Company IP is invalid, unpatentable or unenforceable (other than from patent and trademark offices through the normal prosecution practices).

(l) To the Knowledge of such Credit Party, the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory has not in the past and does not(i) infringed or infringe or violated or violate, or formed or form a reasonable basis for a claim of infringement or violation of, any of the rights of any third parties in or to any Third Party IP or (ii) constituted or constitute a misappropriation of any Third Party IP.

(m) Except as set forth on Schedule 4.6(m) of the Disclosure Letter, to the Knowledge of the Borrower, there are no settlements, covenants not to sue, consents, judgments, orders or similar obligations which: (i) restrict the rights of any Credit Party or any of its Subsidiaries to use any Intellectual Property relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory (in order to accommodate any Third Party IP or otherwise), or (ii) permit any third parties to use any Company IP existing as of the Effective Date and on the applicable Closing Date.

(n) Except as set forth on Schedule 4.6(n) of the Disclosure Letter, to the Knowledge of such Credit Party, (i) there is no, nor has there been any, infringement or violation by any Person of any of the Company IP existing as of the Effective Date and on the applicable Closing Date or any of the rights therein, and (ii) there is no, nor has there been any, misappropriation by any Person of any of the Company IP existing as of the Effective Date and on the applicable Closing Date or any of the subject matter thereof.

(o) Each Credit Party and each of its Subsidiaries has taken all commercially reasonable measures customary in the life sciences industry, to protect the confidentiality and value of all trade secrets owned by such Credit Party or any of its Subsidiaries or used or held for use by such Credit Party or any of its Subsidiaries, in each case relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory. Any disclosure by a Credit Party or any of its Subsidiaries of any such trade secrets to any third party has been pursuant to the terms of a written agreement (including appropriate confidentiality, access, use and non-disclosure provisions) with such third party, and no Credit Party or any of its Subsidiaries has suffered any material data breach or other incident that has resulted in any loss, unauthorized access, use, disclosure or modification of any such trade secrets.

(p) Except as set forth on Schedule 4.6(p) of the Disclosure Letter, to the Knowledge of such Credit Party, Product sold under the Patents in the U.S. within the Current Company IP has been marked with the proper patent notice.

(q) Except as set forth on Schedule 4.6(q) of the Disclosure Letter, to the Knowledge of such Credit Party, at the time of any shipment of Product occurring prior to the applicable Closing Date, the units thereof so shipped complied in all material respects with their relevant specifications and were developed and manufactured in accordance with current Good Manufacturing Practices and other applicable Requirements of Law.

(r) The Collateral Documents create in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a valid and continuing and, upon the making of the filings and the taking of the actions required under the terms of the Loan Documents (except to the extent not required to be perfected pursuant to the terms of the Loan Documents), perfected Lien on and security interest in the Collateral (in each case, solely to the extent perfection is available under applicable law through the making of such filings and taking of such actions), securing the payment of the Obligations, and having priority over all other Liens on and security interests in the Collateral (except Permitted Liens).

4.7 Adverse Proceedings, Compliance with Laws and Settlement Agreements

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(a) As of the Tranche A Closing Date: (i) except as set forth on Schedule 4.7 of the Disclosure Letter, there are no Adverse Proceedings pending or, to the Knowledge of such Credit Party, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against Parent or any of its Subsidiaries; and (ii) neither Borrower nor any of its Subsidiaries (A) is in violation of any Requirements of Law, excluding any Requirement of Law which is being contested in good faith by appropriate proceedings, or (B) is subject to or in default with respect to any final judgments, orders, writs, injunctions, settlement agreements, decrees, rules or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign.

(b) As of the Tranche B Closing Date: (i) except as set forth on Schedule 4.7 of the Disclosure Letter, there are no Adverse Proceedings pending or, to the Knowledge of such Credit Party, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against Parent or any of its Subsidiaries that either individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change; and (ii) neither Parent nor any of its Subsidiaries (A) is in violation of any Requirements of Law (including Environmental Laws), excluding any Requirement of Law which is being contested in good faith by appropriate proceedings, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, or (B) is subject to or in default with respect to any final judgments, orders, writs, injunctions, settlement agreements, decrees, rules or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change.

(c) As of the Tranche C Closing Date: (i) except as set forth on Schedule 4.7 of the Disclosure Letter, there are no Adverse Proceedings pending or, to the Knowledge of such Credit Party, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against Parent or any of its Subsidiaries that either individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change; and (ii) neither Parent nor any of its Subsidiaries (A) is in violation of any Requirements of Law (including Environmental Laws), excluding any Requirement of Law which is being contested in good faith by appropriate proceedings, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, or (B) is subject to or in default with respect to any final judgments, orders, writs, injunctions, settlement agreements, decrees, rules or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change.

(d) As of the Tranche D Closing Date: (i) except as set forth on Schedule 4.7 of the Disclosure Letter, there are no Adverse Proceedings pending or, to the Knowledge of such Credit Party, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against Parent or any of its Subsidiaries that either individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change; and (ii) neither Parent nor any of its Subsidiaries (A) is in violation of any Requirements of Law (including Environmental Laws), excluding any Requirement of Law which is being contested in good faith by appropriate proceedings, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, or (B) is subject to or in default with respect to any final judgments, orders, writs, injunctions, settlement agreements, decrees, rules or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change.

(e) Each of Parent and its Subsidiaries (and, to Parent's Knowledge, each other party thereto) is in compliance in all material respects with the terms of all settlement agreements (relating to any Adverse Proceeding) to which Parent or any Subsidiary is a party.

4.8 Exchange Act Documents; Financial Statements; Financial Condition; No Material Adverse Change; Books and Records

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(a) The Exchange Act Documents filed by Parent with the SEC since December 31, 2020, when they were filed with the SEC, conformed in all material respects to the requirements of the Exchange Act, and as of the time they were filed with the SEC, none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (excluding any projections and forward-looking statements, estimates, budgets and general economic or industry data of a general nature), in the light of the circumstances under which they were made, not misleading; provided, that, with respect to projected financial information, Parent represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projections are not a guarantee of financial performance and are subject to uncertainties and contingencies, many of which are beyond the control of Parent or any Subsidiary, and neither Parent nor any Subsidiary can give any assurance that such projections will be attained, that actual results may differ in a material manner from such projections and any failure to meet such projections shall not be deemed to be a breach of any representation or covenant herein).

(b) The financial statements (including the related notes thereto) of Parent and its Subsidiaries included in the Exchange Act Documents present fairly in all material respects the consolidated financial condition of Parent and such Subsidiaries and their consolidated results of operations as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified. Such financial statements have been prepared in conformity with Applicable Accounting Standards applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes, and any supporting schedules included in the Exchange Act Documents present fairly in all material respects the information required to be stated therein.

(c) Since December 31, 2020, there has not occurred any change or event that has had or could reasonably be expected to have, either alone or in conjunction with any other change(s), event(s) or failure(s), a Material Adverse Change.

(d) The Books of Parent and each of its Subsidiaries contain full, true and correct entries of all dealings and transactions in relation to its business and activities in conformity in all material respects with Applicable Accounting Standards and Requirements of Law.

4.9 Solvency

. Each Credit Party and its Subsidiaries, on a consolidated basis, are Solvent. Without limiting the generality of the foregoing, there has been no proposal made or resolution adopted by any competent corporate body for the dissolution or liquidation of any Credit Party, nor do any circumstances exist which may result in the dissolution or liquidation of any Credit Party (other than in respect of a dissolution or liquidation expressly permitted under Section 6.3(a)(iii)).

4.10 Taxes

. All U.S. federal, state, local and non-U.S. income and other material Tax returns of each Credit Party and each of its Subsidiaries required to be filed by any of them (or an extension has been obtained for the filing thereof) have been timely filed and are correct in all material respects, and all U.S. federal, state, local and non-U.S. Taxes which are due and payable by any Credit Party or any of its Subsidiaries have been paid when due and payable, except where the validity or amount thereof is being contested in good faith by appropriate proceedings; provided that no such Tax or any claim for Taxes that have become due and payable shall be required to be paid if, in each case, (a) the applicable Credit Party has set aside on its books adequate reserves therefor in conformity with Applicable Accounting Standards, or (b) the failure to timely file such Tax returns or the failure to pay such Taxes, could not reasonably be expected to result in a Material Adverse Change. There is no proposed Tax assessment against any Credit Party or any of its Subsidiaries that would, if made, result in a Material Adverse Change.

4.11 Environmental Matters

. Neither Parent nor any of its Subsidiaries nor any of their respective Facilities or operations is subject to any outstanding written order, consent decree or settlement agreement with any Person relating to any Environmental Law, any Environmental Claim, or any Hazardous Materials Activity that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. There are and, to the Knowledge of such Credit Party, have been, no conditions, occurrences, or Hazardous Materials Activities that would reasonably be expected to form the basis of an Environmental Claim against Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. To the Knowledge of such Credit Party, no predecessor of Parent or any of its Subsidiaries has filed any notice under any Environmental Law indicating past or present treatment of Hazardous Materials at any Facility, which would reasonably be expected to form the basis of an Environmental Claim against Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change (but, for the avoidance of doubt, neither Parent nor Borrower has undertaken any investigation of or made any inquiries to, or relating to, any of its or its Subsidiaries' predecessors), and neither Parent's nor any of its Subsidiaries' operations involves the generation, transportation, treatment, storage or disposal of hazardous waste, as defined under 40 C.F.R. Parts 260 – 270 or any foreign or United States state equivalents, which would reasonably be expected to form the basis of an Environmental Claim against Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. No event or condition has occurred or is occurring with respect to any Credit Party relating to any Environmental Law, any Release of Hazardous Materials, or any Hazardous Materials Activity that, individually or in the aggregate, has resulted in, or could reasonably be expected to result in, a Material Adverse Change.

4.12 Material Contracts

. After giving effect to the consummation of the transactions contemplated by this Agreement, except as described on Schedule 4.12 of the Disclosure Letter, each Material Contract is a valid and binding obligation of the applicable Credit Party and, to the Knowledge of such Credit Party, each other party thereto, and is in full force and effect, and neither the applicable Credit Party nor, to the Knowledge of such Credit Party, any other party thereto is in material breach thereof or default thereunder, except where such breach or default (which default has not been cured or waived) could not reasonably be expected to give rise to any cancellation, termination or acceleration right of the applicable counterparty thereto or result in the invalidation thereof. No Credit Party or any of its Subsidiaries has received any written notice from any party to any Material Contract asserting or threatening to assert, circumstances that could reasonably be expected to result in the cancellation, termination or invalidation of any Material Contract (or any provision thereof) or the acceleration of such Credit Party's or Subsidiary's obligations thereunder.

4.13 Regulatory Compliance

. No Credit Party is or is required to be registered as, or is a company "controlled" by, an "investment company" as defined in, or is subject to regulation under, the Investment Company Act of 1940. Each Credit Party has complied in all material respects with the Federal Fair Labor Standards Act (and any foreign or United States state equivalent). Except as could not, either individually or in the aggregate, reasonably be expected to result in a Material Adverse Change, each Plan is in compliance with the applicable provisions of ERISA, the IRC and other U.S. federal or state or foreign Requirements of Law, respectively. (i) No ERISA Event has occurred or is reasonably expected to occur; (ii) neither any Credit Party nor any ERISA Affiliate has incurred, or reasonably expects to incur, any liability (and no event has occurred which, with the giving of notice under Section 4219 of ERISA, would result in such liability) under Section 4201 *et seq*. of ERISA with respect to a Multiemployer Plan; and (iii) neither any Credit Party nor any ERISA Affiliate has engaged in a transaction that would be subject to Section 4069 or 4212(c) of ERISA, except, with respect to each of clauses (i), (ii) and (iii) above, as could not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

4.14 Margin Stock

. No Credit Party is engaged principally, or as one of its important activities, in extending credit for the purpose of, whether immediate or ultimate, of purchasing or carrying Margin Stock. No Credit Party owns any Margin Stock. No Credit Party or any of its Subsidiaries has taken or permitted to be taken any action that might cause any Loan Document to violate Regulation T, U or X of the Federal Reserve Board.

4.15 Subsidiaries; Capitalization

. Schedule 4.15 of the Disclosure Letter includes a complete and accurate list as of the applicable Closing Date of Parent and each of its Subsidiaries, setting forth (a) its name and jurisdiction of incorporation, organization or formation, (b) in the case of each Credit Party (other than the Parent), the number of authorized and issued shares of each class of its Equity Interests outstanding, and (c) the percentage of its outstanding shares of each class owned (directly or indirectly) by Parent or any of its Subsidiaries and the certificate numbers(s) for the same (if any), and (d) the number and effect, if exercised, of all of its outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto. Except as set forth on Schedule 4.15 of the Disclosure Letter, no Credit Party is a Registered Organization.

4.16 Employee Matters

. Neither Parent nor any of its Subsidiaries is engaged in any unfair labor practice that could reasonably be expected to result in a Material Adverse Change. There is (a) no unfair labor practice complaint pending against Parent or any of its Subsidiaries or, to the Knowledge of Parent, threatened in writing against any of them before the National Labor Relations Board, and no grievance or arbitration proceeding arising out of or under any collective bargaining agreement that is pending against Parent or any of its Subsidiaries or, to the Knowledge of Parent, threatened in writing against any of them, (b) no strike or work stoppage in existence or, to the Knowledge of Parent, threatened in writing involving Parent or any of its Subsidiaries, and (c) to the Knowledge of Parent, no union representation question existing with respect to the employees of Parent or any of its Subsidiaries and, to the Knowledge of

Parent, no union organization activity that is taking place that in each case specified in any of clauses (a), (b) and (c) above, individually or taken together with any other matter specified in clause (a), (b) or (c) above, could reasonably be expected to result in a Material Adverse Change.

4.17 Full Disclosure

. None of the documents, certificates or written statements (excluding any projections and forward-looking statements, estimates, budgets and general economic or industry data of a general nature) furnished or otherwise made available to the Collateral Agent or any Lender by or on behalf of any Credit Party for use in connection with the transactions contemplated hereby (in each case, taken as a whole and as modified or supplemented by other information so furnished promptly after the same becomes available, including the information in the Exchange Act Documents) contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein, as of the time when made or delivered, not misleading in light of the circumstances in which the same were made; provided, that, with respect to projected financial information, Parent represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projections are not a guarantee of financial performance and are subject to uncertainties and contingencies, many of which are beyond the control of Parent or any Subsidiary, and neither Parent nor any Subsidiary can give any assurance that such projections will be attained, that actual results may differ in a material manner from such projections and any failure to meet such projections shall not be deemed to be a breach of any representation or covenant herein). To the Knowledge of Parent, there are no facts (other than matters of a general economic or industry nature) that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change and that have not been disclosed herein or in such other documents, certificates and written statements furnished or made available to the Collateral Agent or any Lender for use in connection with the transactions contemplated hereby.

4.18 FCPA; Patriot Act; OFAC; Export and Import Laws

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(a) None of Parent, its Subsidiaries or, to the Knowledge of Parent, any director, officer, agent or employee of Parent or any Subsidiary of Parent has, at any time in the last five (5) years, (i) used any corporate funds of Parent or any Subsidiary of Parent (including Borrower) for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity, (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee or any Person acting in official capacity from corporate funds of Parent or any Subsidiary of Parent (including Borrower), (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**") or the U.K. Bribery Act 2010 ("**UKBA**") or (iv) made any bribe, improper rebate, payoff, influence payment, kickback or other unlawful payment, and no part of the proceeds of any Credit Extension will be used, directly or indirectly, for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else acting in official capacity, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other applicable anti-corruption laws.

(b) (i) The operations of Parent and its Subsidiaries are and have been conducted at all times in the last five (5) years in compliance with applicable financial recordkeeping and reporting requirements of the Bank Secrecy Act of 1970 (as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001) and the anti-money laundering laws, rules and regulations of each jurisdiction (foreign or domestic) in which Parent or any of its Subsidiaries is subject to such jurisdiction's Requirements of Law (collectively, the "**Anti-Money Laundering Laws**") and (ii) no action, suit or proceeding by or before any Governmental Authority or any arbitrator involving Parent or any of its Subsidiaries with respect to the Anti-Money Laundering Laws is pending or to the Knowledge of Parent, threatened in writing.

(c) None of Parent, its Subsidiaries or, to the Knowledge of Parent, any director, officer, agent or employee of Parent or any Subsidiary of Parent is, or is fifty percent (50.0%) or more owned or otherwise controlled by individuals or entities that are, the target or subject of any economic, trade or financial sanctions or restrictive measures administered and enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), the U.S. Department of State, the U.S. Department of Commerce, the United Nations Security Council, the European Union or the United Kingdom (collectively "**Sanctions**"). Borrower will not, directly or, to the Knowledge of Parent, indirectly through an agent, use the proceeds of any Credit Extension, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person, for (i) the purpose of financing the activities of any Person that is the target or subject of Sanctions or (ii) any purpose that could cause any Lender or the Collateral Agent to be in violation of Sanctions.

(d) Borrower will not, directly or, to the Knowledge of Parent, indirectly through an agent or any other Person, use any of the proceeds of any Credit Extension, or lend, contribute or otherwise make available such proceeds of any Credit Extension to any Subsidiary, joint venture partner or other Person, (i) for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other applicable anti-corruption laws, (ii) in violation of any Anti-Money Laundering Laws, or (iii) in violation of Sanctions;

(e) Parent, its Subsidiaries, and to the Knowledge of Parent, their respective directors, officers, agents and employees, are in compliance with all applicable Sanctions. Parent and its Subsidiaries have instituted and maintain appropriate policies reasonably designed to ensure compliance with applicable Sanctions and applicable anti-corruption laws, including the FCPA and UKBA.

(f) Parent and its Subsidiaries are in compliance in all material respects with applicable Export and Import Laws.

4.19 Health Care Matters

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(a) *Compliance with Health Care Laws*. Except as set forth on Schedule 4.19(a) of the Disclosure Letter, each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries and each officer, Affiliate, and employee acting on behalf of such Credit Party or any of its Subsidiaries, is in compliance in all material respects with all Health Care Laws applicable to such Credit Party or Subsidiary.

(b) *Compliance with FDA Laws*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, are in compliance in all material respects with all applicable FDA Laws, including all applicable requirements of the Food Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) (the "**FDCA**") and the regulations promulgated thereunder and applicable FDA Guidance Documents, relating to research, development, testing, approval, post-approval monitoring, post-approval requirements, post-approval commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of Product

in the Territory. Any Product distributed or sold in the Territory at all times during the past five (5) years has been (i) manufactured in all material respects in accordance with current Good Manufacturing Practices (as applicable), and (ii) if and to the extent such Product is required to be approved by the FDA pursuant to the FDCA in order to be legally marketed in the Territory for such Product's intended uses, such Product has been approved for such intended uses, meets in all material respects any additional conditions of approval or licensure by the FDA (as applicable), and no inquiries regarding material issues have been initiated by FDA, except in each case referred to in sub-clauses (i) or (ii) above, to the extent that any failure to ensure the foregoing could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

(c) *Applicability of Controlled Substances Act*. Product does not contain a controlled substance (as that term is defined under the Controlled Substances Act (21 U.S.C. § 801 et seq.)).

(d) *Material Statements*. Within the past four (4) years, neither any Credit Party, nor, to the Knowledge of such Credit Party, any Subsidiary or any officer, Affiliate or employee of any Credit Party or Subsidiary in its capacity as a Subsidiary or as an officer, Affiliate or employee of a Credit Party or Subsidiary (as applicable), nor, to the Knowledge of such Credit Party, any agent of any Credit Party or Subsidiary, (i) has made an untrue statement of a material fact or a fraudulent statement to any Governmental Authority, (ii) has failed to disclose a material fact to any Governmental Authority, or (iii) has otherwise committed an act, made a statement or failed to make a statement that, at the time such statement or disclosure was made (or, in the case of such failure, should have been made) or such act was committed, could reasonably be expected to constitute a material violation of any Health Care Law.

(e) *Proceedings; Audits*. Without limiting the generality of Section 4.7, except as has been set forth on Schedule 4.19(e) of the Disclosure Letter: (i) to the Knowledge of such Credit Party, there is no Adverse Proceeding pending, or threatened in writing, against any Credit Party or any of its Subsidiaries relating to any allegations of non-compliance with any Health Care Laws, Data Protection Laws or FDA Laws; and (ii) to the Knowledge of such Credit Party, there are no facts, circumstances or conditions that, individually or in the aggregate, could reasonably be expected to form the basis for any allegations of non-compliance with any Health Care Laws, Data Protection Laws or FDA Laws.

(f) *Recalls, Safety Notices, Etc*. Neither any Credit Party nor any of its Subsidiaries has initiated or otherwise engaged in any recalls, field notifications, safety warnings, "dear doctor" letters, investigator notices, safety alerts or other notices of action, including as a result of any Risk Evaluation and Mitigation Strategy proposed or enforced by the FDA, relating to an alleged lack of safety or regulatory compliance of Product. Neither any Credit Party nor any of its Subsidiaries has a reasonable expectation that there are grounds for imposition of a clinical hold, as described in 21 C.F.R. § 312.42.

(g) *Preclinical Studies / Clinical Trials*. All pre-clinical and clinical studies relating to Product conducted by or on behalf of any Credit Party or any of its Subsidiaries have been, or are being, conducted in material compliance with all applicable Requirements of Law, including the requirements of Good Laboratory Practices and Good Clinical Practice, including regulations under the Common Rule, including regulations under 45 C.F.R. part 46, and guidance documents issued by the Office for Human Research Protection, the Animal Welfare Act and applicable experimental protocols, procedures and controls (and any applicable foreign or United States state equivalents), and, for the avoidance of doubt, all applicable foreign (and United States state) equivalents. No clinical trial conducted by or on behalf of any Credit Party or any of its Subsidiaries has been terminated or suspended by any Regulatory Agency and neither any Credit Party nor any of its Subsidiaries has received any notice that the FDA, any other Governmental Authority or any institutional review board, ethics committee or safety monitoring committee has recommended, initiated or threatened in writing to initiate any action to suspend or terminate any clinical trial conducted by or on behalf of any Credit Party or any of its Subsidiaries or to otherwise restrict the preclinical research on or clinical study of Product.

(h) *Advertising / Promotion*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, officers, employees and agents has advertised, promoted, marketed and distributed Product in compliance in all material respects with FDA Laws and other Requirements of Law. Except as set forth on Schedule 4.19(h) of the Disclosure Letter, neither any Credit Party nor, to the Knowledge of such Credit Party, any of its Subsidiaries, officers, employees or agents has received any notice (including any notice under 21 C.F.R. § 316.36) of or is subject to any civil, criminal or administrative action, suit, demand, claim, complaint, hearing, investigation, demand letter, warning letter, untitled letter, proceeding or request for information from the FDA or any other Governmental Authority concerning noncompliance with any FDA Laws or other Requirements of Law with regard to advertising, promoting, marketing or distributing Product.

(i) *Recordkeeping / Reporting*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, has maintained records relating to the research, development, testing, manufacture, recall, production, handling, labeling, packaging, storage, supply, promotion, distribution, marketing, commercialization, import, export and sale of Product in compliance in all material respects with FDA Laws, Health Care Laws and other applicable Requirements of Law, and each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, has submitted to the FDA and other Regulatory Authorities in a timely manner all notices and annual or other reports required to be made by it, including adverse experience reports and annual reports (including annual reports specific to holders of Orphan Drug designations), for Product save to the extent that could not reasonably be expected to have a materially adverse impact on such Credit Party's or Subsidiary's rights in respect of Product.

(j) *Prohibited Transactions; No Whistleblowers*. Except as set forth on Schedule 4.19(j) of the Disclosure Letter, within the past six (6) years, to the Knowledge of such Credit Party, neither any Credit Party, any Subsidiary, any of officer, Affiliate or employee of a Credit Party or Subsidiary, nor any other Person acting on behalf of any Credit Party or any Subsidiary, directly or indirectly: (i) has offered or paid any remuneration, in cash or in kind, to, or made any financial arrangements with, any past, present or potential patient, supplier, physician or contractor, in order to illegally obtain business or payments from such Person in material violation of any Health Care Law; (ii) has given or made, or is party to any illegal agreement to give or make, any illegal gift or gratuitous payment of any kind, nature or description (whether in money, property or services) to any past, present or potential patient, supplier, physician or contractor, or any other Person in material violation of any Health Care Law; (iii) has given or made, or is party to any agreement to give or make on behalf of any Credit Party or any of its Subsidiaries, any contribution, payment or gift of funds or property to, or for the private use of, any governmental official, employee or agent where either the contribution, payment or gift or the purpose of such contribution, payment or gift is or was a material violation of the laws of any Governmental Authority having jurisdiction over such payment, contribution or gift; (iv) has established or maintained any unrecorded fund or asset for any purpose or made any materially misleading, false or artificial entries on any of its books or records for any reason; or (v) has made, or is party to any agreement to make, any payment to any Person with the intention or understanding that any part of such payment would be in material violation of any Health Care Law. To the Knowledge of such Credit Party, there are no actions pending or threatened (in writing) against any Credit Party or any of its Subsidiaries or any of their respective Affiliates under any foreign, federal or state whistleblower statute, including under the False Claims Act of 1863 (31 U.S.C. § 3729 et seq.).

(k) *Exclusion*. Except as set forth on Schedule 4.19(k) of the Disclosure Letter, neither any Credit Party nor, to the Knowledge of such Credit Party, any Subsidiary or any officer, Affiliate or employee having authority to act on behalf of any Credit Party or any Subsidiary, is or, to the Knowledge of such Credit Party, has been threatened in writing to be: (i) excluded from any Governmental Payor Program pursuant to 42 U.S.C. § 1320a-

7b and related regulations, to the extent applicable; (ii) "suspended" or "debarred" from selling any products to the U.S. government or its agencies pursuant to the Federal Acquisition Regulation relating to debarment and suspension applicable to federal government agencies generally (42 C.F.R. Subpart 9.4), or other U.S. Requirements of Law; (iii) debarred, disqualified, suspended or excluded from participation in Medicare, Medicaid or any other Governmental Payor Program or is listed on the General Services Administration list of excluded parties, to the extent applicable; (iv) debarred by the FDA; or (v) a party to any other action or proceeding by any Governmental Authority that would prohibit the applicable Credit Party or Subsidiary from distributing or selling Product in the Territory or providing any services to any governmental or other purchaser pursuant to any Health Care Laws.

(l) *Health Information*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, to the extent applicable, is in material compliance with all applicable Data Protection Laws. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, to the extent applicable, has implemented adequate policies and procedures that comply with Data Protection Laws as well as training that is reasonable and customary in the pharmaceutical industry, designed to satisfy the requirements of all applicable Requirements of Law (including HIPAA, Section 5 of the FTC Act, Israeli Data Protection Law, GDPR and CCPA, as applicable) and is otherwise designed to assure continued compliance and to detect non-compliance. Neither any Credit Party nor, to the Knowledge of such Credit Party, any Subsidiary that is not a Credit Party, is a "covered entity" or "business associate" as defined in HIPAA (45 C.F.R. § 160.103).

(m) *Corporate Integrity Agreement*. Neither any Credit Party or Subsidiary or any of their respective Affiliates, nor any officer, director, managing employee or, to the Knowledge of such Credit Party, agent (as those terms are defined in 42 C.F.R. § 1001.1001) of any Credit Party or Subsidiary, is a party to or has any ongoing reporting or disclosure obligations under, or is otherwise subject to, any corporate integrity agreement, monitoring agreement, deferred prosecution agreement, consent decree, settlement order or other similar agreements, or any order, in each case imposed by any U.S. Governmental Authority, concerning compliance with any laws, rules or regulations, issued under or in connection with a Governmental Payor Program.

(n) *ESG Policies*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, to the extent applicable, is using best efforts to follow Nasdaq's global environmental, social and governance (ESG) reporting guide dated May 2019.

4.20 Regulatory Approvals

.

(a) Except as set forth on Schedule 4.20(a) of the Disclosure Letter, each Credit Party and each Subsidiary involved in any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory has all Regulatory Approvals material to the conduct of its business and operations.

(b) Each Credit Party, each Subsidiary and, to the Knowledge of such Credit Party, each licensee of a Credit Party or a Subsidiary of any Intellectual Property relating to Product, is in compliance with, and at all times during the past five (5) years, has complied with all applicable foreign, federal, state and local laws, rules and regulations governing the research, development, testing, approval, designations, marketing, exclusivity, post-approval monitoring, post-approval requirements, post-approval commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of Product in the Territory, including all such regulations promulgated by each applicable Regulatory Agency (including the FDA and applicable foreign or United States state equivalents), except where any instance of failure to comply with any such laws, rules or regulations could not, whether individually or taken together with any other such failures, reasonably be expected to result in a Material Adverse Change. Except as set forth on Schedule 4.20(b) of the Disclosure Letter, no Credit Party or its Subsidiaries has received any written notice from any Regulatory Agency citing action or inaction by any Credit Party or any of its Subsidiaries that would constitute a violation of any applicable foreign, federal, state or local laws, rules or regulations, including a Warning Letter or Untitled Letter from FDA.

4.21 Supply and Manufacturing

.

(a) Except as set forth on Schedule 4.21(a) of the Disclosure Letter, to the Knowledge of such Credit Party, Product at all times has been manufactured in sufficient quantities and of a sufficient quality to satisfy demand of Product in the Specified Territory, without the occurrence of any event or any series of related events causing inventory of Product to have become exhausted prior to satisfying such demand. To the Knowledge of such Credit Party, no event or circumstance (or series of related events or circumstances) has occurred that has caused or could reasonably be expected to cause inventory of Product to become exhausted in any calendar year prior to satisfying the sales demand (if any) of Product in the Specified Territory in such calendar year.

(b) Except as set forth on Schedule 4.21(b) of the Disclosure Letter, to the Knowledge of such Credit Party, no event or circumstance (or series of related events or circumstances) has occurred or, in the reasonable business judgment of Parent, is reasonably likely to occur, that would cause or could reasonably be expected to cause JELMYTO® not to be manufactured in any calendar year in sufficient quantities to satisfy or exceed the greater of (i) the net sales amount for such calendar year set forth in the JELMYTO® Revenue Forecast and (ii) the expected needs of patients with the disease or condition for which JELMYTO® was designated as an Orphan Drug for such calendar year, as reasonably determined by Responsible Officers of the Credit Parties in good faith (provided such calendar year occurs during the full 7-year term of orphan drug exclusive approval granted under 21 C.F.R. §316.34 ending April 15, 2027).

(c) Except as set forth on Schedule 4.21(c) of the Disclosure Letter, to the Knowledge of such Credit Party, (i) no manufacturer (including a contract manufacturer) or producer of Product has been or is currently subject to a Regulatory Agency shutdown, restriction or import or export prohibition, (ii) no manufacturer (including a contract manufacturer) or producer of Product has received in the past five (5) years or is currently subject to (1) a FDA Form 483 or (2) other written Regulatory Agency notice of inspectional observations, warning letter, untitled letter or request to make changes to Product that could reasonably be expected to impact Product, in either case of sub-clause (1) or (2) with respect to any material facility manufacturing or producing Product for import, distribution or sale in the Territory, and (iii) with respect to each such FDA Form 483 received or other written Regulatory Agency notice (if any), all scientific and technical violations or other issues relating to good manufacturing practice requirements documented therein, and any disputes regarding any such violations or issues, have been corrected or otherwise resolved.

(d) Except as disclosed in Schedule 4.21(d) of the Disclosure Letter, no Credit Party or any of its Subsidiaries has received any notice from any party to any Manufacturing Agreement containing any indication by or intent or threat in writing of, such party to reduce or cease, in any material respect, the supply of Product or the active pharmaceutical ingredient incorporated therein in the Territory or any other raw materials needed to fulfill its

contractual obligations related to Product in any Manufacturing Agreement through calendar year 2027 (or such earlier date in accordance with the terms and conditions of such Manufacturing Agreement, as applicable).

4.22 Cybersecurity and Data Protection

.

(a) Except as set forth in Schedule 4.22(a) of the Disclosure Letter, the information technology systems used in the business of each of Parent and its Subsidiaries ("**Systems**") operate and perform in all material respects as required to permit each of Parent and its Subsidiaries to conduct their respective businesses as presently conducted in their respective Specified Territory.

(b) Except as set forth on Schedule 4.22(b) of the Disclosure Letter, Parent and each of its Subsidiaries has implemented and maintains a commercially reasonable privacy and information security program ("**Security Program**") that addresses privacy, physical and cyber security, disaster recovery, business continuity and incident response, and that includes reasonable and appropriate administrative, technical and physical safeguards that are designed to protect the integrity and availability of the Systems and to protect against (i) any unauthorized, accidental, or unlawful access to or acquisition, use, disclosure, processing, loss, destruction, or modification of Personal Data that would require notification to affected individuals or any Governmental Authority under any applicable Data Protection Law (each, a "**Personal Data Breach**"), (ii) any unauthorized or unlawful access to or acquisition, use, disclosure, or loss of Sensitive Information that is not Personal Data, and (iii) material security incidents that would result in unauthorized or unlawful access to or acquisition, use, control, disruption, destruction, or modification of any of the Systems (each, a "**Security Incident**").

(c) Parent and each of its Subsidiaries has conducted commercially reasonable privacy and security audits and penetration tests at reasonable intervals on all Systems that maintain, store, or process Sensitive Information. Parent and each of its Subsidiaries has addressed all material privacy or data security issues identified as "critical," "high risk," or similar level of risk rating that are raised in any such audits or penetration tests (including any third party audits of the Systems).

(d) [Reserved]

(e) Except as set forth on Schedule 4.22(e) of the Disclosure Letter, and except as would not reasonably be expected to result in a Material Adverse Change, to the Knowledge of Parent neither Parent nor any of its Subsidiaries, has, in the past three (3) years, suffered any Security Incidents.

(f) Parent and each of its Subsidiaries is in material compliance with the requirements of (i) their respective Security Programs, (ii) applicable Data Protection Laws, (iii) their respective contractual obligations regarding the privacy, security, and notification of breaches of customer, consumer, patient, clinical trial participant, employee, and other Personal Data, (iv) their respective contractual non-disclosure obligations, and (v) their respective publicly available privacy notices and policies.

(g) Except as set forth on Schedule 4.22(g) of the Disclosure Letter, in the past six (6) years: (i) neither Parent nor any of its Subsidiaries has received any written third party claims or, to the Knowledge of Parent, any threat (in writing) of a third party claim, related to any Personal Data Breaches; and (ii) neither Parent nor any of its Subsidiaries has received any written notice of any claims, investigations (including investigations by any Governmental Authority), or alleged violations relating to any Personal Data Breaches.

(h) Parent and each of its Subsidiaries has maintained all database registrations required under applicable Data Protection Laws.

4.23 Additional Representations and Warranties

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(a) After giving effect to consummation of the transactions contemplated by this Agreement, (i) there is no Indebtedness other than Permitted Indebtedness described in clauses (a) and (b) of the definition of Permitted Indebtedness, and (ii) all amounts due and owing by Parent under the Pre-Paid Forward Contract, if any, have been paid in full.

(b) There are no Hedging Agreements.

(c) Any and all payments required to be made to the Israeli Innovation Authority on account of any grants received by Parent or any of its Subsidiaries from the Israeli Innovation Authority for research and development funding or otherwise have been paid in full, and Parent and its Subsidiaries have full freedom to Transfer technology funded with any such grants and manufacture products developed with any such technology anywhere in the Territory.

5 AFFIRMATIVE COVENANTS

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), each Credit Party shall, and shall cause each of its Subsidiaries to:

5.1 Maintenance of Existence

. (a) Preserve, renew and maintain in full force and effect its and all its Subsidiaries' legal existence under the Requirements of Law in their respective jurisdictions of organization, incorporation or formation; (b) take all commercially reasonable action to maintain all rights, privileges (including its good standing), permits, licenses and franchises necessary or desirable for it and all of its Subsidiaries in the ordinary course of its business, except in the case of clause (a) (other than with respect to Parent or Borrower) and clause (b) above, (i) to the extent that failure to do so could not reasonably be expected to result in a Material Adverse Change or (ii) pursuant to a transaction permitted by this Agreement; and (c) comply with all Requirements of Law of any Governmental Authority to which it is subject, except where the failure to do so could not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change.

5.2 Financial Statements, Notices, Reports

. Deliver to the Collateral Agent:

(a) Financial Statements.

(i) Annual Financial Statements. As soon as available, but in any event within ninety (90) days after the end of each fiscal year of Parent (or such earlier date on which Parent is required to file a Form 10-K under the Exchange Act, as applicable), beginning with the fiscal year ending December 31, 2021, a consolidated balance sheet of Parent and its Subsidiaries as of the end of such fiscal year, and the related consolidated statements of income, cash flows and stockholders' equity for such fiscal year, all prepared in accordance with Applicable Accounting Standards, with such consolidated financial statements to be audited and accompanied by (i) a report and opinion of Parent's independent certified public accounting firm of recognized national standing (which report and opinion shall be prepared in accordance with Applicable Accounting Standards and shall not be subject to any qualification as to "going concern" or scope of audit), stating that such financial statements fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of the dates and for the periods specified in accordance with Applicable Accounting Standards, and (ii) if and only if Parent is required to comply with the internal control provisions pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 requiring an attestation report of such independent certified public accounting firm, an attestation report of such independent certified public accounting firm as to Parent's internal controls pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 attesting to management's assessment that such internal controls meet the requirements of the Sarbanes-Oxley Act of 2002; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC);

(ii) Quarterly Financial Statements. As soon as available, but in any event within forty-five (45) days after the end of each of the first three (3) fiscal quarters of each fiscal year of Parent (or such earlier date on which Parent is required to file a Form 10-Q under the Exchange Act, if applicable), beginning with the fiscal quarter ending March 31, 2022, a consolidated balance sheet of Parent and its Subsidiaries as of the end of such fiscal quarter, and the related consolidated statements of income and cash flows and for such fiscal quarter and (in respect of the second and third fiscal quarters of such fiscal year) for the then-elapsed portion of Parent's fiscal year, all prepared in accordance with Applicable Accounting Standards, subject to normal year-end audit adjustments and the absence of disclosures normally made in footnotes; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC). Such consolidated financial statements shall be certified by a Responsible Officer of Parent as, to his or her knowledge, fairly presenting, in all material respects, the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of the dates and for the periods specified in accordance with Applicable Accounting Standards consistently applied, and on a basis consistent with the audited consolidated financial statements referred to under Section 5.2(a)(i), subject to normal year-end audit adjustments and the absence of footnotes; provided, however, that such certification by a Responsible Officer of Parent shall be deemed to have made if a similar certification is required under the Sarbanes-Oxley Act of 2002 and such certification shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC);

(iii) Quarterly Compliance Certificate. Upon delivery (or within five (5) Business Days following any deemed delivery) of financial statements pursuant to Section 5.2(a)(i) or Section 5.2(a)(ii), a duly completed Compliance Certificate signed by a Responsible Officer of Parent, certifying, among other things, that (A) such financial statements fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of the applicable dates and for the applicable periods in accordance with Applicable Accounting Standards consistently applied, and are not subject to any qualification as to "going concern" or scope of audit, and (B) no Event of Default or Default has occurred or, if such an Event of Default or Default has occurred, specifying the nature and extent thereof and any corrective action taken or proposed to be taken with respect thereto; and

(iv) Information During Event of Default. As promptly as practicable (and in any event within five (5) Business Days of the request therefor), such additional information regarding the business or financial affairs of Parent or any of its Subsidiaries, or compliance with the terms of this Agreement or any other Loan Documents, as the Collateral Agent may from time to time reasonably request during the existence of any Event of Default (subject to reasonable requirements of confidentiality, including requirements imposed by Requirements of Law or contract, in each case in a form reasonably acceptable to the Collateral Agent; provided that Borrower shall not be obligated to disclose any information that is reasonably subject to the assertion of attorney-client privilege or attorney work-product).

(b) Notice of Defaults or Events of Default, ERISA Events and Material Adverse Changes. Written notice as promptly as practicable (and in any event within five (5) Business Days) after a Responsible Officer of any Credit Party shall have obtained knowledge thereof, of the occurrence of any (i) Default or Event of Default, (ii) ERISA Event or (iii) Material Adverse Change.

(c) Legal Action Notice. Prompt written notice (which shall be deemed given to the extent timely reported in a Form 8-K under the Exchange Act and available on the SEC's EDGAR system (or any successor system adopted by the SEC)) of any legal action, litigation, investigation or proceeding pending or threatened in writing against Parent or any of its Subsidiaries (i) that could reasonably be expected to result in uninsured damages or costs to Parent or any of its Subsidiaries in an amount in excess of the materiality thresholds applied by Borrower in accordance with the Exchange Act and related regulations and standards for purposes of its Exchange Act reporting, or (ii) that alleges violations of any Health Care Laws, FDA Laws, Data Protection Laws or any other applicable statutes, rules, regulations, standards, guidelines, policies and order administered or issued by any U.S. or foreign Governmental Authority which, individually or together with any other such allegations, could reasonably be expected to result in a Material Adverse Change; and in each case of sub-clause (i) or (ii) above, provide such additional information (including a description in reasonable detail regarding any material development) as the Collateral Agent may reasonably request in relation thereto; provided that Borrower shall not be obligated to disclose any information that is reasonably subject to the assertion of attorney-client privilege or attorney work-product.

5.3 Taxes

. Timely file all U.S. federal, state, local and non-U.S. income and other material Tax returns required to be filed by any of them (or an extension has been obtained for the filing thereof) and pay all U.S. federal, state, local and non-U.S. Taxes before any penalty or fine accrue thereon; provided, however, that no such Tax or any claim for Taxes that have become due and payable shall be required to be paid if, in each case, (a) it is being contested in good faith by appropriate proceedings and with respect to which adequate reserves have been set aside on its books and maintained in conformity with Applicable Accounting Standards, or (b) to the extent that the failure to do so could not reasonably be expected to result in a Material Adverse Change.

5.4 Insurance

. Maintain with financially sound and reputable independent insurance companies or underwriters, insurance with respect to its properties and business against loss or damage of the kinds customarily insured against by Persons of comparable size engaged in the same or similar business, of such types and in such amounts (after giving effect to any self-insurance reasonable and customary for similarly situated Persons of comparable size engaged in the same or similar businesses as Parent and its Subsidiaries) as are customarily carried under similar circumstances by such other Persons. Subject to the timing requirements of Section 5.14 (solely with respect to any such policies in effect as of the Tranche A Closing Date), any products liability or general liability insurance maintained in the United States regarding Collateral shall name the Collateral Agent, on behalf of the Lenders and the other Secured Parties, as additional insured or loss payee, as applicable (the additional insured clauses or endorsements for which, in form and substance reasonably satisfactory to the Collateral Agent). So long as no Event of Default shall have occurred and be continuing, Parent and its Subsidiaries may retain all or any portion of the proceeds of any insurance of Parent and its Subsidiaries (and each Lender shall promptly remit to Borrower any proceeds received by it with respect to any such insurance).

5.5 Operating Accounts

. In the case of any Credit Party, promptly following the establishment of any new Collateral Account (but prior to the movement of any cash or other funds into such Collateral Account), at or with any bank or other depository or financial institution located in the United States, subject such account to a Control Agreement or other appropriate instrument that is reasonably acceptable to the Collateral Agent. For each Collateral Account that each Credit Party at any time maintains in the United States, such Credit Party shall cause the applicable bank or other depository or financial institution located in the United States or Israel at or with which any Collateral Account is maintained to execute and deliver, and such Credit Party shall execute and deliver, to the Collateral Agent, a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect the Collateral Agent's Lien, for the benefit of Lenders and the other Secured Parties, in such Collateral Account in accordance with the terms hereunder, which Control Agreement may not be terminated without the prior written consent of the Collateral Agent. The provisions of the previous two (2) sentences shall not apply to (1) accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of any Credit Party's employees, (2) zero balance accounts, (3) accounts (including trust accounts) used exclusively for escrow, customs, insurance or fiduciary purposes, (4) merchant accounts, (5) accounts used exclusively for compliance with any Requirements of Law to the extent such Requirements of Law prohibit the granting of a Lien thereon, (6) accounts which constitute cash collateral in respect of a Permitted Lien and (7) any other accounts designated as an Excluded Account by a Responsible Officer of Borrower or Parent in writing delivered to the Collateral Agent, the cash balance of which such accounts do not exceed $5,000,000 in the aggregate at any time (all such accounts in sub-clauses (1) through (7) above, collectively, the "**Excluded Accounts**"). Notwithstanding the foregoing, the Credit Parties shall have until the date that is ninety (90) days (or such longer period as the Collateral Agent may agree in its sole discretion) following (i) the Tranche A Closing Date to comply with the provisions of this Section 5.5 with regards to Collateral Accounts (other than Excluded Accounts) of the Credit Parties in existence on the Tranche A Closing Date (or opened during such 90-day period (or such longer period as the Collateral Agent may agree in its sole discretion)) and (ii) the closing date of any Acquisition or other Investment to comply with the provisions of this Section 5.5 with regards to Collateral Accounts (other than Excluded Accounts) of the Credit Parties acquired in connection with such Acquisition or other Investment.

5.6 Compliance with Laws

. Comply in all respects with the Requirements of Law and all orders, writs, injunctions, decrees and judgments applicable to it or to its business or its assets or properties (including Environmental Laws, ERISA, Anti-Money Laundering Laws, OFAC, FCPA, Health Care Laws, FDA Laws, Data Protection Laws and the Federal Fair Labor Standards Act (and any foreign or United States state equivalents), including in connection with governing the research, development, testing, approval, post-approval monitoring, post-approval requirements, post-approval commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of Product in the Territory, except, in each case, if the failure to comply therewith could not, individually or taken together with any other such failures, reasonably be expected to result in a Material Adverse Change.

5.7 Protection of Intellectual Property Rights

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(a) Except as could not reasonably be expected to result in a Material Adverse Change or as expressly permitted under clause (b) below, use best efforts to: (i) protect, defend and maintain the validity and enforceability of the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory, including defending any future or current oppositions, interference proceedings, reissue proceedings, reexamination proceedings, *inter partes* review proceedings, derivation proceedings, post grant review proceedings, cancellation proceedings, injunctions, lawsuits, hearings, investigations, complaints, arbitrations, mediations, demands, International Trade Commission investigations, decrees, or any other disputes, disagreements, or claims, challenging the legality, validity, patentability, enforceability, inventorship or ownership of such Company IP; (ii) maintain the confidential nature of any trade secrets and trade secret rights which are used in the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory; and (iii) not allow any Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory to be abandoned, disclaimed, forfeited or dedicated to the public by Parent or any of its Subsidiaries (other than through the abandonment of Current Company IP in the exercise of the Borrower's normal prosecution practices and reasonable business judgment, e.g., the abandonment of a continuation application that is no longer needed to maintain the pendency of another patent application) or any Company IP Agreement to be terminated, as applicable, without the Collateral Agent's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed); provided, however, that with respect to any such Company IP that is not owned by Parent or any of its Subsidiaries, the obligations in clauses (i) and (iii) above shall apply only to the extent Parent or any of its Subsidiaries have the right to take such actions or to cause any licensee or other third party to take such actions pursuant to applicable agreements or contractual rights.

(b) (i) Except as Parent may otherwise determine in its reasonable business judgment, use all commercially reasonable efforts, either directly or indirectly, with respect to any licensee or licensor under the terms of any Credit Party's (or any of its Subsidiary's) agreement with the respective licensee or licensor, as applicable, to take commercially reasonable actions (including taking legal action to specifically enforce the applicable terms of any license agreement) and prepare, execute, deliver and file agreements, documents or instruments which are necessary to (A) prosecute and maintain the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory and (B) diligently defend or assert the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory against material infringement, misappropriation, violation or interference by any other Persons and, in the case of Copyrights, Trademarks and Patents within such material Company IP, against any claims of invalidity, unpatentability or unenforceability (including by bringing any legal action for infringement, dilution, violation, derivation or defending any counterclaim of invalidity or action of a non-Affiliate third party for declaratory judgment of non-infringement or non-interference); and (ii) use all commercially reasonable efforts to cause any licensee or licensor of any material Company IP not to, and such Credit Party shall not, disclaim, forfeit, dedicate to the public or abandon, or fail to take any action necessary to prevent the disclaimer, forfeiture or abandonment

of such Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory (other than through the lapse, expiration or abandonment of Current Company IP in the exercise of the Borrower's normal prosecution practices and reasonable business judgment, *e.g.*, the abandonment of a continuation application that is no longer needed to maintain the pendency of another patent application), except clauses (i) and (ii) above shall apply only to the extent Parent or any of its Subsidiaries have the right to take such actions or to cause any licensor, licensee or other third party to take such actions pursuant to applicable agreements or contractual rights, and taking such actions would not otherwise breach, terminate or otherwise violate the terms of the applicable agreements.

(c) Save as contemplated by any Permitted License, use all commercially reasonable efforts to protect, defend and maintain market and data exclusivity for the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory through the Term Loan Maturity Date, and use all commercially reasonable efforts to not allow for the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of a bioequivalent version of Product in the Territory before the Term Loan Maturity Date, in each case if such bioequivalent version infringes or violates, or could reasonably be expected to infringe or violate, any of the rights of any Credit Party or its Subsidiary in or to any material Company IP, without the Collateral Agent's prior written consent. Parent agrees to (i) notify the Collateral Agent in writing of, and (ii) keep the Collateral Agent reasonably informed regarding, and (iii) at the reasonable request of the Collateral Agent in writing, consult with and consider in good faith any comments of the Collateral Agent regarding, the commencement of and any material filings in any opposition, interference proceeding, reissue proceeding, reexamination proceeding, *inter partes* review proceeding, post-grant review proceeding, derivation proceeding, cancellation proceeding, injunction, lawsuit, hearing, investigation, complaint, arbitration, mediation, demand, International Trade Commission investigation, decree, or any other dispute, disagreement, or claim, in each case challenging the legality, validity, patentability, enforceability, inventorship or ownership of any material Company IP (including any claim in any Patent within the Company IP that is material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory).

(d) Provide written notice to the Collateral Agent within thirty (30) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Each Credit Party shall take such commercially reasonable steps as the Collateral Agent reasonably requests to obtain the consent of, or waiver by, any Person whose consent or waiver is necessary for (i) any Restricted License to, without giving effect to Section 9-408 of the Code, be deemed "Collateral" and for the Collateral Agent to have a security interest in it that might otherwise be restricted or prohibited by Requirements of Law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (ii) the Collateral Agent to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with the Collateral Agent's rights and remedies under this Agreement and the other Loan Documents.

5.8 Books and Records

. Maintain proper Books, in which entries that are full, true and correct in all material respects and are in conformity with Applicable Accounting Standards consistently applied shall be made of all material financial transactions and matters involving the assets, properties and business of such Credit Party (or such Subsidiary).

5.9 Access to Collateral; Audits

. Allow the Collateral Agent, or its agents or representatives, at any time after the occurrence and during the continuance of an Event of Default, during normal business hours and upon reasonable advance notice, to visit and inspect any of the Collateral or to inspect and copy and (at the sole discretion of the Collateral Agent) audit any Credit Party's Books. The foregoing inspections and audits, if any, shall be at the relevant Credit Party's expense.

5.10 Use of Proceeds

. (a) Use the proceeds of the Term Loans solely to fund its general corporate and working capital requirements; and (b) not use the proceeds of the Term Loans, directly or indirectly, for the purpose of purchasing or carrying any Margin Stock, for the purpose of reducing or retiring any Indebtedness that was originally incurred to purchase or carry any Margin Stock, for the purpose of extending credit to any other Person for the purpose of purchasing or carrying any Margin Stock or for any other purpose that might cause any Term Loan to be considered a "purpose credit" within the meaning of Regulation T, U or X of the Federal Reserve Board. If requested by the Collateral Agent, Borrower shall complete and sign Part I of a copy of Federal Reserve Form G-3 referred to in Regulation U and deliver such copy to the Collateral Agent.

5.11 Further Assurances

. Subject to the limitations in Section 5.12(d), promptly upon the reasonable written request of the Collateral Agent, execute, acknowledge and deliver such further documents and do such other acts and things in order to effectuate or carry out more effectively the purposes of this Agreement and the other Loan Documents at its expense, including after the Tranche A Closing Date taking such steps as are reasonably deemed necessary or desirable by the Collateral Agent to maintain, protect and enforce its Lien, for the benefit of Lenders and the other Secured Parties, on Collateral securing the Obligations created under the Collateral Documents and the other Loan Documents in accordance with the terms of the Collateral Documents and the other Loan Documents, subject to Permitted Liens.

5.12 Additional Collateral; Guarantors

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(a) From and after the Tranche A Closing Date, except as otherwise approved in writing by the Collateral Agent, each Credit Party (other than Borrower) shall, and each Credit Party shall cause each of its Subsidiaries (other than Excluded Subsidiaries), and Parent may at its election cause any Excluded Subsidiaries (and the Collateral Agent and Lenders shall cooperate with any such election) to guarantee the Obligations (and to execute and deliver to the Collateral Agent a joinder to the Security Agreement (in the form attached thereto)), and each Credit Party (other than Borrower) shall, and each Credit Party shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of such Credit Party's or Subsidiary's properties and assets constituting Collateral, whether now existing or hereafter acquired or existing (including in connection with an Asset Acquisition), to secure such guaranty (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the form(s) attached thereto), as applicable); provided, that such Credit Party's obligations to take the foregoing actions with respect to any assets acquired as part of an Asset Acquisition and to cause any Subsidiaries incorporated, organized, formed or acquired (including by Stock Acquisition) after the Tranche A Closing Date, including all such Subsidiary's properties and assets

(including in connection with an Asset Acquisition), to take the foregoing actions shall, in each case, be subject to the timing requirements of Section 5.13 or Section 5.14, as applicable. Additionally, from and after the Tranche A Closing Date, each Credit Party shall, and shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens, the limitations set forth herein and the limitations set forth in the other Loan Documents), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of such Credit Party's or Subsidiary's properties and assets constituting Collateral, whether now existing or hereafter acquired or existing (including in connection with an Asset Acquisition), to secure the payment and performance in full of all of the Obligations (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the form(s) attached thereto), as applicable); provided, that such Credit Party's obligations to take the foregoing actions with respect to any assets acquired as part of an Asset Acquisition and to cause any Subsidiaries incorporated, organized, formed or acquired (including by Stock Acquisition) after the Tranche A Closing Date, including all such Subsidiary's properties and assets (including in connection with an Asset Acquisition), to take the foregoing actions shall, in each case, be subject to the timing requirements of Section 5.13 or Section 5.14, as applicable. Furthermore, except as otherwise approved in writing by the Collateral Agent, from and after the Tranche A Closing Date, each Credit Party shall, and shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens, the limitations set forth herein and the limitations set forth in the other Loan Documents), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of the Equity Interests (other than Excluded Equity Interests) in each of its Subsidiaries (other than Excluded Subsidiaries) (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the form(s) attached thereto), as applicable). In connection with each pledge of certificated Equity Interests required under the Loan Documents, the Credit Parties shall deliver, or cause to be delivered, to the Collateral Agent, in addition to a pledge amendment to the Security Agreement (in the form attached thereto), such certificate(s) together with stock powers or assignments, as applicable, properly endorsed for transfer to the Collateral Agent or duly executed in blank, in each case reasonably satisfactory to the Collateral Agent. In connection with each pledge of uncertificated Equity Interests required under the Loan Documents, the Credit Parties shall deliver, or cause to be delivered, to the Collateral Agent, in addition to a pledge amendment to the Security Agreement (in the form attached thereto), an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent, substantially in the form attached to the Security Agreement.

(b) In the event any Credit Party acquires any fee title to real estate in the U.S. with a fair market value (reasonably determined in good faith by a Responsible Officer of such Credit Party) in excess of $5,000,000, unless otherwise agreed by the Collateral Agent, such Person shall execute or deliver, or cause to be executed or delivered, to the Collateral Agent, (i) within sixty (60) days after such acquisition, an appraisal complying with the Financial Institutions Reform, Recovery and Enforcement Act of 1989, (ii) within forty-five (45) days after receipt of notice from the Collateral Agent that such real estate is located in a Special Flood Hazard Area, Federal Flood Insurance, (iii) within sixty (60) days after such acquisition, a fully executed Mortgage, in form and substance reasonably satisfactory to the Collateral Agent, together with an A.L.T.A. lender's title insurance policy issued by a title insurer reasonably satisfactory to the Collateral Agent, in form and substance (including any endorsements) and in an amount reasonably satisfactory to the Collateral Agent insuring that the Mortgage is a valid and enforceable first priority Lien on the respective property, free and clear of all defects, encumbrances and Liens (other than Permitted Liens), (iv) simultaneously with such acquisition, then-current A.L.T.A. surveys, certified to the Collateral Agent by a licensed surveyor sufficient to allow the issuer of the lender's title insurance policy to issue such policy without a survey exception and (v) within sixty (60) days after such acquisition, an environmental site assessment prepared by a qualified firm reasonably acceptable to the Collateral Agent, in form and substance reasonably satisfactory to the Collateral Agent.

(c) If any Credit Party becomes (or any New Subsidiary is) a Registered Organization, Borrower or such Credit Party shall (or shall cause such New Subsidiary to) promptly notify the Collateral Agent of such occurrence and provide the Collateral Agent with such Credit Party's (or New Subsidiary's) organizational identification number.

(d) If, as a result of a change in law including any change to a provision of the IRC or future guidance from the IRS or United States Department of Treasury, either: (i) a Credit Party's pledge of the stock of a Foreign Subsidiary or Foreign Subsidiary Holdco or (ii) a Foreign Subsidiary (in the event Borrower elected pursuant to Section 5.12(a) to cause such Foreign Subsidiary to be a Guarantor hereunder) or Foreign Subsidiary Holdco being a Guarantor hereunder would reasonably be expected to result in an income inclusion for any Credit Party under Section 956 of the IRC (or a successor or similar provision), or the United States Treasury Regulations promulgated thereunder which causes a material adverse tax consequence for a Credit Party, the parties hereto shall cooperate in good faith to amend this Agreement, the Security Agreement and any other applicable Loan Document to eliminate (or, if it is not possible to eliminate, mitigate) such material adverse tax consequence for such Credit Party. Further, if any Credit Party or any of its Subsidiaries at any time after the Tranche A Closing Date forms or acquires a Foreign Subsidiary or Foreign Subsidiary Holdco, the parties hereto shall cooperate in good faith to determine if either (x) a Credit Party's pledge of the stock of such Foreign Subsidiary or Foreign Subsidiary Holdco or (y) such Foreign Subsidiary Holdco being a Guarantor hereunder would result in an income inclusion for any Credit Party under Section 956 of the IRC (or a successor or similar provision), or the United States Treasury Regulations promulgated thereunder which causes a material adverse tax consequence for a Credit Party. If such material adverse tax consequence for a Credit Party exists, the parties hereto shall cooperate in good faith to structure such pledge or guarantee in a manner that eliminates (or, if it is not possible to eliminate, mitigates to the point that it is not material) such material adverse tax consequence for such Credit Party. If it is not possible to eliminate (or mitigate) the material adverse tax consequence, then, as applicable, and solely if, at each instance, such pledge or guaranty, as applicable, is the cause of such material adverse tax consequence (A) a pledge of up to sixty-five percent (65.0%) of the issued and outstanding voting Equity Interests and one hundred percent (100%) the issued and outstanding non-voting Equity Interests of the Foreign Subsidiary or Foreign Subsidiary Holdco directly owned by a Credit Party shall be permitted and (B) a guarantee by a Foreign Subsidiary Holdco will not be required.

(e) Notwithstanding anything to the contrary herein, in no event shall any Credit Party or any Subsidiary be required to enter into or deliver any foreign law-governed documents, file or record any documents or agreements (including any agreements relating to Intellectual Property) with any foreign Governmental Authority or take any other actions under foreign law with respect to Collateral held in any jurisdiction other than the United States, Israel or the jurisdiction of such Credit Party or Subsidiary, or, solely upon the occurrence and during the continuance of an Event of Default and by written notice to the Credit Parties, as the Collateral Agent may in its sole discretion otherwise require.

5.13 Formation or Acquisition of Subsidiaries

. If any Credit Party or any of its Subsidiaries at any time after the Tranche A Closing Date incorporates, organizes, forms or acquires (including by a Stock Acquisition) a Subsidiary (including by division) other than an Excluded Subsidiary (a "**New Subsidiary**") or if any Credit Party makes an Asset Acquisition (other than an Asset Acquisition in the ordinary course of business), as promptly as practicable but in no event later than thirty (30) days after such incorporation, organization, formation or acquisition or Asset Acquisition: (a) without limiting the generality of clause (c) below, such Credit Party will cause such New Subsidiary or Credit Party, as applicable, to the extent required or applicable to execute and deliver to the Collateral Agent a joinder to the Security Agreement (in the form attached thereto) and any relevant IP Agreement or other Collateral Documents, as applicable; (b) such Credit Party will deliver (or cause to be delivered) to the Collateral Agent (i) true, correct and complete copies of the Operating Documents of such New Subsidiary, (ii) a Secretary's Certificate, certifying that the copies of the Operating Documents of such New Subsidiary are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent) and (iii) a good standing certificate for such New

Subsidiary certified by the Secretary of State (or the equivalent thereof) of its jurisdiction of organization, incorporation or formation (where applicable in the subject jurisdiction); and (c) such Credit Party will cause such New Subsidiary to satisfy all requirements contained in this Agreement (including Section 5.12) and each other Loan Document if and to the extent applicable to such New Subsidiary. The parties hereto agree that any New Subsidiary shall constitute a Credit Party for all purposes hereunder as of the date of the execution and delivery of any joinder contemplated by clause (a) above or the date such New Subsidiary provides any guarantee of the Obligations as contemplated by Section 5.12. Any document, agreement or instrument executed or issued pursuant to this Section 5.13 shall be a Loan Document.

5.14 Post-Closing Requirements

. Parent will, and will cause each of its Subsidiaries, as applicable, to take each of the actions set forth on Schedule 5.14 of the Disclosure Letter within the time period prescribed therefor on such schedule (or such longer period as the Collateral Agent may agree in its sole discretion), which shall include, among other things, that: (a) notwithstanding anything to the contrary in Section 3.1(g) or Section 5.4, the Credit Parties shall have until the date that is thirty (30) days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to comply with the provisions of Section 5.4 with regards to naming the Collateral Agent, on behalf of the Lenders and the other Secured Parties, as additional insured or loss payee, on any products liability or general liability insurance in the United States regarding Collateral in effect on the Tranche A Closing Date; (b) notwithstanding anything to the contrary in Section 5.5, the Credit Parties shall have until the date that is ninety (90) days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to comply with the provisions of Section 5.5 with regards to Collateral Accounts of the Credit Parties in existence on the Tranche A Closing Date or opened during such 90-day period; (c) notwithstanding anything to the contrary in Section 6.2(b), the Credit Parties shall have until the date that is thirty (30) days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to comply with the provisions of Section 6.2(b)(ii) with regards to the location of the primary Books of any Credit Party or any of its Subsidiaries or the location of any material portion of the Collateral on the Tranche A Closing Date or during such 30-day period; and (d) notwithstanding anything to the contrary in Section 3.1(j), the Credit Parties shall have until the date that is 21 days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to deliver (x) a copy of the amendment to the Security Agreement/Debenture Unlimited in Amount, dated April 4, 2021, between Parent and RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2), acknowledging the creation of a first priority security interest in and Lien upon the Collateral in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties and providing that such security interest and Lien is senior in priority to any and all security interests and Liens in favor of RTW Investments ICAV thereunder, and (y) evidence of the filing of such amended Security Agreement/Debenture Unlimited in Amount with the Israeli Registrar of Companies (such evidence to be in form and substance reasonably satisfactory to the Collateral Agent). All representations and warranties and covenants contained in this Agreement and the other Loan Documents shall be deemed modified to the extent necessary to take the actions set forth on Schedule 5.14 of the Disclosure Letter within the time periods set forth therein, rather than elsewhere provided in the Loan Documents, such that to the extent any such action set forth in Schedule 5.14 of the Disclosure Letter is not overdue, the applicable Credit Party shall not be in breach of any representation or warranty or covenant contained in this Agreement or any other Loan Document applicable to such action for the period from the Tranche A Closing Date until the date on which such action is required to be fulfilled as set forth on Schedule 5.14 of the Disclosure Letter.

5.15 Environmental

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(a) Deliver to the Collateral Agent:

(i) as soon as practicable following receipt thereof, copies of all environmental audits, investigations, analyses and reports of any kind or character, whether prepared by personnel of Parent or any of its Subsidiaries or by independent consultants, governmental authorities or any other Persons, with respect to significant environmental matters at any Facility or with respect to any material Environmental Claims;

(ii) promptly upon a Responsible Officer of any Credit Party or any of its Subsidiaries obtaining knowledge of the occurrence thereof, written notice describing in reasonable detail (A) any Release required to be reported to any federal, state, local or foreign governmental or regulatory agency under any applicable Environmental Laws, (B) any remedial action taken by any Credit Party or any other Person in response to (x) any Hazardous Materials Activities, the existence of which, individually or in the aggregate, could reasonably be expected to result in one or more Environmental Claims resulting in a Material Adverse Change, or (y) any Environmental Claims that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, and (C) any Credit Party's discovery of any occurrence or condition on any real property adjoining or in the vicinity of any Facility that could cause such Facility or any part thereof to be subject to any material restrictions on the ownership, occupancy, transferability or use thereof under any Environmental Laws, provided, that with respect to real property adjoining or in the vicinity of any Facility, Borrower shall have no duty to affirmatively investigate or make any efforts to become or stay informed regarding any such adjoining or nearby properties;

(iii) as soon as practicable following the sending or receipt thereof by any Credit Party, a copy of any and all written communications with respect to (A) any Environmental Claims that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, (B) any Release required to be reported to any federal, state, local or foreign governmental or regulatory agency, and (C) any request for information from any Governmental Authority that suggests such Governmental Authority is investigating whether any Credit Party or any of its Subsidiaries may be potentially responsible for any Hazardous Materials Activity that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change;

(iv) prompt written notice describing in reasonable detail (A) any proposed acquisition of stock, assets, or property by Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to (x) expose Parent or any of its Subsidiaries to, or result in, Environmental Claims that could reasonably be expected to result in a Material Adverse Change or (y) affect the ability of Parent or any of its Subsidiaries to maintain in full force and effect all material Governmental Approvals required under any Environmental Laws for their respective operations and (B) any proposed action to be taken by Parent or any of its Subsidiaries to modify current operations in a manner that, individually or taken together with any other such proposed actions, could reasonably be expected to subject Parent or any of its Subsidiaries to any additional material obligations or requirements under any Environmental Laws; and

(v) with reasonable promptness, such other documents and information as from time to time may be reasonably requested by the Collateral Agent in relation to any matters disclosed pursuant to this Section 5.15(a).

(b) Each Credit Party shall, and shall cause each of its Subsidiaries to, promptly take any and all actions reasonably necessary to (i) cure any violation of applicable Environmental Laws by Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, and (ii) make an appropriate response to any Environmental Claim against Parent or any of its Subsidiaries and

discharge any obligations it may have to any Person thereunder where failure to do so, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change.

5.16 Inventory; Returns; Maintenance of Properties

. Keep all Inventory which constitutes Product in good and marketable condition, free from material defects and otherwise keep all Inventory which constitutes Product in material compliance with all applicable FDA Laws (including, for the avoidance of doubt, all foreign or United States state equivalents), as applicable. Returns and allowances between a Credit Party and its Account Debtors shall follow such Credit Party's customary practices. Each Credit Party will, and will cause each of its Subsidiaries to, maintain or cause to be maintained in good repair, working order and condition, ordinary wear and tear, casualty and condemnation excepted, all material tangible properties used or useful in its respective business, and from time to time will make or cause to be made all commercially reasonable repairs, renewals and replacements thereof except where failure to do so could not reasonably be expected to result in a Material Adverse Change.

5.17 Regulatory Obligations; Maintenance of FDA Approval; Manufacturing, Marketing and Distribution

- . (a)(i) Comply in all material respects with FDA post-approval requirements (and applicable foreign or United States state equivalents) for Product in the Territory, (ii) maintain all Regulatory Approvals required or otherwise material to manufacture, market and distribute Product in the Territory, (iii) with respect to each calendar year commencing with calendar year 2022, maintain manufacturing capacity to sell JELMYTO® in the Territory in sufficient quantities to satisfy or exceed either (x) the net sales amount for such calendar year set forth in the JELMYTO® Revenue Forecast or (y) the expected needs of patients with the disease or condition for which JELMYTO® was designated as an Orphan Drug for such calendar year, as reasonably determined by Responsible Officers of the Credit Parties in good faith; unless, however, that, with respect to any such calendar year, if the net sales amount for such calendar year set forth in the JELMYTO® Revenue Forecast would not be sufficient to meet reasonably anticipated demand for such calendar year, in which case, maintain manufacturing capacity to sell JELMYTO® in the Territory in sufficient quantities to satisfy or exceed the needs of patients with the disease or condition for which JELMYTO® was designated as an Orphan Drug for such calendar year.

(b) Deliver to the Collateral Agent, as promptly as practicable after a Responsible Officer of any Credit Party shall have obtained knowledge thereof, written notice describing in reasonable detail any instance where the Credit Party or any of its Subsidiaries has a reasonable expectation that there are grounds for imposition of a clinical hold, as described in 21 C.F.R. § 312.42.

5.18 Collateral Documents

. Comply in all respects with all of its covenants, agreements, undertakings and obligations arising under each Collateral Document to which it is a party.

6 NEGATIVE COVENANTS

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), such Credit Party shall not, and shall cause each of its Subsidiaries not to:

6.1 Dispositions

. Convey, sell, lease, transfer, exchange, assign, covenant not to sue, enter into a coexistence agreement, exclusively or nonexclusively license out, or otherwise dispose of (including any sale-leaseback or any transfer of assets pursuant to a plan of division), directly or indirectly and whether in one or a series of transactions (collectively, "**Transfer**"), all or any part of its properties or assets constituting Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party) or any Company IP that does not constitute Collateral under the Loan Documents but is related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory; except, in each case of this Section 6.1, for Permitted Transfers not otherwise expressly prohibited under Section 6.6(b).

6.2 Fundamental Changes; Location of Collateral

.

(a) Without at least ten (10) days prior written notice to the Collateral Agent, solely in the case of a Credit Party: (i) change its jurisdiction of organization, incorporation or formation, (ii) change its organizational structure or type, (iii) change its legal name, or (iv) change any organizational number (if any) assigned by its jurisdiction of organization, incorporation or formation.

(b) Maintain its primary Books at or deliver any Collateral with a fair market value (reasonably determined in good faith by a Responsible Officer of Borrower), individually or together with any other Collateral, in excess of $1,000,000 to, one or more mortgaged or leased locations or one or more warehouses, processors or bailees, as applicable, unless, subject to the timing requirements of Section 5.14 (solely with respect to such locations, warehouses, processors or bailees where such Books or Collateral is located on the Tranche A Closing Date or during the 60-day period following the Tranche A Closing Date), such Credit Party uses commercially reasonable efforts to deliver to the Collateral Agent a Collateral Access Agreement for such mortgaged or leased location or such warehouse, processor or bailee governing such Books or such Collateral (as applicable) and the location at which such Books are maintained or to which such Collateral has been delivered (as applicable), in each case in form and substance reasonably satisfactory to the Collateral Agent, as promptly as practicable (and in no event later than sixty (60) days after) such Books are maintained or such Collateral is delivered to such mortgaged or leased location or warehouse, processor or bailee (as applicable). Notwithstanding anything to the contrary herein, such obligation to deliver Collateral Access Agreements will not apply to any inventory or assets while in transit.

6.3 Mergers, Acquisitions, Liquidations or Dissolutions

.

(a) Merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve, or permit any of its Subsidiaries to merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve with or into any other Person, except that:

(i) any Subsidiary of Parent may merge or consolidate with or into a Credit Party, provided that the Credit Party is the surviving entity,

(ii) any Subsidiary of Parent may merge or consolidate with any other Subsidiary of Parent, provided that if any party to such merger or consolidation is a Credit Party then either (x) such Credit Party is the surviving entity or (y) the surviving or resulting entity executes and delivers to the Collateral Agent a joinder to the Security Agreement in the form attached thereto and any relevant IP Agreement or other Collateral Documents, as applicable, and otherwise satisfies the requirements of Section 5.13 substantially contemporaneously with completion of such merger or consolidation;

(iii) any Subsidiary of Parent may divide itself into two (2) or more entities or be dissolved or liquidated, provided that if such Subsidiary is a Credit Party, the properties and assets of such Subsidiary are allocated or distributed to an existing or newly-formed Credit Party; and

(iv) any Permitted Acquisition or Permitted Investment may be structured as a merger or consolidation.

(b) make, or permit any of its Subsidiaries to make, Acquisitions outside the ordinary course of business, including any purchase of the assets of any division or line of business of any other Person, other than Permitted Acquisitions or Permitted Investments. For the avoidance of doubt, nothing herein shall prohibit any Credit Party or its Subsidiaries from entering into in-licensing agreements; provided that, in each case, no Indebtedness not otherwise permitted hereunder is incurred or assumed in connection therewith.

6.4 Indebtedness

. Directly or indirectly, create, incur, assume or guaranty, or otherwise become or remain directly or indirectly liable with respect to, any Indebtedness (including any Indebtedness consisting of obligations evidenced by a bond, debenture, note or other similar instrument) that is not Permitted Indebtedness; provided, however, that the accrual of interest, the accretion of accreted value and the payment of interest in the form of additional Indebtedness shall not be deemed to be an incurrence of Indebtedness for purposes of this Section 6.4.

6.5 Encumbrances

. Except for Permitted Liens, (i) create, incur, allow, or suffer to exist any Lien on any Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party), or (ii) permit (other than pursuant to the terms of the Loan Documents) any material portion of the Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party) not to be subject to the first priority security interest granted in the Loan Documents or otherwise pursuant to the Collateral Documents, in each case of this clause (ii), other than as a direct result of any action by the Collateral Agent or any Lender or failure of the Collateral Agent or any Lender to perform an obligation thereof under the Loan Documents.

6.6 No Further Negative Pledges; Negative Pledge

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(a) No Credit Party nor any of its Subsidiaries shall enter into any agreement, document or instrument directly or indirectly prohibiting (or having the effect of prohibiting) or limiting the ability of such Credit Party or Subsidiary to create, incur, assume or suffer to exist any Lien upon any Collateral, whether now owned or hereafter acquired, in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, with respect to the Obligations or under the Loan Documents, in each case of this Section 6.6, other than Permitted Negative Pledges.

(b) Notwithstanding Section 6.1, no Credit Party will Transfer, or create, incur, allow or suffer to exist any Lien on, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party, except for: (i) Permitted Liens; (ii) transfers between or among Credit Parties, provided that any and all steps as may be reasonably required to be taken in order to create and maintain a first priority security interest in and Lien upon such Equity Interests in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, are taken contemporaneously with the completion of any such transfer; and (iii) sales, assignments, transfers, exchanges or other dispositions to qualify directors if required by Requirements of Law or otherwise permitted under this Agreement, provided that such sale, assignment, transfer, exchange or other disposition shall be for the minimum number of Equity Interests as are necessary for such qualification under Requirements of Law.

6.7 Maintenance of Collateral Accounts

. Maintain any Collateral Account except in accordance with the terms of Section 5.5 hereof.

6.8 Distributions; Investments

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(a) Pay any dividends or make any distribution or payment on, or redeem, retire or repurchase any of its Equity Interests, except, in each case of this Section 6.8, for Permitted Distributions, Permitted Transactions and Permitted Equity Derivatives.

(b) Directly or indirectly make any Investment other than Permitted Acquisitions and Permitted Investments.

For the avoidance of doubt, nothing in this Section 6.8 shall prohibit any Credit Party or its Subsidiaries from entering into in-licensing agreements; provided, however, that, in each case, no Indebtedness that is not Permitted Indebtedness is incurred or assumed in connection therewith.

6.9 No Restrictions on Subsidiary Distributions

. No Credit Party nor any of its Subsidiaries shall enter into any agreement, document or instrument directly or indirectly prohibiting (or having the effect of prohibiting) or limiting the ability of any Subsidiary of Parent to (a) pay dividends or make any other distributions on any of such Subsidiary's Equity Interests owned by Parent or any other Subsidiary of Parent, (b) repay or prepay any Indebtedness owed by such Subsidiary to Parent or any other Subsidiary of Parent, (c) make loans or advances to Borrower or any other Subsidiary of Parent, or (d) transfer, lease or license any Collateral to Borrower or any other Subsidiary of Parent, except, in each case of this Section 6.9, for Permitted Subsidiary Distribution Restrictions.

6.10 Subordinated Debt; Permitted Convertible Indebtedness

. Notwithstanding anything to the contrary in this Agreement:

(a) Make or permit any voluntary or optional prepayment or repayment of the outstanding principal amount of any Subordinated Debt other than in accordance with the express terms of a subordination, intercreditor or other similar agreement relating to such Subordinated Debt, if any, that is in form and substance reasonably satisfactory to the Collateral Agent;

(b) Make or permit any payment of interest (including accrued and unpaid interest) in cash on or in respect of any Subordinated Debt at any time that a Default or Event of Default shall have occurred and be continuing other than in accordance with the express terms of a subordination, intercreditor or other similar agreement relating to such Subordinated Debt, if any, that is in form and substance reasonably satisfactory to the Collateral Agent; or

(c) Amend, restate, supplement or otherwise modify any terms, conditions or other provisions of any Subordinated Debt, or any agreement, instrument or other document relating thereto, in any manner which would contravene in any respect any of the foregoing or adversely affect the payment or priority subordination thereof (as applicable) to Obligations owed to Lenders, in each case except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt, if any, is subject, without the prior written consent of the Collateral Agent (in its sole discretion).

(d) For the avoidance of doubt, no Credit Party shall, and shall cause each of its Subsidiaries not to, directly or indirectly, create, incur, assume or guaranty, or otherwise become directly or indirectly liable with respect to, any Subordinated Debt except as otherwise expressly permitted hereunder.

(e) Make or permit any voluntary or optional prepayment or repayment of the outstanding amount of any Indebtedness under the Pre-Paid Forward Contract or other PPFC Documents (including any principal or interest), or amend, restate, supplement or otherwise modify any terms, conditions or other provisions of such Indebtedness or the Pre-Paid Forward Contract or other PPFC Documents in any manner which would contravene in any respect any of the foregoing or adversely affect the payment or priority subordination thereof (as applicable) to Obligations owed to Lenders, in each case other than in accordance with the express terms of the RTW Intercreditor Agreement.

(f) No Credit Party shall, and shall cause each of its Subsidiaries not to, directly or indirectly, make (or exercise any option with respect thereto) any payment, prepayment, repurchase or redemption for cash of any Permitted Convertible Indebtedness unless and until all of the Obligations are paid in full, other than to the extent made solely with the proceeds of any issuance of Equity Interests or Permitted Convertible Indebtedness, provided, that nothing in this Section 6.10(e) shall prohibit or otherwise restrict (v) scheduled cash interest payments, (w) required cash payments of accrued but unpaid interest upon repurchase or redemption thereof, (x) cash payments in lieu of any fractional share issuable upon conversion thereof, (y) required cash payments of any amounts due upon the scheduled maturity thereof or (z) any ordinary course fees or other expenses in connection therewith.

6.11 Amendments or Waivers of Organizational Documents

. Amend, restate, supplement or otherwise modify, or waive, any provision of its Operating Documents in a manner that would reasonably be expected to result in a Material Adverse Change.

6.12 Compliance

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(a) Become an "investment company" under the Investment Company Act of 1940, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose;

(b) No ERISA Affiliate shall cause or suffer to exist (i) any event that would result in the imposition of a Lien on any assets or properties of any Credit Party or a Subsidiary of a Credit Party with respect to any Plan or Multiemployer Plan or (ii) any other ERISA Event that, in the case of clauses (i) and (ii), could reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change; or

(c) Permit the occurrence of any other event with respect to any present pension, profit sharing or deferred compensation plan which could reasonably be expected to result in a Material Adverse Change.

6.13 Compliance with Sanctions and Anti-Money Laundering Laws

. The Collateral Agent and each Lender hereby notifies each Credit Party that pursuant to the requirements of Sanctions and Anti-Money Laundering Laws, and such Person's policies and practices, the Collateral Agent and each Lender is required to obtain, verify and record certain information and documentation that identifies each Credit Party and its principals, which information includes the name and address of each Credit Party and its principals and such other information that will allow the Collateral Agent and each Lender to identify such party in accordance with Sanctions and Anti-Money Laundering Laws. No Credit Party will, nor will any Credit Party permit any of its Subsidiaries or controlled Affiliates to, directly or indirectly, knowingly enter into any documents or contracts with any Sanctioned Person to the extent such action is prohibited under Sanctions or Anti-Money Laundering Laws. Each Credit Party shall notify the Collateral Agent and each Lender in writing promptly (but in any event within five (5) Business Days after) a Responsible Officer of any Credit Party becomes aware that any Credit Party or any Subsidiary or Affiliate of any Credit Party is a Sanctioned Person or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. No Credit Party will, nor will any Credit Party permit any of its Subsidiaries or Affiliates to, directly or indirectly, (i) conduct any prohibited business or engage in any prohibited transaction or deal with any Sanctioned Person, including the making or receiving of any contribution of funds, goods or services to or for the benefit of any Sanctioned Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Sanctions, or (iii) engage in or conspire to engage in any transaction that evades or avoids or violates, or has the purpose of evading or avoiding, or attempts to violate, any of prohibitions under applicable Sanctions or Anti-Money Laundering Laws.

6.14 Amendments or Waivers of Company IP Agreements

. (a) Waive, amend, cancel or terminate, exercise or fail to exercise, any material rights constituting or relating to any of the Company IP Agreements or (b) breach, default under, or take any action or fail to take any action that, with the passage of time or the giving of notice or both, would constitute a default or event of default under any of the Company IP Agreements, in each case of this Section 6.14, which, individually or taken together with any other such waivers, amendments, cancellations, terminations, exercises or failures, could reasonably be expected to materially and adversely impact the ability to develop, commercialize or exploit JELMYTO® in the Specified Territory or any Credit Party's or Subsidiary's rights in respect of JELMYTO®.

7 EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

7.1 Payment Default

. Any Credit Party fails to (a) make any payment of any principal of the Term Loans when and as the same shall become due and payable, whether at the due date thereof (including pursuant to Section 2.2(c)) or at a date fixed for prepayment (whether voluntary or mandatory) thereof or by acceleration thereof or otherwise, or (b) within five (5) Business Days after the same becomes due and payable, any payment of interest or premium pursuant to Section 2.2, including any applicable Additional Consideration, Makewhole Amount or Prepayment Premium, or any other Obligations (which such five (5) Business Day cure period shall not apply to any such payments due on the Term Loan Maturity Date or such earlier date pursuant to Section 2.2(c)(ii) or Section 2.2(c)(iii) hereof or the date of acceleration pursuant to Section 8.1(a) hereof). A failure to pay any such interest, premium or Obligations pursuant to the foregoing clause (b) prior to the end of such five (5) Business Day-period shall not constitute an Event of Default (unless such payment is due on the Term Loan Maturity Date or such earlier date pursuant to Section 2.2(c)(ii) or Section 2.2(c)(iii) hereof or the date of acceleration pursuant to Section 8.1(a) hereof).

7.2 Covenant Default

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(a) The Credit Parties: (i) fail or neglect to perform any obligation in Sections 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.10, 5.12, 5.13, 5.14 5.16 or 5.17 or (ii) violate or breach any covenant or agreement in Section 6; or

(b) The Credit Parties fail or neglect to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents on its part to be performed, kept or observed and such failure or neglect continues for twenty (20) days, after the earlier of the date on which (i) a Responsible Officer of any Credit Party becomes aware of such failure or neglect and (ii) written notice thereof shall have been given to Borrower by the Collateral Agent or any Lender. Cure periods provided under this Section 7.2(b) shall not apply, among other things, to any of the covenants referenced in clause (a) above.

(c) The Tranche C Closing Date does not occur by September 30, 2024, unless (i) each of the conditions precedent to each Lender's obligation to advance its Applicable Percentage of the Tranche C Loan has been satisfied (or waived in accordance with Section 11.5) prior to September 30, 2024 and (ii) the failure of the Tranche C Closing Date to occur by September 30, 2024 is solely caused by the failure of Lenders to fund the Tranche C Loan by September 30, 2024 in accordance with Section 3.7.

7.3 Material Adverse Change

. A Material Adverse Change occurs.

7.4 Attachment; Levy; Restraint on Business

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(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of any Credit Party or of any entity under the control of any Credit Party (including a Subsidiary) in excess of $10,000,000 on deposit or otherwise maintained with the Collateral Agent, or (ii) a notice of lien or levy is filed against any of material portion of Collateral by any Governmental Authority, and the same under sub-clauses (i) and (ii) hereof are not, within thirty (30) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, that no Credit Extensions shall be made during any thirty (30) day cure period; or

(b) (i) Any material portion of Collateral is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Parent and its Subsidiaries from conducting any material part of their business, taken as a whole.

7.5 Insolvency

.

(a) An involuntary proceeding shall be commenced or an involuntary petition shall be filed in a court of competent jurisdiction seeking: (i) relief in respect of any Credit Party, or of a substantial part of the property of any Credit Party, under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law; (ii) the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for any Credit Party or for a substantial part of the property or assets of any Credit Party; or (iii) the winding-up or liquidation of any Credit Party, and such proceeding or petition shall continue undismissed or unstayed for sixty (60) days or an order or decree approving or ordering any of the foregoing shall be entered; or

(b) Any Credit Party shall: (i) voluntarily commence any proceeding or file any petition seeking relief under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law; (ii) consent to the institution of, or fail to contest in a timely and appropriate manner, any proceeding or the filing of any petition described in clause (a) above; (iii) apply for or consent to the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for any Credit Party or for a substantial part of the property or assets of any Credit Party; (iv) file an answer admitting the material allegations of a petition filed against it in any such proceeding; (v) make a general assignment for the benefit of creditors; (vi) become unable, admit in writing its inability or fail generally to pay its debts as they become

due; (vii) take any action for the purpose of effecting any of the foregoing; or (viii) wind up or liquidate (except as otherwise expressly permitted hereunder).

7.6 Other Agreements

.

(a) Any Credit Party fails to pay any Indebtedness (other than the Indebtedness represented by this Agreement and the other Loan Documents) within any applicable grace period after such payment is due and payable (including at final maturity) or after the acceleration of any such Indebtedness by the holder(s) thereof because of a default, in each case, if the total amount of such Indebtedness unpaid or accelerated exceeds $10,000,000.

(b) Parent fails to make any payments under the terms of the Pre-Paid Forward Contract when due or payable (after expiration of any applicable grace period) or an insolvency event or similar event occurs under the terms of the Pre-Paid Forward Contract.

7.7 Judgments

. One or more final, non-appealable judgments, orders, or decrees for the payment of money in an amount in excess of $10,000,000 (but excluding any final judgments, orders, or decrees for the payment of money that are covered by independent third-party insurance as to which liability has not been denied by such insurance carrier or by an indemnification claim against a solvent and unaffiliated Person that is not a Credit Party as to which such Person has not denied liability for such claim), shall be rendered against one or more Credit Parties and the same are not, within thirty (30) days after the entry thereof, discharged or execution thereof stayed or bonded pending appeal, or such judgments are not discharged prior to the expiration of any such stay.

7.8 Misrepresentations

. Any Credit Party or any Person acting for any Credit Party makes or is deemed to make any representation, warranty, or other statement now or later in this Agreement, any other Loan Document or in any writing delivered to the Collateral Agent or any Lender or to induce the Collateral Agent or any Lender to enter this Agreement or any other Loan Document, and such representation, warranty, or other statement is incorrect in any material respect (or, to the extent any such representation, warranty or other statement is qualified by materiality or Material Adverse Change, in any respect) when made or deemed to be made.

7.9 Loan Documents; Collateral

. Any material provision of any Loan Document shall for any reason cease to be valid and binding on or enforceable against any Credit Party, or any Credit Party shall so state in writing or bring an action to limit its obligations or liabilities thereunder; or any Collateral Document shall for any reason (other than pursuant to the terms thereof) cease to create a valid security interest in any material portion of the Collateral purported to be covered thereby or such security interest shall for any reason (other than pursuant to the terms of the Loan Documents) cease to be a perfected and first priority security interest in any material portion of the Collateral subject thereto, subject only to Permitted Liens, in each case, other than as a direct result of any action by the Collateral Agent or any Lender or failure of the Collateral Agent or any Lender to perform an obligation thereof under the Loan Documents.

7.10 ERISA Event

. An ERISA Event occurs that, individually or taken together with any other ERISA Events, results or could reasonably be expected to result in a Material Adverse Change, or the imposition of a Lien under Section 303(k) of ERISA on any Collateral that could reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change.

7.11 Intercreditor Agreement

. A material default or breach occurs under the RTW Intercreditor Agreement or any other subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt or Permitted Convertible Indebtedness, or any creditor party to such an agreement with the Collateral Agent (or Lenders) and any Credit Party breaches the terms of such agreement in any material respect; provided, that material defaults or breaches for the purposes of this Section 7.11 shall include breaches of payment, enforcement and subordination provisions or restrictions. For the avoidance of doubt, default or breaches by any Secured Party shall not constitute an Event of Default hereunder.

8 RIGHTS AND REMEDIES UPON AN EVENT OF DEFAULT

8.1 Rights and Remedies

. While an Event of Default occurs and continues, the Collateral Agent may, or at the request of the Required Lenders, will, without notice or demand:

(a) declare all Obligations (including, for the avoidance of doubt, any and all amounts payable pursuant to Section 2.2(e), Section 2.2(f), Section 2.4 and Section 2.7, in each case as applicable) immediately due and payable (but if an Event of Default described in Section 7.5 occurs, all Obligations, including any and all amounts payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, are automatically and immediately due and payable without any notice, demand or other action by the Collateral Agent or any Lender), whereupon all Obligations for principal, interest, premium or otherwise (including, for the avoidance of doubt, any and all amounts payable pursuant to Section 2.2(e), Section 2.2(f), Section 2.4 and Section 2.7, in each case as applicable) shall become due and payable by Borrower without presentment for payment, demand, notice of protest or other demand or notice of any kind, which are all expressly waived by the Credit Parties hereby;

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement;

(c) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that the Collateral Agent considers advisable, notify any Person owing Borrower money of the Collateral Agent's security interest, for the benefit of the Lenders and the other Secured Parties, in such funds, and verify the amount of the Collateral Accounts;

(d) make any payments and do any acts it considers necessary or reasonable to protect the Collateral or the Collateral Agent's security interest, for the benefit of Lenders and the other Secured Parties, in the Collateral. Parent or Borrower, as applicable, shall assemble the Collateral if the Collateral Agent or the Required Lenders requests and make it available as the Collateral Agent designates or the Required Lenders designate. The Collateral Agent or its agents or representatives may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien that appears to be prior or superior to its security interest, for the benefit of Lenders and the other Secured Parties, and pay all expenses incurred. Each of Parent and Borrower grants the Collateral Agent an irrevocable, royalty-free license or other right to enter, use, operate and occupy (and for its agents or representatives to enter, use, operate and occupy), without charge, any such premises to exercise any of the Collateral Agent's or any Lender's rights or remedies under this Section 8.1 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral);

(e) apply to the Obligations (i) any balances and deposits of Borrower it holds, (ii) any amount held by the Collateral Agent owing to or for the credit or the account of Borrower or (iii) any balance from any Collateral Account of any Credit Party or instruct the bank at which any such Collateral Account is maintained to pay the balance of any such Collateral Account to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct;

(f) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. With respect to any and all Intellectual Property owned or held by any Credit Party and included in Collateral, each Credit Party hereby grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, as of the Tranche A Closing Date: (i) an irrevocable, non-exclusive, assignable, royalty-free license or other right to use (and for its agents or representatives to use), without charge, including the right to sublicense, use and practice, any and all such Intellectual Property in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral, and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; and (ii) in connection with the Collateral Agent's exercise of its rights or remedies under this Section 8.1 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral), each Credit Party's rights under all licenses and all franchise contracts inure to the benefit of all Secured Parties;

(g) place a "hold" on any account maintained with the Collateral Agent or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(h) demand and receive possession of the Books of any Credit Party regarding Collateral; and

(i) exercise all rights and remedies available to the Collateral Agent or any Lender under the Collateral Documents or any other Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Each of the Collateral Agent and Lender agrees that in connection with any foreclosure or other exercise of rights under this Agreement or any other Loan Document with respect to any Intellectual Property included in the Collateral, the rights of the licensees under any license of such Intellectual Property will not be terminated, limited or otherwise adversely affected so long as no default exists thereunder in a way that would permit the licensor to terminate such license (commonly termed a non-disturbance). Without limitation to any other provision herein or in any other Loan Document, while an Event of Default occurs and continues, at the Collateral Agent's or the Required Lenders' request, representatives from Borrower and the Collateral Agent shall promptly meet (in person or telephonically) to discuss in good faith how to collect, receive, appropriate and realize upon Borrower's rights and interests in, to and under any Company IP Agreement, including in connection with any foreclosure or other exercise of the Collateral Agent's or any Lender's rights with respect thereto. If Borrower and the Collateral Agent do not mutually agree with respect thereto within ten (10) Business Days after such request by the Collateral Agent (or such later date as agreed by the Collateral Agent), then the Collateral Agent may request Borrower to, and Borrower (promptly following the receipt of such request) shall, use reasonable best efforts to obtain the written consent of any counterparty to the exercise by the Collateral Agent or any Lender of any and all rights and remedies under this Agreement or any other Loan Document with respect to any Company IP Agreement, in form and substance reasonably satisfactory to the Collateral Agent.

8.2 Power of Attorney

. Borrower hereby irrevocably appoints the Collateral Agent and any Related Party thereof as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's name on any checks or other forms of payment or security; (b) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Collateral Accounts directly with depository banks where the Collateral Accounts are maintained, for amounts and on terms the Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's products liability or general liability insurance policies maintained in any jurisdiction regarding Collateral; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of the Collateral Agent or a third party as the Code permits. Borrower hereby appoints the Collateral Agent and any Related Party thereof as its lawful attorney-in-fact to file or record any documents necessary to perfect or continue the perfection of the Collateral Agent's security interest, for the benefit of Lenders and the other Secured Parties, in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) have been satisfied in full and no Lender is under any further obligation to make Credit Extensions hereunder. The foregoing appointment of the Collateral Agent and any Related Party thereof as Borrower's attorney in fact, and all of the Collateral Agent's (or such Related Party's) rights and powers, coupled with an interest, are irrevocable until all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) have been fully repaid and performed and each Lender's obligation to provide Credit Extensions terminates.

8.3 Application of Payments and Proceeds Upon Default

. If an Event of Default has occurred and is continuing, the Collateral Agent shall apply any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Collateral Accounts or disposition of any other Collateral, or otherwise, to the Obligations in such order as the Collateral Agent shall determine in its sole discretion. Any surplus shall be paid to Borrower or other Persons legally entitled thereto; Borrower shall remain liable to Lenders for any deficiency. If the Collateral Agent or any Lender directly or indirectly enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, the Collateral Agent or such Lender, as applicable, shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by the applicable Lender(s) of cash therefor.

8.4 Collateral Agent's Liability for Collateral

. So long as the Collateral Agent complies with Requirements of Law regarding the safekeeping of the Collateral in the possession or under the control of the Collateral Agent and absent bad faith, gross negligence or willful misconduct of the Collateral Agent, the Collateral Agent shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; or (c) any act or default of any other Person. In no event shall the Collateral Agent or any Lender have any liability for any diminution in the value of the Collateral for any reason except as a result of Collateral Agent's bad faith, gross negligence or willful misconduct. Borrower bears all risk of loss, damage or destruction of the Collateral.

8.5 No Waiver; Remedies Cumulative

. The Collateral Agent's or any Lender's failure, at any time or times, to require strict performance by Borrower or any other Person of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of the Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Each of the Collateral Agent's and Lender's rights and remedies under this Agreement and the other Loan Documents are cumulative. Each of the Collateral Agent and Lenders has all rights and remedies provided under the Code, by law, or in equity. The exercise by the Collateral Agent or any Lender of one right or remedy is not an election and shall not preclude the Collateral Agent or any Lender from exercising any other remedy under this Agreement or other remedy available at law or in equity, and the waiver by the Collateral Agent or any Lender of any Event of Default is not a continuing waiver. The Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

8.6 Demand Waiver; Makewhole Amount; Prepayment Premium; Additional Consideration

. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by the Collateral Agent on which Borrower is liable. Borrower acknowledges and agrees that if the maturity of all Obligations shall be accelerated pursuant to Section 8.1(a) by reason of the occurrence of an Event of Default, the applicable Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, shall become due and payable by Borrower upon such acceleration, whether such acceleration is automatic or is effected by the Collateral Agent's or any Lender's declaration thereof, as provided in Section 8.1(a), and shall also become due and payable in the event the Obligations are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other similar means, and Borrower shall pay the applicable Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, as compensation to Lenders for the loss of its investment opportunity and not as a penalty, and Borrower waives any right to object thereto in any voluntary or involuntary bankruptcy, insolvency or similar proceeding or otherwise. Borrower further acknowledges and agrees that if the maturity of all Obligations shall be accelerated pursuant to Section 8.1(a) by reason of the occurrence of an Event of Default, each of the Tranche C Additional Consideration and the Tranche D Additional Consideration that is payable pursuant to Section 2.7(b) and Section 2.7(c), to the extent not already paid, shall become due and payable by Borrower upon such acceleration, whether such acceleration is automatic or is effected by the Collateral Agent's or any Lender's declaration thereof, as provided in Section 8.1(a), and shall also become due and payable in the event the Obligations are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other similar means, and Borrower's obligation to pay the Tranche C Additional Consideration pursuant to Section 2.7(b) and the Tranche D Additional Consideration pursuant to Section 2.7(c), as applicable, shall be compensation to Lenders for its commitment to fund the Tranche C Loan and the Tranche D Loan, respectively, and the loss of its investment opportunity in connection therewith and not a penalty, and Borrower waives any right to object thereto in any voluntary or involuntary bankruptcy, insolvency or similar proceeding or otherwise.

9 NOTICES

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; (d) when delivered, if hand-delivered by messenger; or (e) if sent by electronic mail, when received in readable form, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address (if any) indicated below. Any party to this Agreement may change its mailing or electronic mail address or facsimile number by giving all other parties hereto written notice thereof in accordance with the terms of this Section 9.

If to Borrower or any other Credit Party:

c/o UroGen Pharma Ltd.
400 Alexander Park Drive
Princeton, New Jersey 08540
Attn: Chief Financial Officer
Email: don.kim@urogen.com and legal@urogen.com

with copies to (which shall not constitute notice) to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121-1909
Attn: Charles J. Bair
Facsimile: 858 550 6420
Email: cbair@cooley.com

If to Collateral Agent: BioPharma Credit Plc
c/o Link Group, Company Matters Ltd.
6th Floor
65 Gresham Street
London EC2V 7NQ
United Kingdom
Attn: Company Secretary

Tel: +44 01 392 477 500
Fax: +44 01 392 438 288
Email: biopharmacreditplc@linkgroup.co.uk

with copies (which shall not constitute notice) to:

Pharmakon Advisors, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Fax: +1 (917) 210-4048
Email: pharmakon@pharmakonadvisors.com

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: (212) 872-8081
Fax: (212) 872-1002
Email: gsecol@akingump.com

If to any Lender: To the address of such Lender set forth on Exhibit D attached hereto

with copies (which shall not constitute notice) to:

Pharmakon Advisors LP
110 East 59th Street, #2800
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Fax: +1 (917) 210-4048
Email: pharmakon@pharmakonadvisors.com

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: (212) 872-8081
Fax: (212) 872-1002
Email: gsecol@akingump.com

10 CHOICE OF LAW, VENUE, AND JURY TRIAL WAIVER

THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT. Except as contemplated by the immediately succeeding paragraph, each party hereto submits to the exclusive jurisdiction of the courts of the State of New York sitting in New York County, and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, and agrees that all claims in respect of any such action, litigation or proceeding may be heard and determined in such New York State court or, to the fullest extent permitted by Requirements of Law, in such Federal court; provided, however, that nothing in this Agreement shall be deemed to operate to preclude the Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of the Collateral Agent or any Lender. Each Credit Party expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and each Credit Party hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or *forum non conveniens* and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Each Credit Party hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to such party at the address set forth in (or otherwise provided in accordance with the terms of) Section 9 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of such party's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

The preceding paragraph notwithstanding, each of the Collateral Agent or Lenders may, in its sole discretion and election, initiate and file legal proceedings in any matter related to this Agreement in the State of Israel. In any such event, the competent courts in Tel-Aviv-Jaffa, Israel, shall have sole and exclusive jurisdiction in relation to any such proceeding.

TO THE FULLEST EXTENT PERMITTED BY REQUIREMENTS OF LAW, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ITS RIGHT TO A JURY TRIAL IN ANY CLAIM, SUIT, ACTION OR PROCEEDING WITH RESPECT TO, OR DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH, THIS AGREEMENT, ANY OTHER LOAN DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREIN AND THEREIN OR RELATED HERETO OR THERETO (WHETHER FOUNDED IN

CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO OTHER PARTY AND NO RELATED PARTY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10 AND (C) HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

11 GENERAL PROVISIONS

11.1 Successors and Assigns

.

(a) This Agreement binds and is for the benefit of the parties hereto and their respective successors and permitted assigns.

(b) No Credit Party may transfer, pledge or assign this Agreement or any other Loan Document or any rights or obligations hereunder or thereunder without the prior written consent of each Lender. Subject to Section 11.1(d), any Lender may at any time sell, transfer, assign or pledge this Agreement or any other Loan Document or any of its rights or obligations hereunder or thereunder, or grant a participation in all or any part of, or any interest in, such Lender's obligations, rights or benefits under this Agreement and the other Loan Documents, including with respect to any Term Loan (or any portion thereof), to any other Lender, any Affiliate of any Lender or any third Person without Borrower's consent (any such sale, transfer, assignment, pledge or grant of a participation, a "**Lender Transfer**"); provided, however, that no Lender may make a Lender Transfer to a Disqualified Assignee without Borrower's prior written consent except after the occurrence and during the continuance of an Event of Default (in which case such consent is not required); provided, further, that no Lender may make a Lender Transfer to any third Person if such Lender Transfer would result in material adverse tax consequences to Borrower or Parent, in the reasonable judgment of the Collateral Agent after consultation with Borrower, without Borrower's prior written consent except after the occurrence and during the continuance of an Event of Default (in which case such consent is not required).

(c) In the case of a Lender Transfer in the form of a participation granted by any Lender to any third party, (i) such Lender's obligations under this Agreement shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of its obligations hereunder, (iii) Borrower shall continue to deal solely and directly with such Lender in connection with such Lender's rights and obligations under this Agreement and (iv) any agreement or instrument pursuant to which such Lender sells such participation shall provide that such Lender shall retain the sole right to enforce this Agreement and to approve any amendment, restatement, supplement or other modification hereto, in each case subject to the terms and conditions of this Agreement. Borrower agrees that each participant shall be entitled to the benefits of Sections 2.5 and 2.6 (subject to the requirements and limitations therein, including the requirements under Section 2.6(d) (it being understood that the documentation required under Section 2.6(d) shall be delivered to the applicable Lender)) to the same extent as if it were a Person that had acquired its interest by assignment pursuant to clause (b) above; provided that, with respect to any participation, such participant shall not be entitled to receive any greater payment under Sections 2.5 or 2.6 than the applicable Lender (i.e., the party that participated the interest) would have been entitled to receive, except to the extent of any entitlement to receive a greater payment resulting from a Change in Law that occurs after such participant acquired the applicable participation.

(d) The Collateral Agent (as a non-fiduciary agent on behalf of Borrower) shall record any Lender Transfer in the Note Register. Each Lender shall provide Borrower and the Collateral Agent with written notice of a Lender Transfer delivered no later than five (5) Business Days prior to the date on which such Lender Transfer is consummated. If any Lender sells a participation, such Lender shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and principal amounts (and stated interest) of each participant's interest in the Term Loans or other obligations under the Loan Documents (the "**Participant Register**"); provided, however, that such Lender shall have no obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan, letter of credit or other obligation is in "registered form" within the meaning of Section 163(f), 871(h)(2) and 881(c)(2) of the IRC and any related regulations (and any other relevant or successor provisions of the IRC or such regulations). The entries in the Participant Register shall be conclusive absent manifest error, and the Collateral Agent and each Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary.

(e) Any attempted transfer, pledge or assignment of this Agreement or any other Loan Document or any rights or obligations hereunder or thereunder in violation of this Section 11.1 shall be null and void and neither Borrower nor any transfer agent shall give any effect in the Note Register to such attempted transfer.

11.2 Indemnification

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(a) Borrower agrees to indemnify and hold harmless each of the Collateral Agent, Lenders and its and their respective Affiliates (and its or their respective successors and assigns) and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof (each such Person, an "**Indemnified Person**") from and against any and all Indemnified Liabilities; provided, however, that (i) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities to the extent such Indemnified Liabilities arise from the bad faith, gross negligence or willful misconduct of such Indemnified Person (or any of such Indemnified Person's Affiliates or controlling Persons or any of their respective directors, officers, managers, partners, members, agents, sub-agents or advisors), in each case, as determined by a final, non-appealable judgment of a court of competent jurisdiction, (ii) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities if and to the extent such Indemnified Liabilities arise from a material breach of any obligation of such Indemnified Person hereunder, and (iii) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities if and to the extent such Indemnified Liabilities arise from any claim by one Indemnified Person against another Indemnified Person that does not relate to any act or omission of Borrower or any Credit Party (other than against the Collateral Agent or any intercreditor agent in their respective capacities as such), and (iv) no Credit Party shall be liable for any settlement of any claim or proceeding effected by any Indemnified Person without the prior written consent of such Credit Party (which consent shall not be unreasonably withheld, conditioned or delayed), but if settled with such consent or if there shall be a final judgment against an Indemnified Person, each of the Credit Parties shall, jointly and severally with each other Credit Parties, indemnify and hold harmless such Indemnified Person from and against any loss or liability by reason of such settlement or judgment in the manner set forth in this Agreement. This Section 11.2(a) shall not apply with respect to Taxes other than any Taxes that represent liabilities, obligations, losses, damages, penalties, claims, costs, expenses and disbursements arising from any non-Tax claim.

(b) To the extent permitted by Requirements of Law, no party to this Agreement shall assert, and each party to this Agreement hereby waives, any claim against any other party hereto (and its or their successors and assigns), and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) (whether or not the claim therefor is based on contract, tort or duty imposed by any applicable legal requirement) arising out of, in connection with, arising out of, as a result of, or in any way related to, this Agreement or any Loan Document or any agreement or instrument contemplated hereby or thereby or referred to herein or therein, the transactions contemplated hereby or thereby, any Credit Extension or the use of the proceeds thereof or any act or omission or event occurring in connection therewith, and each party to this Agreement hereby waives, releases and agrees not to sue upon any such claim or any such damages, whether or not accrued and whether or not known or suspected to exist in its favor.

(c) Any action taken by any Credit Party under or with respect to any Loan Document, even if required under any Loan Document or at the request of the Collateral Agent or any Lender, shall be at the expense of such Credit Party, and neither the Collateral Agent nor any Secured Party shall be required under any Loan Document to reimburse any Credit Party or any Subsidiary of any Credit Party therefor except as expressly provided therein. In addition, and without limiting the generality of Section 2.4, Borrower agrees to pay or reimburse upon demand each of the Collateral Agent and Lenders (and their respective successors and assigns) and each of their respective Related Parties, if applicable, for any and all fees, expenses and disbursements of the kind or nature described in clause (b) of the definition of "Lender Expenses" incurred by it.

11.3 Severability of Provisions

. In case any provision in or obligation hereunder or under any other Loan Document shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

11.4 Correction of Loan Documents

. The Collateral Agent or Required Lenders may correct patent errors and fill in any blanks in the Loan Documents consistent with the agreement of the parties hereto so long as the Collateral Agent or Required Lenders, as applicable, provides the Credit Parties and the other parties hereto with written notice of such correction and allows the Credit Parties at least ten (10) days to object to such correction in writing delivered to the Collateral Agent and each Lender. In the event of such objection, such correction shall not be made except by an amendment to this Agreement in accordance with Section 11.5.

11.5 Amendments in Writing; Integration

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(a) No amendment, restatement or modification of or supplement to any provision of this Agreement or any other Loan Document, or waiver, discharge or termination of any obligation hereunder or thereunder, no approval or consent hereunder or thereunder (including any consent to any departure by Borrower or any other Credit Party herefrom or therefrom), shall in any event be effective unless the same shall be in writing and signed by Borrower (on its own behalf and on behalf of each other Credit Party) and the Required Lenders; provided, however, that no such amendment, restatement, modification, supplement, waiver, discharge, termination, approval or consent shall, unless in writing and signed by the Collateral Agent and the Required Lenders, affect the rights or duties of, or any amounts payable to, the Collateral Agent under this Agreement or any other Loan Document. Any such waiver, approval or consent granted shall be limited to the specific circumstance expressly described in it and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver, approval or consent.

(b) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations among the parties hereto about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

11.6 Counterparts

. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

11.7 Survival; Termination Prior to Term Loan Maturity Date

. All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to this Section 11.7 and all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted and any other obligations which, by their terms, are to survive the termination of this Agreement) have been paid in full and satisfied in accordance with the terms of this Agreement. The obligation of Borrower or any other the Credit Parties in Section 11.2 to indemnify Indemnified Persons shall survive until the statute of limitations with respect to such claim or cause of action shall have run. So long all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted and any other obligations which, by their terms, are to survive the termination of this Agreement and for which no claim has been made) have been paid in full and satisfied in accordance with the terms of this Agreement, this Agreement shall be terminated (a) prior to the Term Loan Maturity Date by Borrower, effective five (5) Business Days (or such shorter period as the Collateral Agent may agree in its sole discretion) after written notice of termination is delivered to the Collateral Agent and the Lenders, or (b) if no such notice is delivered, automatically on the Term Loan Maturity Date.

11.8 Confidentiality

. Any information regarding the Credit Parties and their Subsidiaries and their businesses provided to the Collateral Agent or any Lender by or on behalf of any Credit Party pursuant to the Loan Documents shall be deemed "Confidential Information"; provided, however, that Confidential Information does not include information that is either: (i) in the public domain or in the possession of the Collateral Agent, any Lender or any of their respective Affiliates or when disclosed to the Collateral Agent, any Lender or any of their respective Affiliates, or becomes part of the public domain after disclosure to the Collateral Agent, any Lender or any of their respective Affiliates, in each case, other than as a result of a breach by the Collateral Agent, any Lender or any of their respective Affiliates of the obligations under this Section 11.8; or (ii) disclosed to the Collateral Agent, any Lender or any of their respective Affiliates by a third party if the Collateral Agent, such Lender or such Affiliate, as applicable, does not know (following due and careful enquiry) that the third party is prohibited from disclosing the information. Neither the Collateral Agent nor any Lender shall disclose any Confidential Information to a third party or use Confidential Information for any purpose other than the exercise of its rights and the performance of its duties or obligations under the Loan Documents. The foregoing in this Section 11.8 notwithstanding, the Collateral Agent and each Lender may disclose Confidential Information: (a) to any of

its Subsidiaries or Affiliates; (b) to prospective transferees, purchasers or participants of any interest in the Term Loans (including, for the avoidance of doubt, in connection with any proposed Lender Transfer), provided that no such disclosure to any Competitors shall be permitted hereunder without Borrower's prior written consent (which consent shall not be required after the occurrence and during the continuance of an Event of Default); (c) as required by law, regulation, subpoena, or other order, provided, that (x) prior to any disclosure under this clause (c), the Collateral Agent or such Lender, as applicable, agrees to endeavor to provide Borrower with prior written notice thereof and with respect to any law, regulation, subpoena or other order, to the extent that the Collateral Agent or such Lender is permitted to provide such prior notice to Borrower pursuant to the terms hereof, and (y) any disclosure under this clause (c) shall be limited solely to that portion of the Confidential Information as may be specifically compelled by such law, regulation, subpoena or other order; (d) to the extent requested by regulators having jurisdiction over the Collateral Agent or such Lender or as otherwise required in connection with the Collateral Agent's or such Lender's examination or audit by such regulators; (e) as the Collateral Agent or such Lender considers reasonably necessary in exercising remedies under the Loan Documents; (f) to third-party service providers of the Collateral Agent or such Lender; and (g) to any of the Collateral Agent's or such Lender's Related Parties; provided, however, that the third parties to which Confidential Information is disclosed pursuant to clauses (a), (b), (f) and (g) are bound by obligations of confidentiality and non-use that are no less restrictive than those contained herein.

The provisions of this Section 11.8 shall survive the termination of this Agreement.

11.9 Attorneys' Fees, Costs and Expenses

. In any action or proceeding between any Credit Party and the Collateral Agent or any Lender arising out of or relating to the Loan Documents, the prevailing party shall be entitled to recover its reasonable attorneys' fees and other costs and expenses incurred, in addition to any other relief to which it may be entitled.

11.10 Right of Set-Off

. In addition to any rights now or hereafter granted under Requirements of Law and not by way of limitation of any such rights, upon the occurrence of an Event of Default and at any time thereafter during the continuance of any Event of Default, each Lender is hereby authorized by each Credit Party at any time or from time to time, without prior notice to any Credit Party, any such notice being hereby expressly waived by Borrower (on its own behalf and on behalf of each other Credit Party), to set off and to appropriate and to apply any and all deposits (general or special, including Indebtedness evidenced by certificates of deposit, whether matured or unmatured, but not including trust accounts) and any other Indebtedness at any time held or owing by such Lender to or for the credit or the account of any Credit Party against and on account of the obligations and liabilities of any Credit Party to such Lender hereunder and under the other Loan Documents, including all claims of any nature or description arising out of or connected hereto or with any other Loan Document, irrespective of whether or not (a) the Collateral Agent or such Lender shall have made any demand hereunder or (b) the principal of or the interest on the Term Loans or any other amounts due hereunder shall have become due and payable pursuant to Section 2 and although such obligations and liabilities, or any of them, may be contingent or unmatured. Each Lender agrees promptly to notify Borrower and the Collateral Agent after any such set off and application made by such Lender; provided, that the failure to give such notice shall not affect the validity of such set off and application.

11.11 Marshalling; Payments Set Aside

. Neither the Collateral Agent nor any Lender shall be under any obligation to marshal any assets in favor of any Credit Party or any other Person or against or in payment of any or all of the Obligations. To the extent that any Credit Party makes a payment or payments to any Lender, or the Collateral Agent or any Lender enforces any Liens or exercises its rights of setoff, and such payment or payments or the proceeds of such enforcement or setoff or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside or required to be repaid to a trustee, receiver or any other party under any bankruptcy law, any other state or federal law, common law or any equitable cause, then, to the extent of such recovery, the obligation or part thereof originally intended to be satisfied, and all Liens, rights and remedies therefor or related thereto, shall be revived and continued in full force and effect as if such payment or payments had not been made or such enforcement or setoff had not occurred.

11.12 Electronic Execution of Documents

. The words "execution," "execute," "signed," "signature," and words of like import in this Agreement and the other Loan Documents shall be deemed to include electronic signatures or electronic records, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any Requirements of Law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

11.13 Captions

. Section headings herein are included herein for convenience of reference only and shall not constitute a part hereof for any other purpose or be given any substantive effect.

11.14 Construction of Agreement

. The parties hereto mutually acknowledge that they and their respective attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty, this Agreement shall be construed without regard to which of the parties hereto caused the uncertainty to exist.

11.15 Third Parties

. Nothing in this Agreement, whether express or implied, is intended to: (a) except as expressly provided in Section 11.2(a), confer any benefits, rights or remedies under or by reason of this Agreement on any Persons other than the express parties to it and their respective successors and permitted assigns; (b) relieve or discharge the obligation or liability of any Person not an express party to this Agreement; or (c) give any Person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

11.16 No Advisory or Fiduciary Duty

. The Collateral Agent and each Lender may have economic interests that conflict with those of the Credit Parties. Each Credit Party agrees that nothing in the Loan Documents or otherwise will be deemed to create an advisory, fiduciary or agency relationship or fiduciary or other implied duty between any Lender or the Collateral Agent, on the one hand, and such Credit Party, its Subsidiaries, and any of their respective stockholders or affiliates,

on the other hand. Each Credit Party acknowledges and agrees that (i) the transactions contemplated by the Loan Documents are arm's-length commercial transactions between each Lender and the Collateral Agent, on the one hand, and such Credit Party, its Subsidiaries and their respective affiliates, on the other hand, (ii) in connection therewith and with the process leading to such transaction, the Collateral Agent and each Lender is acting solely as a principal and not the advisor, agent or fiduciary of such Credit Party, its Subsidiaries or their respective affiliates, management, stockholders, creditors or any other Person, (iii) neither the Collateral Agent nor any Lender has assumed an advisory or fiduciary responsibility in favor of any Credit Party, its Subsidiaries or their respective affiliates with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Collateral Agent or any Lender or any of their respective affiliates has advised or is currently advising such Credit Party, its Subsidiaries or their respective affiliates on other matters) or any other obligation to such Credit Party, its Subsidiaries or their respective affiliates except the obligations expressly set forth in the Loan Documents, and (iv) each Credit Party, its Subsidiaries and their respective affiliates have consulted their own legal and financial advisors to the extent each deemed appropriate. Each Credit Party further acknowledges and agrees that it is responsible for making its own independent judgment with respect to such transactions and the process leading thereto. Each Credit Party agrees that it will not claim that the Collateral Agent or any Lender has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to such Credit Party, its Subsidiaries or their respective affiliates in connection with such transaction or the process leading thereto.

11.17 Credit Parties' Agent

. Each of the Credit Parties hereby irrevocably appoints Borrower, as its agent, attorney-in-fact and legal representative for all purposes, including requesting disbursement of the Term Loans and receiving account statements and other notices and communications to Credit Parties (or any of them) from the Collateral Agent or the Lenders, executing amendments, waivers or other modifications of or supplements to Loan Documents and executing or designating new Loan Documents. The Collateral Agent or the Lenders may rely, and shall be fully protected in relying, on any request for the Term Loans, disbursement instruction, report, information or any other notice or communication made or given by Borrower and any amendment, waiver or other modification of or supplement to a Loan Document or the execution or designation of new Loan Documents executed or made by Borrower, whether in its own name or on behalf of one or more of the other Credit Parties, and the Collateral Agent or the Lenders shall not have any obligation to make any inquiry or request any confirmation from or on behalf of any other Credit Party as to the binding effect on it of any such request, instruction, report, information, other notice, communication, amendment, supplement, waiver, other modification, execution or designation, nor shall the joint and several character of the Credit Parties' obligations hereunder be affected thereby.

11.18 Reaffirmation of Loan Documents; Confirmation of Liens

. Except to the extent that any Loan Document (as defined in the Prior Loan Agreement) is being explicitly terminated, replaced or amended and restated in connection with the amendment and restatement being implemented hereby, each such Loan Document shall continue to be in full force and effect and is hereby ratified and confirmed in all respects, except that, from and after the Effective Date, each reference in any such Loan Document to the "Loan Agreement," "thereunder," "thereof" or words of like import shall be deemed to mean references to this Loan Agreement. As of the Effective Date, Borrower, Parent and each other Credit Party hereby (a) reaffirm each of its covenants, agreements and obligations contained in any such Loan Document, (b) reaffirm each guarantee, pledge and grant of a security interest made in favor of the Collateral Agent under or in connection with the Prior Loan Agreement and any Loan Documents entered into in connection therewith and (c) agree that notwithstanding the amendment and restatement of the Prior Loan Agreement, such guarantees, pledges and grants of security interest in favor of the Collateral Agent shall continue in full force and effect.

11.19 Effect of Amendment and Restatement

.

(a) On the Effective Date, the Prior Loan Agreement shall be amended, restated and superseded in its entirety. The parties hereto acknowledge and agree that (i) this Loan Agreement and the other documents entered into in connection herewith do not constitute a novation, payment and reborrowing, or termination of the "Obligations" (as defined in the Prior Loan Agreement) under the Prior Loan Agreement, as in effect prior to the Effective Date but rather a substitution of certain of the terms contained therein, as set forth herein and (ii) such "Obligations" are in all respects continuing (as amended and restated hereby) as indebtedness and obligations outstanding under this Loan Agreement. On and after the Effective Date, the rights and obligations of the parties hereto shall be governed by this Loan Agreement, except that the rights and obligations of the parties hereto with respect to the period prior to the Effective Date shall be governed by the provisions of the Prior Loan Agreement as it existed prior to such amendment and restatement; provided, however, that waivers granted under the Prior Loan Agreement prior to the Effective Date shall no longer be effective as of the Effective Date.

(b) In connection with the amendment and restatement of the Prior Loan Agreement, Borrower, Parent and each other Credit Party release, waive and discharge any claims or causes of action which it may have against the Collateral Agent, and each of the Lenders (as each such term is defined in the Prior Loan Agreement) and any of the other holders of the Obligations (as defined in the Prior Loan Agreement) arising under the Prior Loan Agreement or any of the other Loan Documents (as defined in the Prior Loan Agreement) or relating to any of their performance thereunder.

12 COLLATERAL AGENT

12.1 Appointment and Authority

. Each Lender hereby irrevocably appoints BioPharma Credit PLC to act on its behalf as the Collateral Agent hereunder and under the other Loan Documents and authorizes the Collateral Agent to take such actions on its behalf and to exercise such powers as are delegated to the Collateral Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto. Except for the first two (2) sentences of Section 12.6 and the first sentence and penultimate paragraph of Section 12.8, the provisions of this Section 12 are solely for the benefit of the Collateral Agent and Lenders, and neither Borrower nor any other Credit Party shall have rights as a third party beneficiary of any of such provisions. Subject to Section 12.8 and Section 11.5, any action required or permitted to be taken by the Collateral Agent hereunder shall be taken with the prior approval of the Required Lenders.

12.2 Rights as a Lender

. The Person serving as the Collateral Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Collateral Agent and the term "Lender" or "Lenders" shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Collateral Agent hereunder in its individual capacity. Such Person and its Affiliates may lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with Borrower or any Subsidiary or other Affiliate thereof as if such Person were not the Collateral Agent hereunder and without any duty to account therefor to any Lender.

12.3 Exculpatory Provisions

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(a) The Collateral Agent shall not have any duties or obligations to the Lenders except those expressly set forth herein and in the other Loan Documents to which it is a party. Without limiting the generality of the foregoing, with respect to the Lenders, the Collateral Agent:

(i) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default or Event of Default has occurred and is continuing;

(ii) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents to which it is a party that the Collateral Agent is required to exercise as directed in writing by the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in such other Loan Documents), provided that the Collateral Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Collateral Agent to liability or that is contrary to any Loan Document or Requirements of Law; and

(iii) shall not, except as expressly set forth herein and in the other Loan Documents to which it is a party, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to Borrower or any of its Affiliates that is communicated to or obtained by the Person serving as the Collateral Agent or any of its Affiliates in any capacity.

(b) The Collateral Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Lenders (or such other number or percentage of the Lenders as shall be necessary, or as the Collateral Agent shall believe in good faith shall be necessary, under the circumstances as provided in Section 11.5) or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and nonappealable judgment. The Collateral Agent shall be deemed not to have knowledge of any Default or Event of Default unless and until notice describing such Default or Event of Default is given to the Collateral Agent in writing by Borrower or a Lender.

(c) The Collateral Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Section 3 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Collateral Agent.

12.4 Reliance by Collateral Agent

. The Collateral Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Collateral Agent also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. The Collateral Agent may consult with legal counsel (who may be counsel for Borrower), independent accountants, manufacturing consultants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants, consultants or experts.

12.5 Delegation of Duties

. The Collateral Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Loan Document by or through any one or more sub-agents appointed by the Collateral Agent. The Collateral Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The exculpatory provisions of this Section 12 shall apply to any such sub-agent and to the Related Parties of the Collateral Agent and any such sub-agent. The Collateral Agent shall not be responsible for the negligence or misconduct of any sub-agent except to the extent that a court of competent jurisdiction determines in a final and nonappealable judgment that the Collateral Agent acted with gross negligence or willful misconduct in the selection of such sub-agent.

12.6 Resignation of Collateral Agent

. The Collateral Agent may at any time give notice of its resignation to the Lenders and Borrower. Upon the receipt of any such notice of resignation, the Required Lenders shall have the right, in consultation with Borrower so long as no Default or Event of Default has occurred and is continuing, to appoint a successor (which shall not be a Competitor except after the occurrence and during the continuance of an Event of Default). If no successor shall have been so appointed by the Required Lenders and shall have accepted such appointment within thirty (30) days after the retiring Collateral Agent gives notice of its resignation, then the retiring Collateral Agent may, on behalf of the Lenders, appoint a successor Collateral Agent that is a Related Party of the Collateral Agent or any Lender; provided that, whether or not a successor has been appointed or has accepted such appointment, such resignation shall become effective upon delivery of the notice thereof. Upon the acceptance of a successor's appointment as Collateral Agent hereunder, such successor shall succeed to and become vested with all of the rights, powers, privileges and duties of the retiring (or retired) Collateral Agent, and the retiring Collateral Agent shall be discharged from all of its duties and obligations under the Loan Documents (if not already discharged therefrom as provided above in this Section 12.6). After the retiring Collateral Agent's resignation, the provisions of this Section 12 and Section 10 shall continue in effect for the benefit of such retiring Collateral Agent, its sub-agents and their respective Related Parties in respect of any actions taken or omitted to be taken by any of them while the retiring Collateral Agent was acting as Collateral Agent. Upon any resignation by the Collateral Agent, all payments, communications and determinations provided to be made by, to or through the Collateral Agent shall instead be made by, to or through each Lender directly, until such time as a Person accepts an appointment as Collateral Agent in accordance with this Section 12.6.

12.7 Non-Reliance on Collateral Agent and Other Lenders

. Each Lender acknowledges that it has, independently and without reliance upon the Collateral Agent or any other Lender or any of their respective Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement and make Credit Extensions hereunder. Each Lender also acknowledges that it will, independently and without reliance upon the Collateral Agent or any other Lender or any of their respective Related Parties and based on such documents and information as it shall from time to time

deem appropriate, continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Loan Document or any related agreement or any document furnished hereunder or thereunder.

12.8 Collateral and Guaranty Matters

. Each Lender agrees that any action taken by the Collateral Agent or the Required Lenders in accordance with the provisions of this Agreement or of the other Loan Documents, and the exercise by the Collateral Agent or Required Lenders of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Lenders. Without limiting the generality of the foregoing, the Lenders irrevocably authorize and instruct the Collateral Agent, and the Collateral Agent agrees:

(a) to release any Lien on any property granted to or held by the Collateral Agent under any Collateral Document (i) upon payment and satisfaction in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with the terms of this Agreement, (ii) that is sold, transferred, disposed or to be sold, transferred, disposed as part of or in connection with any sale, transfer or other disposition (other than any sale to a Credit Party) permitted hereunder, (iii) subject to Section 11.5, if approved, authorized or ratified in writing by the Required Lenders, or (iv) to the extent such property is owned by a Guarantor, upon the release of such Guarantor from its obligations under the Loan Documents pursuant to clause (c) below;

(b) to subordinate any Lien on any property granted to or held by the Collateral Agent under any Loan Document to the holder of any Lien on such property that is permitted by clause (d), (i), (j), (m), (n) and (r) of the definition of "Permitted Liens" (solely with respect to modifications, replacements, extensions or renewals of Liens permitted under clause (d), (i), (j), (m) and (n) of the definition of "Permitted Liens");

(c) to release any Guarantor (other than Parent or Borrower) from its obligations under each Collateral Document if such Person ceases to be a Subsidiary as a result of a transaction permitted hereunder or upon payment and satisfaction in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with this Agreement;

(d) to enter into non-disturbance and similar agreements in connection with the licensing of Intellectual Property permitted pursuant to the terms of this Agreement; and

(e) to enter into any subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt.

Without prejudice to the obligation to fulfill the foregoing, upon request by the Collateral Agent at any time the Required Lenders will confirm in writing the Collateral Agent's authority to release or subordinate its interest in particular types or items of property, or to release any Guarantor (other than Parent or Borrower) from its obligations under each Collateral Document pursuant to this Section 12.8.

In each case as specified in this Section 12.8, the Collateral Agent will (and each Lender irrevocably authorizes and instructs the Collateral Agent to), at Borrower's expense, execute and deliver to the applicable Credit Party such documents as such Credit Party may reasonably request (i) to evidence the release or subordination of such item of Collateral from the Liens and security interests granted under the Collateral Documents, (ii) to enter into non-disturbance or similar agreements in connection with the licensing of Intellectual Property, (iii) to enter into any subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt or (iv) to evidence the release of any Guarantor (as applicable) from its obligations under each Collateral Document, in each case in accordance with the terms of the Loan Documents and this Section 12.8 and in form and substance reasonably acceptable to the Collateral Agent.

Without limiting the generality of Section 12.10 below, the Collateral Agent shall deliver to the Lenders notice of any action taken by it under this Section 12.8 promptly after the taking thereof; provided that delivery of or failure to deliver any such notice shall not affect the Collateral Agent's rights, powers, privileges and protections under this Section 12.

12.9 Reimbursement by Lenders

. To the extent that Borrower for any reason fails to indefeasibly pay any amount required under Section 2.4 to be paid by it to the Collateral Agent (or any sub-agent thereof) or any Related Party of any of the foregoing, each Lender severally agrees to pay to the Collateral Agent (or any such sub-agent) or such Related Party, as the case may be, such Lender's *pro rata* share (based upon the percentages as used in determining the Required Lenders as of the time that the applicable unreimbursed expense or indemnity payment is sought) of such unpaid amount; provided that the unreimbursed expense or indemnified loss, damage, liability or related expense, as the case may be, was incurred by or asserted against the Collateral Agent (or any such sub-agent) in its capacity as such or against any Related Party of any of the foregoing acting for the Collateral Agent (or any sub-agent) in connection with such capacity.

12.10 Notices and Items to Lenders

. The Collateral Agent shall deliver to the Lenders each notice, report, statement, approval, direction, consent, exemption, authorization, waiver, certificate, filing or other item received by it pursuant to this Agreement or any other Loan Document (including any item received by it pursuant to Section 3 or set forth on Schedule 5.14 of the Disclosure Letter); provided, that any delivery of or failure to deliver any such notice, report, statement, approval, direction, consent, exemption, authorization, waiver, certificate, filing or item shall not otherwise alter or effect the rights of the Lenders or the Collateral Agent under this Agreement or any other Loan Document or the validity of such item. In addition, to the extent the Collateral Agent or the Required Lenders deliver any notices, approvals, authorizations, directions, consents or waivers to Borrower pursuant to this Agreement or any other Loan Document, the Collateral Agent or the Required Lenders, as applicable, will also deliver such notice, approval, authorization, direction, consent or waiver to the other Lenders on or about the same time such notice, approval, authorization, direction, consent or waiver is provided to Borrower; provided, that the delivery of or failure to deliver such notice, approval, authorization, direction, consent or waiver to the other Lenders shall not in any way effect the obligations of Borrower, or the rights of the Collateral Agent or the Required Lenders, in respect of such notice, approval, authorization, direction, consent or waiver or the validity thereof.

13 DEFINITIONS

13.1 Definitions

. For the purposes of and as used in the Loan Documents: (a) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (b) except as the context otherwise requires (including to the extent otherwise expressly provided in any Loan Document), (i) references to any law, statute, treaty, order, policy, rule or regulation include any amendments, supplements and successors thereto and (ii) references to any contract, agreement, instrument or other document include any amendments, restatements, supplements or modifications thereto or thereof from time to time to the extent permitted by the provisions thereof; (c) the word "shall" is mandatory; (d) the word "may" is permissive; (e) the word "or" has the inclusive meaning represented by the phrase "and/or"; (f) the words "include", "includes" and "including" are not limiting; (g) the singular includes the plural and the plural includes the singular; (h) numbers denoting amounts that are set off in parentheses are negative unless the context dictates otherwise; (i) each authorization herein shall be deemed irrevocable and coupled with an interest; (j) all accounting terms shall be interpreted, and all determinations relating thereto shall be made, in accordance with Applicable Accounting Standards; (k) references to any time of day shall be to New York time; (l) the words "herein", "hereof", "hereby", "hereto" and "hereunder" refer to this Agreement as a whole; and (m) unless otherwise expressly provided, references to specific sections, articles, clauses, sub-clauses, annexes and exhibits are to this Agreement and references to specific schedules are to the Disclosure Letter. As used in this Agreement, the following capitalized terms have the following meanings:

"Account" means any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes all accounts receivable, book debts, and other sums owing to Credit Parties.

"Account Debtor" means any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"Acquisition" means (a) any Stock Acquisition, or (b) any Asset Acquisition.

"Additional Consideration" means, individually or collectively, as the context dictates, the Tranche A/B Additional Consideration, the Tranche C Additional Consideration and the Tranche D Additional Consideration.

"Adjusted Term SOFR" means, for purposes of any calculation, the rate per annum equal to (a) Term SOFR for such calculation plus (b) the Term SOFR Adjustment; provided that if Adjusted Term SOFR as so determined shall ever be less than the Floor, then Adjusted Term SOFR shall be deemed to be the Floor.

"Advance Request Form" means a Loan Advance Request Form in substantially the form attached hereto as Exhibit A.

"Adverse Proceeding" means any action, suit, proceeding, hearing (whether administrative, judicial or otherwise), governmental investigation or arbitration (whether or not purportedly on behalf of any Credit Party or any of its Subsidiaries) at law or in equity, or before or by any Governmental Authority, domestic or foreign (including any Environmental Claims), whether pending or, to the Knowledge of such Credit Party, threatened in writing against or adversely affecting any Credit Party or any of its Subsidiaries or any property of any Credit Party or any of its Subsidiaries.

"Affiliate" means, with respect to any Person, each other Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company or limited liability partnership, that Person's managers and members. As used in this definition, "control" means (a) direct or indirect beneficial ownership of at least fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in a Person or (b) the power to direct or cause the direction of the management of such Person by contract or otherwise. In no event shall the Collateral Agent or any Lender be deemed to be an Affiliate of Parent or any of its Subsidiaries.

"Agreement" is defined in the preamble hereof.

"Anti-Money Laundering Laws" is defined in Section 4.18(b).

"Applicable Accounting Standards" means with respect to Parent and its Subsidiaries, generally accepted accounting principles in the United States as set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination, consistently applied.

"Applicable Margin" means, for any day, as to any Term Loan, a rate *per annum* equal to seven and one-quarter percent (7.25%).

"Applicable Percentage" means, at any time: (a) with respect to the Tranche A Loan or the Tranche A Loan Amount, the percentage equal to a fraction, the numerator of which is (i) on or prior to the Tranche A Closing Date, the amount of such Lender's Tranche A Commitment at such time and the denominator of which is the Tranche A Loan Amount at such time or (ii) thereafter, the outstanding principal amount of such Lender's portion of the Tranche A Loan at such time, and the denominator of which is the aggregate outstanding principal amount of the Tranche A Loan at such time; (b) with respect to the Tranche B Loan or the Tranche B Loan Amount, the percentage equal to a fraction, the numerator of which is (i) on or prior to the Tranche B Closing Date, the amount of such Lender's Tranche B Commitment at such time and the denominator of which is the Tranche B Loan Amount at such time or (ii) thereafter, the outstanding principal amount of such Lender's portion of the Tranche B Loan at such time, and the denominator of which is the aggregate outstanding principal amount of the Tranche B Loan at such time; and (c) with respect to the Term Loans and the Term Loan Commitments, the percentage equal to a fraction, the numerator of which is, the sum of the amount of such Lender's outstanding Term Loan Commitments and the amount of such Lender's portion of the outstanding principal amount of the Term Loans at such time, and the denominator of which is the sum of the amount of all outstanding Term Loan Commitments and the aggregate outstanding principal amount of the Term Loans at such time.

"ASC" is defined in Section 1.

"Asset Acquisition" means, with respect to Parent or any of its Subsidiaries, any purchase, exclusive or nonexclusive in-license or other acquisition of any properties or assets of any other Person (including any purchase or other acquisition of any business unit, line of business or division of such Person). Notwithstanding the foregoing, "Asset Acquisition" does not include any in-license or any collaboration, co-promotion or co-marketing arrangement pursuant to which Parent or any Subsidiary acquires rights to research, develop, use, make, promote, sell or market the products of another Person.

"Available Tenor" means, as of any date of determination and with respect to the then-current Benchmark, as applicable, (a) if such Benchmark is a term rate, any tenor for such Benchmark (or component thereof) that is or may be used for determining the length of an interest period pursuant to this

Agreement or (b) otherwise, any payment period for interest calculated with reference to such Benchmark (or component thereof) that is or may be used for determining any frequency of making payments of interest calculated with reference to such Benchmark pursuant to this Agreement, in each case, as of such date and not including, for the avoidance of doubt, any tenor for such Benchmark that is then-removed from the definition of "Interest Period" pursuant to Section 2.3(e).

"Bankruptcy Code" means Title 11 of the United States Code entitled "Bankruptcy," as now and hereafter in effect, or any successor statute (and any foreign equivalent).

"Benchmark" means, initially, the Term SOFR Reference Rate; provided that if a Benchmark Transition Event has occurred with respect to the Term SOFR Reference Rate or the then-current Benchmark, then "Benchmark" means the applicable Benchmark Replacement to the extent that such Benchmark Replacement has replaced such prior benchmark rate pursuant to Section 2.3(e).

"Benchmark Replacement" means, with respect to any Benchmark Transition Event, the first alternative set forth in the order below that can be determined by the Collateral Agent for the applicable Benchmark Replacement Date:

(a) the sum of (i) Daily Simple SOFR and (ii) 0.26161% (26.161 basis points); or

(b) the sum of: (i) the alternate benchmark rate that has been selected by the Collateral Agent giving due consideration to (A) any selection or recommendation of a replacement benchmark rate or the mechanism for determining such a rate by the Relevant Governmental Body or (B) any evolving or then-prevailing market convention for determining a benchmark rate as a replacement to the then-current Benchmark for Dollar-denominated syndicated credit facilities and (ii) the related Benchmark Replacement Adjustment;

provided that, if the Benchmark Replacement as determined pursuant to clause (a) or (b) above would be less than the Floor, the Benchmark Replacement will be deemed to be the Floor for the purposes of this Agreement and the other Loan Documents.

"Benchmark Replacement Adjustment" means, with respect to any replacement of the then-current Benchmark with an Unadjusted Benchmark Replacement, the spread adjustment, or method for calculating or determining such spread adjustment, (which may be a positive or negative value or zero) that has been selected by the Collateral Agent and Borrower giving due consideration to (a) any selection or recommendation of a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of such Benchmark with the applicable Unadjusted Benchmark Replacement by the Relevant Governmental Body or (b) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of such Benchmark with the applicable Unadjusted Benchmark Replacement for Dollar-denominated syndicated credit facilities at such time.

"Benchmark Replacement Date" means a date and time determined by the Collateral Agent in its reasonable discretion, which date shall be no later than the earliest to occur of the following events with respect to the then-current Benchmark:

(a) in the case of clause (a) or (b) of the definition of "Benchmark Transition Event," the later of (i) the date of the public statement or publication of information referenced therein and (ii) the date on which the administrator of such Benchmark (or the published component used in the calculation thereof) permanently or indefinitely ceases to provide all Available Tenors of such Benchmark (or such component thereof); and

(b) in the case of clause (c) of the definition of "Benchmark Transition Event," the first date on which such Benchmark (or the published component used in the calculation thereof) has been determined and announced by the regulatory supervisor for the administrator of such Benchmark (or such component thereof) to be non-representative; provided that such non-representativeness will be determined by reference to the most recent statement or publication referenced in such clause (c) and even if any Available Tenor of such Benchmark (or such component thereof) continues to be provided on such date.

For the avoidance of doubt, the "Benchmark Replacement Date" will be deemed to have occurred in the case of clause (a) or (b) above with respect to any Benchmark upon the occurrence of the applicable event or events set forth therein with respect to all then-current Available Tenors of such Benchmark (or the published component used in the calculation thereof).

"Benchmark Transition Event" means the occurrence of one or more of the following events with respect to the then-current Benchmark:

(a) a public statement or publication of information by or on behalf of the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that such administrator has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof), permanently or indefinitely; provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof);

(b) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof), the Federal Reserve Board, the Federal Reserve Bank of New York, an insolvency official with jurisdiction over the administrator for such Benchmark (or such component), a resolution authority with jurisdiction over the administrator for such Benchmark (or such component) or a court or an entity with similar insolvency or resolution authority over the administrator for such Benchmark (or such component), which states that the administrator of such Benchmark (or such component) has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof) permanently or indefinitely; provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof); or

(c) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that all Available Tenors of such Benchmark (or such component thereof) are not, or as of a specified future date will not be, representative.

For the avoidance of doubt, a "Benchmark Transition Event" will be deemed to have occurred with respect to any Benchmark if a public statement or publication of information set forth above has occurred with respect to each then-current Available Tenor of such Benchmark (or the published component used in the calculation thereof).

"Benchmark Unavailability Period" means, the period (if any) (a) beginning at the time that a Benchmark Replacement Date has occurred if, at such time, no Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Loan Document in accordance

with Section 2.3(e) and (b) ending at the time that a Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Loan Document in accordance with Section 2.3(e).

"Board of Directors" means, with respect to any Person, (i) in the case of any corporation, the board of directors of such Person, (ii) in the case of any limited liability company, the board of managers of such Person, or if there is none, the Board of Directors of the managing member of such Person, (iii) in the case of any partnership or exempted limited partnership, the Board of Directors of the general partner of such Person and (iv) in any other case, the functional equivalent of the foregoing.

"Board of Governors" means the Board of Governors of the United States Federal Reserve System, or any successor thereto.

"Books" means all books and records including ledgers, records regarding a Credit Party's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Borrower" is defined in the preamble hereof.

"Borrowing Resolutions" means, with respect to any Credit Party, those resolutions adopted by such Credit Party's Board of Directors and delivered by such Credit Party to the Collateral Agent pursuant to Section 3.1(d) or Section 3.2(b), as applicable, approving the Loan Documents to which such Credit Party is a party and the transactions contemplated thereby (including the Term Loans).

"Business Day" means any day that is not a Saturday or a Sunday or a day on which banks are authorized or required to be closed in New York, New York, London, England or Tel Aviv, Israel.

"Capital Lease" means, as applied to any Person, any lease of, or other arrangement conveying the right to use, any property by that Person as lessee that has been or should be accounted for as a capital lease on a balance sheet of such Person prepared in accordance with Applicable Accounting Standards (subject to Section 1 hereof).

"Capital Lease Obligations" means, at any time, with respect to any Capital Lease, any lease entered into as part of any sale leaseback transaction of any Person or any synthetic lease, the amount of all obligations of such Person that is (or that would be, if such synthetic lease or other lease were accounted for as a Capital Lease) capitalized on a balance sheet of such Person prepared in accordance with Applicable Accounting Standards.

"Cash Equivalents" means

(a) securities issued or directly and fully guaranteed or insured by the United States government or any agency or instrumentality of the United States government or by the government of Israel or any other member country of the Organisation for Economic Co-operation and Development ("OECD") (provided that the full faith and credit of the United States or such other member country of OECD, as applicable, is pledged in support of those securities) or any agency or instrumentality of Israel or the OECD, in each case, having maturities of not more than two (2) years from the date of acquisition;

(b) certificates of deposit, time deposits with maturities of one year or less from the date of acquisition, bankers' acceptances with maturities not exceeding one year and overnight bank deposits and demand deposits, in each case, with any commercial bank having (i) capital and surplus in excess of $500,000,000 in the case of U.S. banks or (ii) capital and surplus in excess of $100,000,000 (or the U.S. dollar equivalent as of the date of determination) in the case of non-U.S. banks or a rating for its long-term unsecured and noncredit enhanced debt obligations of "A" or higher by Standard & Poor's Rating Services or Fitch Ratings Ltd or "A2" or higher by Moody's Investors Service Limited;

(c) commercial paper or marketable short-term money market or readily marketable direct obligations and similar securities having a credit rating of either A-1 or higher by Standard & Poor's Rating Service or F1 or higher by Fitch Ratings Ltd or P-1 or higher Moody's Investors Service Limited, and, in each case, maturing within two (2) years after the date of acquisition;

(d) repurchase obligations with a term of not more than seven (7) days for underlying securities of the types described in clauses (a) and (c) above entered into with any financial institution meeting the qualifications specified in clause (b) above;

(e) investment funds investing ninety-five percent (95.0%) of their assets in securities of the types described in clauses (a) through (d) above and clause (f) below;

(f) investments in money market funds which have a credit rating of either A-1 or higher by Standard & Poor's Rating Service or F1 or higher by Fitch Ratings Ltd or P-1 or higher by Moody's Investors Service Limited (or, if at any time none of Fitch Ratings Ltd, Moody's Investors Service Limited or Standard & Poor's Rating Service shall be rating such obligations, an equivalent rating from another rating agency) and that have portfolio assets of at least $1,000,000,000; and

(g) other investments in accordance with the Borrower's investment policy as of the Tranche A Closing Date or otherwise approved in writing by the Collateral Agent.

"CCPA" means the provisions of the California Consumer Privacy Act, as amended by the California Privacy Rights Act and codified at Cal. Civ. Code § 1798.100 et seq., with any implementing regulations.

"Change in Control" means: (a) a transaction or series of transactions (including any merger or consolidation involving Borrower or Parent) whereby any "person" or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act, but excluding any employee benefit plan of such Person or its Subsidiaries, and any Person acting in its capacity as trustee, agent or other fiduciary or administrator of any such plan) (i) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of fifty percent (50.0%) or more of any class of outstanding Equity Interests of Parent ordinarily entitled to vote in the election of directors (or compatible voting Equity Interests), or (ii) obtains the power (whether or not exercised) to elect a majority of directors of Parent; (b) a sale, directly or indirectly, of all or substantially all of the consolidated assets of Parent and its Subsidiaries or of Borrower and its Subsidiaries, as the case may be, in one transaction or a series of transactions (whether by way of merger, stock purchase, asset purchase or otherwise); (c) a merger or consolidation involving Borrower or Parent, as the case may be, in which Borrower or Parent (as applicable) is not the surviving Person; or (d) Parent ceasing to own, directly or indirectly, 100% of the outstanding Equity Interests of Borrower in one transaction or a series of transactions.

"Change in Law" means the occurrence, after the date of this Agreement, of any of the following: (a) the adoption or taking into effect of any law, treaty, order, policy, rule or regulation, (b) any change in any law, treaty, order, policy, rule or regulation or in the administration, published interpretation or application thereof by any Governmental Authority or (c) the making or issuance of any request, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided that notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"Closing Date" means the Tranche A Closing Date or the Tranche B Closing Date, as applicable.

"CMIA" means the California Confidentiality of Medical Information Act, codified at Cal. Civ. Code pt. 2.6 § 56 et seq.

"Code" means the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 of the Code shall govern; provided, further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, the Collateral Agent's Lien, for the benefit of Lenders and the other Secured Parties, on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"Collateral" means, collectively, "Collateral", as such term is defined in the Security Agreement, "Charged Assets", as such term is defined in the Israeli Security Agreement, and any and all other assets and properties of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Collateral Document, but in any event excluding all Excluded Property.

"Collateral Access Agreement" means an agreement, in form and substance reasonably satisfactory to the Collateral Agent and to which the Collateral Agent is a party, pursuant to which a mortgagee or lessor of real property on which Collateral is stored or otherwise located, or a warehouseman, processor or other bailee of Inventory or other property owned by any Credit Party, acknowledges the Liens and security interests of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, and waives (or, if approved by the Collateral Agent in its sole discretion, subordinates) any Liens or security interests held by such Person on any such Collateral, and, in the case of any such agreement with a mortgagee or lessor, permits the Collateral Agent and any Lender (and its representatives and designees) reasonable access to any Collateral stored or otherwise located thereon.

"Collateral Account" means any Deposit Account of a Credit Party maintained with a bank or other depository or financial institution located in the United States, any Securities Account of a Credit Party maintained with a securities intermediary located in the United States, or any Commodity Account of a Credit Party maintained with a commodity intermediary located in the United States, in each case, other than an Excluded Account.

"Collateral Agent" is defined in the preamble hereof.

"Collateral Documents" means the Security Agreement, the Israeli Security Agreement, the Control Agreements, the IP Agreements, any Mortgages and all other instruments, documents and agreements delivered by any Credit Party pursuant or incidental to this Agreement or any of the other Loan Documents, in each case, in order to grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, or perfect a Lien on any Collateral as security for the Obligations, and all amendments, restatements, modifications or supplements thereof or thereto.

"Commodity Account" means any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"Common Rule" means the U.S. Federal Policy for the Protection of Human Subjects, codified at 45 C.F.R. part 46, and any foreign (or United States state) equivalents.

"Company IP" means any and all of the following, as they exist in and throughout the Territory: (a) Current Company IP; (b) improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications with respect to any Current Company IP, any patent issued with respect to any of the Current Company IP, including any patent right claiming the apparatus, system, component or composition of matter of, or the method of making or using, Product in the Territory, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent and all foreign and international counterparts of any of the foregoing, and any confirmation patent or registration patent or patent of addition based on any such patent; (c) trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how, operating manuals, confidential or proprietary information, research in progress, algorithms, data, databases, data collections, designs, processes, procedures, methods, protocols, materials, formulae, drawings, schematics, blueprints, flow charts, models, strategies, prototypes, techniques, and the results of experimentation and testing, including samples, in each case, as specifically related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory; and (d) to the extent not described in clauses (a), (b) or (c) above, any and all IP Ancillary Rights specifically relating to any of the foregoing (other than all income, royalties, proceeds and liabilities at any time due and payable or asserted under or with respect to any of the foregoing), including, for the avoidance of doubt, all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights.

"Company IP Agreement" means each material contract or agreement, pursuant to which Parent or any of its Subsidiaries has the legal right to exploit Current Company IP or other Intellectual Property that is owned by another Person and material to the business of Parent and its Subsidiaries, to research, develop, manufacture, produce, use, supply, commercialize, market, import, store, transport, offer for sale, distribute or sell Product, including (a) the License Agreement, dated as of November 8, 2019, by and between Parent and Agenus Inc., and (b) the Collaboration Agreement, effective as of October 14, 2020, by and between Parent and The University of Texas M.D. Anderson Cancer Center.

"Competitor" means, at any time of determination, any Person that is engaged in the same, substantially the same or similar line of business as Parent and its Subsidiaries as of such time.

"Compliance Certificate" means that certain certificate in the form attached hereto as Exhibit E.

"Connection Income Taxes" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

"Conforming Changes" means, with respect to either the use or administration of Term SOFR or the use, administration, adoption or implementation of any Benchmark Replacement, any technical, administrative or operational changes (including changes to the definition of "Business Day," the definition of "U.S. Government Securities Business Day," the definition of "Interest Period" or any similar or analogous definition (or the addition of a concept of "interest period"), timing and frequency of determining rates and making payments of interest, timing of borrowing requests or prepayment, conversion or continuation notices, the applicability and length of lookback periods and other technical, administrative or operational matters) that the Collateral Agent decides (after consultation with Borrower) may be appropriate to reflect the adoption and implementation of any such rate or to permit the use and administration thereof by the Collateral Agent in a manner substantially consistent with market practice (or, if the Collateral Agent decides that adoption of any portion of such market practice is not administratively feasible or if the Collateral Agent determines that no market practice for the administration of any such rate exists, in such other manner of administration as the Collateral Agent decides is reasonably necessary in connection with the administration of this Agreement and the other Loan Documents).

"Contingent Obligation" means, for any Person, (a) any direct or indirect liability, contingent or not, of that Person for any indebtedness, lease, dividend, letter of credit or other obligation of another Person directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable (other than by endorsements of instruments in the course of collection) and (b) any obligation of that Person to pay an earn-out payment, milestone payment or similar contingent payment or contingent compensation (including purchase price adjustments but excluding royalties payable and sales milestones based on net sales) to a counterparty incurred or created in connection with an Acquisition, Transfer or Investment or otherwise in connection with any collaboration, development or similar agreement, in each instance where such contingent payment or compensation becomes due and payable upon the occurrence of an event or the performance of an act (and not solely with the passage of time). The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it reasonably determined by such Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement. Notwithstanding anything to the contrary in the foregoing, Permitted Equity Derivatives shall not constitute a Contingent Obligation.

"Control Agreement" means, with respect to any Credit Party, any control agreement entered into among such Credit Party, the Collateral Agent and, in the case of a Deposit Account, the bank or other depository or financial institution located in the United States at which such Credit Party maintains such Deposit Account, or, in the case of a Securities Account or a Commodity Account, the securities intermediary or commodity intermediary located in the United States at which such Credit Party maintain such Securities Account or Commodities Account, in either case, pursuant to which the Collateral Agent obtains control (within the meaning of the Code), or otherwise has a perfected first priority security interest (subject to any Permitted Liens), over such Collateral Account.

"Convertible Indebtedness Redemption" is defined in Section 2.2(c)(iii).

"Convertible Indebtedness Redemption Notice" is defined in Section 2.2(c)(iii).

"Copyrights" means any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret (and all related IP Ancillary Rights).

"Credit Extension" means any Term Loan or any other extension of credit by any Lender for Borrower's benefit pursuant to this Agreement.

"Credit Party" means Parent, each other Guarantor and Borrower.

"Current Company IP" is defined in Section 4.6(c).

"Daily Simple SOFR" means, for any day, SOFR, with the conventions for this rate (which will include a lookback) being established by the Collateral Agent in accordance with the conventions for this rate recommended by the Relevant Governmental Body for determining "Daily Simple SOFR" for Dollar-denominated bilateral business loans; provided, that if the Collateral Agent decides that any such convention is not administratively feasible for the Collateral Agent, then the Collateral Agent may establish another convention in its reasonable discretion.

"Data Protection Laws" means any and all applicable foreign or domestic (including U.S. federal, state and local), statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to privacy, security, notification of breaches, or confidentiality of Personal Data that are applicable to the Parent or any of its Subsidiaries, including, to the extent applicable, HIPAA, Section 5 of the FTC Act and other consumer protection laws, Israeli Data Protection Law, GDPR, CCPA and other comprehensive state privacy laws, CMIA and other U.S. state medical information privacy laws and genetic testing laws.

"Default" means any breach of or default under any term, provision, condition, covenant or agreement contained in this Agreement or any other Loan Document or any other event, in each case that, with the giving of notice or the lapse of time or both, would constitute an Event of Default.

"Default Rate" is defined in Section 2.3(b).

"Deposit Account" means any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"Disclosure Letter" means the disclosure letter, dated the Effective Date, delivered by the Credit Parties to the Collateral Agent pursuant to Section 3.1(a), as may be updated on the applicable Closing Date, if required, as permitted and in accordance with Section 3.1(b) and Section 3.2(a).

"Disqualified Assignee" means (a) any Competitor, or (b) any vulture or distressed debt fund.

"Disqualified Equity Interest" means any Equity Interest that, by its terms (or by the terms of any security or other Equity Interests into which it is convertible or for which it is exchangeable) or upon the happening of any event or condition: (a) matures or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise (except if redeemable or convertible into other Equity Interest that would not constitute a Disqualified Equity Interest or as a result of a change of control, asset sale or similar event so long as any and all rights of the holders thereof upon the occurrence of a change of control, asset sale or similar event shall be subject to the prior repayment in full in cash of the Term Loans and the satisfaction in full of all other Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with the terms of

this Agreement); (b) is redeemable at the option of the holder thereof, in whole or in part (except if redeemable or convertible into other Equity Interest that would not constitute a Disqualified Equity Interest or as a result of a change of control, asset sale or similar event so long as any rights of the holders thereof upon the occurrence of a change of control, asset sale or similar event shall be subject to the prior repayment in full in cash of the Term Loans and the satisfaction in full of all other Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto have been asserted) in accordance with this Agreement); (c) provides for the scheduled payments of dividends or distributions in cash; or (d) is convertible into or exchangeable for (i) Indebtedness which is not Permitted Indebtedness or (ii) any other Equity Interest that would constitute a Disqualified Equity Interest; in each case described in clauses (a) through (d) above, prior to the date that is 180 days after the Term Loan Maturity Date; provided that, if any such Equity Interest is issued pursuant to any plan for the benefit of any employee, director, manager or consultant of the Borrower or its Subsidiaries or by any such plan to such employee, director, manager or consultant, such Equity Interest shall not constitute a "Disqualified Equity Interest" solely because it may be required to be repurchased by the Borrower or its Subsidiaries in order to satisfy applicable statutory or regulatory obligations or as a result of the termination, death or disability of such employee, director, manager or consultant.

"Dollars," "**dollars**" or use of the sign "**$**" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "$" sign to denote its currency or may be readily converted into lawful money of the United States.

"Domestic Subsidiary" means, with respect to any Credit Party, a Subsidiary of such Credit Party that is incorporated or organized under the laws of the United States.

"Effective Date" is defined in the preamble hereof.

"Environmental Claim" means any investigation, notice, notice of violation, claim, action, suit, proceeding, demand, abatement order or other order or directive (conditional or otherwise), by any Governmental Authority or any other Person, arising (i) pursuant to or in connection with any actual or alleged violation of any Environmental Law; (ii) in connection with any Hazardous Material or any actual or alleged Hazardous Materials Activity; or (iii) in connection with any actual or alleged damage, injury, threat or harm to health, safety, natural resources or the environment.

"Environmental Laws" means any and all current or future, foreign or domestic, statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to (i) environmental matters, including those relating to any Hazardous Materials Activity; (ii) the generation, use, storage, transportation or disposal of Hazardous Materials; or (iii) occupational safety and health, industrial hygiene, land use or the protection of human, plant or animal health or welfare, in each case, in any manner applicable to any Credit Party or any of its Subsidiaries or any Facility.

"Equity Interests" means, with respect to any Person, collectively, any and all shares, interests, participations or other equivalents (however designated) of capital stock of a corporation, any and all equivalent ownership interests in such Person (other than a corporation), including partnership interests and membership interests, and any and all warrants, rights or options to purchase or other arrangements or rights to acquire (by purchase, conversion, dividend, distribution or otherwise) any of the foregoing (and all other rights, powers, privileges, interests, claims and other property in any manner arising therefrom or relating thereto); provided, however, that any Permitted Convertible Indebtedness or other Indebtedness convertible into Equity Interests (or into any combination of cash and Equity Interests based on the value of such Equity Interests) shall not constitute Equity Interests unless and until (and solely to the extent) so converted into Equity Interests.

"ERISA" means the Employee Retirement Income Security Act of 1974, and its regulations.

"ERISA Affiliate" means, with respect to any Person, any trade or business (whether or not incorporated) that, together with such Person, is treated as a single employer under Section 414(b) or (c) of the IRC or, solely for purposes of Section 302 of ERISA or Section 412 of the IRC, Section 412(m) or (o) of the IRC.

"ERISA Event" means (a) any "reportable event," as defined in Section 4043 of ERISA or the regulations issued thereunder, with respect to a Plan (other than an event for which the 30-day notice period is waived by regulation); (b) with respect to a Plan, the failure by Borrower or its Subsidiaries or their ERISA Affiliates to satisfy the minimum funding standard of Section 412 of the IRC and Section 302 of ERISA, whether or not waived; (c) the failure by Borrower or its Subsidiaries or their ERISA Affiliates to make by its due date a required installment under Section 430(j) of the IRC with respect to any Plan or to make any required contribution to a Multiemployer Plan; (d) the filing pursuant to Section 412(c) of the IRC or Section 302(c) of ERISA of an application for a waiver of the minimum funding standard with respect to any Plan; (e) the incurrence by Borrower or any of its ERISA Affiliates of any liability under Title IV of ERISA with respect to the termination of any Plan; (f) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates from the Pension Benefit Guaranty Corporation (referred to and defined in ERISA) or a plan administrator of any notice relating to the intention to terminate any Plan or Plans under Section 4041 or 4041A of ERISA or to appoint a trustee to administer any Plan under Section 4042 of ERISA, or the occurrence of any event or condition which could reasonably be expected to constitute grounds under ERISA for the termination of, or the appointment of a trustee to administer, any Plan under Section 4041 Section 4042 of ERISA; (g) the incurrence by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any liability with respect to the withdrawal from any Plan or Multiemployer Plan; (h) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any notice, concerning the imposition of Withdrawal Liability or a determination that a Multiemployer Plan is, or is expected to be, insolvent, within the meaning of Section 4245 or Section 4241, respectively, of ERISA; (i) the "substantial cessation of operations" by Borrower or its Subsidiaries or their ERISA Affiliates within the meaning of Section 4062(e) of ERISA with respect to a Plan; or (j) the occurrence of a nonexempt prohibited transaction (within the meaning of Section 4975 of the IRC or Section 406 of ERISA) which could reasonably be expected to result in material liability to Borrower or its Subsidiaries.

"Event of Default" is defined in Section 7.

"Exchange Act" means the Securities Exchange Act of 1934.

"Exchange Act Documents" means any and all documents filed by Parent with the SEC pursuant to the Exchange Act.

"Excluded Accounts" is defined in Section 5.5.

"Excluded Equity Interests" means, collectively: (i) any Equity Interests in any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) are validly prohibited by Requirements of Law; (ii) any Equity Interests in any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured

Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party and such consent, approval or waiver has not been obtained by Borrower following Borrower's commercially reasonable efforts to obtain the same; (iii) any Equity Interests in any Subsidiary that is a non-Wholly-Owned Subsidiary that the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, the Operating Documents or the joint venture agreement or shareholder agreement with respect to, or any other contract with such third party relating to such non-Wholly-Owned Subsidiary, including any contract evidencing Indebtedness of such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Document, joint venture agreement, shareholder agreement or other contract is in effect; and (iv) any Equity Interests in any other Subsidiary with respect to which, Borrower and the Collateral Agent reasonably determine by mutual agreement that the cost (including Tax costs) of granting the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a security interest in and Lien upon, and pledging to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Equity Interests, to secure the Obligations (and any guaranty thereof) are excessive, relative to the value to be afforded to the Secured Parties thereby.

"Excluded License" means an exclusive license or sublicense, to a Person other than a Subsidiary of Parent, of any Intellectual Property within the Territory covering a Product that is tantamount to a sale of substantially all rights to the Intellectual Property covering such Product because it conveys to the licensee or sublicensee exclusive rights to practice such Intellectual Property in the Territory for consideration that is not based upon (a) the future development or commercialization of Product in the Territory (e.g., pursuant to so-called earn-out payments or royalties based on net sales), or (b) the performance of services by the licensee or sublicensee (other than transition services), such as, for example, consideration of only upfront advances or initial license fees or similar initial payments in consideration of such rights with no anticipated subsequent payments or only *de minimis* subsequent payments to Parent or any of its Subsidiaries.

"Excluded Property" has the meaning set forth for such term in the Security Agreement.

"Excluded Subsidiaries" means, collectively: (i) any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) are validly prohibited by Requirements of Law; (ii) any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than Parent or an Affiliate of Parent) and such consent, approval or waiver has not been obtained by Parent or such Subsidiary following Parent's and such Subsidiary's commercially reasonable efforts to obtain the same; (iii) any Subsidiary that is a non-Wholly-Owned Subsidiary, with respect to which, the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, the properties and assets of such non-Wholly-Owned Subsidiary, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Parent or an Affiliate of Parent) the right to terminate its obligations under, such non-Wholly-Owned Subsidiary's Operating Documents or the joint venture agreement or shareholder agreement with respect thereto or any other contract with such third party relating to such non-Wholly-Owned Subsidiary, including any contract evidencing Indebtedness of such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Document, joint venture agreement, shareholder agreement or other contract is in effect; and (iv) any Subsidiary that owns properties and assets with an aggregate fair market value (as reasonably determined in good faith by a Responsible Officer of Parent) of less than $5,000,000; (v) any Foreign Subsidiary; and (vi) any other Subsidiary with respect to which, Parent and the Collateral Agent reasonably determine by mutual agreement that the cost (including Tax costs) of granting the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a security interest in and Lien upon, and pledging to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests of such Subsidiary to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to the Secured Parties thereby.

"Excluded Taxes" means any of the following Taxes imposed on or with respect to Lender or required to be withheld or deducted from a payment to Lender, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of Lender being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) U.S. federal withholding Taxes imposed on amounts payable to or for the account of Lender with respect to any Obligation pursuant to a law in effect on the date on which (i) Lender acquires such interest in any Obligation or (ii) Lender changes its lending office, except in each case to the extent that, pursuant to Section 2.6, amounts with respect to such Taxes were payable either to Lender's assignor immediately before Lender became a party hereto or to Lender immediately before it changed its lending office, (c) Taxes attributable to Lender's failure to comply with Section 2.6(d), and (d) any withholding Taxes imposed under FATCA.

"Export and Import Laws" means any applicable law, regulation, order or directive that applies to the import, export, re-export, transfer, disclosure or provision of goods, software, technology or technical assistance including, without limitation, restrictions or controls administered pursuant to the U.S. Export Administration Regulations, 15 C.F.R. Parts 730-774, administered by the U.S. Department of Commerce, Bureau of Industry and Security; U.S. Customs regulations; and similar import and export laws, regulations, orders and directives of other jurisdictions to the extent applicable.

"Facility" means, with respect to any Credit Party, any real property (including all buildings, fixtures or other improvements located thereon) now, hereafter or heretofore owned, leased, operated or used by such Credit Party or any of its Subsidiaries or any of their respective predecessors or Affiliates.

"FATCA" means Sections 1471 through 1474 of the IRC, as of the date of this Agreement (including, for the avoidance of doubt, any agreements between the governments of the United States and the jurisdiction in which the applicable Lender is resident implementing such provisions), or any amended or successor version that is substantively comparable and not materially more onerous to comply with, and any current or future regulations promulgated thereunder or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the IRC, any intergovernmental agreement entered into in connection with the implementation of the foregoing sections of the IRC and any fiscal or regulatory legislation, regulations, rules or practices adopted pursuant to, or official interpretations implementing such Sections of the IRC or intergovernmental agreements.

"FCPA" is defined in Section 4.18(a).

"FDA" means the United States Food and Drug Administration (and any foreign or United States state equivalent).

"FDA Laws" means all applicable statutes (including the FDCA), rules and regulations implemented administered or enforced by the FDA (and any foreign or United States state equivalents), including FDA Guidance Documents.

"FDA Guidance Documents" means all applicable guidance documents issued by the FDA.

"FDCA" is defined in Section 4.19(b).

"Federal Reserve Board" means the Board of Governors of the Federal Reserve System.

"First Amendment Effective Date" means June 29, 2023.

"Floor" means a rate of interest equal to 2.50% *per annum*.

"Foreign Lender" means a Lender that is not a "United States person" as defined in Section 7701(a)(30) of the IRC.

"Foreign Subsidiary" means, with respect to any Credit Party, any Subsidiary of such Credit Party that is not a Domestic Subsidiary.

"Foreign Subsidiary Holdco" means, with respect to any Credit Party, a Subsidiary of such Credit Party that (i) is organized, incorporated or formed under the laws of the United States and (ii) has no material assets other than equity in one or more Foreign Subsidiaries or Indebtedness of one or more Foreign Subsidiaries and any other assets incidental thereto.

"GDPR" means, collectively, (i) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (the "**EU GDPR**") and (ii) the EU GDPR as it forms part of the laws of the United Kingdom by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019.

"Good Clinical Practices" means the standards set forth in 21 C.F.R. Parts 50, 54, 56, 312, 314 and 316 (and any foreign or United States state equivalents) and FDA's implementing guidance documents (and any foreign or United States state equivalents), and FDA-adopted International Council for Harmonisation ("**ICH**") Good Clinical Practice guidance, including E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1).

"Good Laboratory Practices" means the standards set forth in 21 C.F.R. Part 58 (and any foreign or United States state equivalent) and FDA's implementing guidance documents (and any foreign or United States state equivalents).

"Good Manufacturing Practices" means the standards set forth in 21 C.F.R. Parts 210, 211, 600 and 610 (and any foreign or United States state equivalents) and FDA's implementing guidance documents (and any foreign or United States state equivalents).

"Governmental Approval" means any consent, authorization, approval, licensure, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" means any nation or government, any state or other political subdivision thereof, any agency (including Regulatory Agencies and data protection authorities), government department, authority, instrumentality, regulatory body, commission, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"Governmental Payor Programs" means all governmental third party payor programs in which any Credit Party or its Subsidiaries participates, including Medicare, Medicaid, TRICARE or any other U.S. federal or state health care programs.

"Guarantor" means, at any time, any Person that is, pursuant to the terms of any Loan Document, a guarantor of any of the Obligations at that time.

"Hazardous Materials" means any chemical, material or substance, exposure to which is prohibited, limited or regulated by any Governmental Authority or which may or could pose a hazard to the health and safety of the owners, occupants or any Persons in the vicinity of any Facility or to the indoor or outdoor environment.

"Hazardous Materials Activity" means any past, current, proposed or threatened activity, event or occurrence involving any Hazardous Materials, including the use, manufacture, possession, storage, holding, presence, existence, location, Release, threatened Release, discharge, placement, generation, transportation, processing, construction, treatment, abatement, removal, remediation, disposal, disposition or handling of any Hazardous Materials, and any corrective action or response action with respect to any of the foregoing.

"Health Care Laws" means, collectively: (a) applicable federal, state or local laws, rules, regulations, codes, orders, ordinances, statutes and requirements issued under or in connection with Medicare, Medicaid or any other Governmental Payor Program; (b) applicable federal and state laws and regulations governing the privacy, security, confidentiality, or notification of breaches regarding health information, including HIPAA and Section 5 of the FTC Act; (c) applicable federal, state and local fraud and abuse laws of any Governmental Authority, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code and the regulations promulgated pursuant to such statutes; (d) the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173) and the regulations promulgated thereunder; (e) the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h); (f) any applicable reporting and disclosure requirements, including any arising under Section 603 of the Veteran's Health Care Act (Quarterly and Annual Non-Federal Average Manufacturer Price and Federal Ceiling Price), Best Price, Federal Supply Schedule Contract Prices and Tricare Retail Pharmacy Refunds, and Medicare Part D; (g) health care laws, rules, codes, statutes, regulations, orders, ordinances and requirements pertaining to Medicare or Medicaid; (h) federal, state or local laws, rules, regulations, ordinances, statutes and requirements relating to (x) the regulation of managed care, third party payors and Persons bearing the financial risk for the provision or arrangement of health care services, (y) billings to insurance companies, health maintenance organizations and other Managed Care Plans or otherwise relating to insurance fraud and (z) any insurance, health maintenance organization or managed care Requirements of Law; (i) the interoperability, information blocking, and health information technology certification regulations promulgated under the 21st Century Cures Act (to the extent effective); (j) CDC regulations (including regulations implemented by the CDC Division of Select Agents and Toxins ("DSAT") or

otherwise relating to the Federal Select Agent Program ("FSAP"), such as 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73); and (k) any other applicable domestic or foreign health care laws, rules, codes, regulations, manuals, orders, ordinances, and statutes relating to the research, development, testing, approval, licensure, post-approval or post-licensure monitoring, post-approval or post-licensure requirements, post-approval or post-licensure commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of or payment for Product.

"Hedging Agreement" means any interest rate, currency, commodity or equity swap, collar, cap, floor or forward rate agreement, or other agreement or arrangement designed to protect a Person against fluctuations in interest rates, currency exchange rates or commodity or equity prices or values (including any option with respect to any of the foregoing and any combination of the foregoing agreements or arrangements), and any confirmation execution in connection with any such agreement or arrangement. Notwithstanding anything to the contrary in the foregoing, any Permitted Equity Derivative shall not constitute a Hedging Agreement.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996, as amended and supplemented by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, any and all rules or regulations promulgated from time to time thereunder, and any U.S. state or federal laws with regard to the security, privacy, or notification of breaches of the confidentiality of health information which are not preempted pursuant to 45 C.F.R. Part 160, Subpart B.

"IFRS" means international accounting standards within the meaning of IAS Regulation 1606/2002 to the extent applicable to the relevant financial statements.

"Indebtedness" means, with respect to any Person, without duplication: (a) all indebtedness for advanced or borrowed money of, or credit extended to, such Person; (b) all obligations issued, undertaken or assumed by such Person as the deferred purchase price of assets, properties, services or rights (other than (i) accrued expenses and trade payables entered into in the ordinary course of business which are not more than one hundred and eighty (180) days past due or subject to a bona fide dispute, (ii) obligations to pay for services provided by employees and individual independent contractors in the ordinary course of business which are not more than one hundred and twenty (120) days past due or subject to a bona fide dispute, (iii) liabilities associated with customer prepayments and deposits, and (iv) prepaid or deferred revenue arising in the ordinary course of business), including (A) any obligation or liability to pay deferred purchase price or other similar deferred consideration for such assets, properties, services or rights where such deferred purchase price or consideration becomes due and payable solely upon the passage of time, and (B) any obligation described in clause (b) of the definition of "Contingent Obligation" that is due and payable (or that becomes due and payable) solely with the passage of time (and not upon the occurrence of an event or the performance of an act); (c) the face amount of all letters of credit issued for the account of such Person and, without duplication, all drafts drawn thereunder and all reimbursement or payment obligations with respect to letters of credit, surety bonds, performance bonds and other similar instruments issued by such Person; (d) all obligations of such Person evidenced by notes, bonds, debentures or other debt securities or similar instruments (including debt securities convertible into Equity Interests, including Permitted Convertible Indebtedness)), including obligations so evidenced incurred in connection with the acquisition of properties, assets or businesses; (e) all indebtedness of such Person created or arising under any conditional sale or other title retention agreement or incurred as financing, in either case with respect to property acquired by such Person (even though the rights and remedies of the seller or bank under such agreement in the event of default are limited to repossession or sale of such property); (f) all Capital Lease Obligations of such Person; (g) the principal balance outstanding under any synthetic lease, off-balance sheet loan or similar off balance sheet financing product by such Person; (h) Disqualified Equity Interests; (i) all indebtedness referred to in clauses (a) through (g) above of other Persons secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien upon or in assets or properties (including accounts and contracts rights) owned by such Person, even though such Person has not assumed or become liable for the payment of such indebtedness of such other Persons; and (i) all Contingent Obligations of such Person described in clause (a) of the definition thereof in respect of Indebtedness. For the avoidance of doubt, "Indebtedness" shall include Permitted Convertible Indebtedness, but shall not include any Permitted Equity Derivative.

"Indemnified Liabilities" means, collectively, any and all liabilities, obligations, losses, damages (including natural resource damages), penalties, claims, actions, judgments, suits, costs, reasonable and documented out-of-pocket fees, expenses and disbursements of any kind or nature whatsoever (including the reasonable and documented fees, expenses and disbursements of one counsel for Indemnified Persons plus, as applicable, one local legal counsel in each relevant material jurisdiction and one intellectual property legal counsel, and in the case of an actual or perceived conflict of interest, one additional counsel for such affected Indemnified Persons, in connection with any investigative, administrative or judicial proceeding or hearing commenced or threatened in writing by any Person, whether or not any such Indemnified Person shall have commenced such proceeding or hearing or be designated as a party or a potential party thereto, and any fees or expenses incurred by Indemnified Persons in enforcing any indemnity hereunder) whether direct, indirect or consequential and whether based on any federal, state or foreign laws, statutes, rules or regulations, on common law or equitable cause or on contract or otherwise, that may be imposed on, incurred by, or asserted against any such Indemnified Person, in any manner relating to or arising out of this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby (including any Lender's agreement to make Credit Extensions or the use or intended use of the proceeds thereof, or any enforcement of any of the Loan Documents (including any sale of, collection from, or other realization upon any of the Collateral or the enforcement of any guaranty of the Obligations)).

"Indemnified Person" is defined in Section 11.2(a).

"Indemnified Taxes" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of any Credit Party under any Loan Document and (b) to the extent not otherwise described in clause (a) above, Other Taxes.

"Insolvency Proceeding" means, with respect to any Person, any proceeding by or against such Person under the Bankruptcy Code, or any other domestic or foreign bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief; provided, however, that, solely with respect to any Person incorporated, organized or formed in any jurisdiction other than the United States, "Insolvency Proceeding" shall not include any winding-up petition against such Credit Party which is frivolous or vexatious and is discharged or dismissed within thirty (30) days of the commencement thereof or any step or procedure in connection with any transaction otherwise permitted under this Agreement.

"Intellectual Property" means all:

(a) Copyrights, Trademarks, and Patents;

(b) trade secrets and trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals;

(c) (i) all computer programs, including source code and object code versions, (ii) all data, databases and compilations of data, whether machine readable or otherwise, and (iii) all documentation, training materials and configurations related to any of the foregoing (collectively, "**Software**");

(d) all right, title and interest arising under any contract or Requirements of Law in or relating to Internet Domain Names;

(e) design rights;

(f) IP Ancillary Rights (including all IP Ancillary Rights related to any of the foregoing); and

(g) all other intellectual property or industrial property rights.

"Interest Date" means the last day of each calendar quarter, commencing with the last day of the calendar quarter during which the First Amendment Effective Date occurs.

"Interest Period" means (a) the period commencing on (and including) the Tranche A Closing Date and ending on (and including) the first Interest Date occurring in the calendar quarter immediately following the Tranche A Closing Date, provided, that if such Interest Date is not a Business Day, the applicable Interest Period shall end on the first Business Day immediately following such Interest Date, and (b) thereafter, each period beginning on (and including) the first day following the end of the preceding Interest Period and ending on the earlier of (and including) (x) the next Interest Date, provided, that if any such last day is not a Business Day, the applicable Interest Period shall end on the first Business Day immediately preceding such Interest Date, (y) the next Payment Date, provided, that if any such day is not a Business Day, the applicable Interest Period shall end on the first Business Day immediately following such Payment Date and (z) the Term Loan Maturity Date. For the avoidance of doubt, if an Interest Period ends on a Payment Date, the next Interest Period shall commence on (and include) the first day following such Payment Date and shall end on (and include) the earlier of the next Interest Date, the next Payment Date or the Term Loan Maturity Date, as described above.

"Internet Domain Name" means all right, title and interest (and all related IP Ancillary Rights) arising under any contract or Requirements of Law in or relating to Internet domain names.

"Inventory" means all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes all merchandise (including Product), materials (including raw materials), parts, components (including component materials and component raw materials), supplies, packing and shipping materials, work in process and finished products, technology (including software, systems, and solutions), and all elements needed to fulfill obligations related to Product under any Manufacturing Agreements including such inventory as is temporarily out of a Credit Party's or Subsidiary's custody or possession or in transit (prior to title having transferred) and including any returned goods and any documents of title representing any of the above.

"Investment" means (a) any beneficial ownership interest in any Person (including Equity Interests), (b) any Acquisition or (c) the making of any advance, loan, extension of credit or capital contribution in or to, any Person. The amount of an Investment shall be the amount actually invested (which, in the case of any Investment by a Credit Party or any of its Subsidiaries constituting the contribution of an asset or property, shall be based on the good faith estimate of the fair market value of such asset or property at the time such Investment is made as reasonably determined by a Responsible Officer of such Credit Party), less the amount of cash received or returned for such Investment, without adjustment for subsequent increases or decreases in the value of such Investment or write-ups, write-downs or write-offs with respect thereto; provided that in no event shall such amount be less than zero.

"IP Agreements" means, collectively, (a) those certain IP Security Agreement(s) entered into by and between Parent and the Collateral Agent, dated as of the Tranche A Closing Date, and (b) any IP Security Agreement entered into by and between any relevant Credit Party and the Collateral Agent after the Tranche A Closing Date in accordance with the Loan Documents.

"IP Ancillary Rights" means, with respect to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals, all income, royalties, proceeds and liabilities at any time due or payable or asserted under or with respect to any of the foregoing or otherwise with respect thereto, including all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights.

"IP Security Agreement" means "IP Security Agreement", as such term is defined in the Security Agreement.

"IRC" means the Internal Revenue Code of 1986, as amended, or any successor statute.

"IRS" means the United States Internal Revenue Service or any successor agency.

"Israeli Data Protection Law" means, collectively, the Israeli Protection of Privacy Law, 5741-1981 (including any regulations promulgated thereunder), the Israeli Protection of Privacy (Data Security) Regulations, 5777-2017, the guidelines issued by the Israeli Privacy Protection Authority, the Israeli Basic Law: Human Dignity and Liberty, 5752-1992, the Israeli Patient's Rights Law, 5756-1996; the directives and applicable circulars issued by the Israeli Ministry of Health relating to Secondary Use of Medical Data, and other Israeli statutes and regulations concerning protection of privacy, information security, or processing of personal data.

"Israeli Security Agreement" means, collectively, (a) that certain Israeli law-governed Fixed Charge Debenture (Unlimited in Amount), dated as of the Tranche A Closing Date, by and between Parent and the Collateral Agent, for the benefit of Lenders and the other Secured Parties, pursuant to which Parent grants the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first ranking fixed charge over all of Parent's rights, title, interest and benefits in the Charged Assets (as such term is defined therein), (b) that certain Israeli law-governed Floating Charge Debenture (Unlimited in Amount), dated as of the Tranche A Closing Date, by and between Parent and the Collateral Agent, for the benefit of Lenders and the other Secured Parties, pursuant to which Parent grants the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first ranking floating charge over all of Parent's rights, title, interest and benefits in the Charged Assets (as such term is defined therein), (c) that certain Israeli law-governed Fixed Charge Debenture (Unlimited in Amount), dated as of the Effective Date, by and between Parent and the Collateral Agent, for the benefit of Lenders and the other Secured Parties, pursuant to which Parent grants the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first ranking fixed charge over all of Parent's rights, title, interest and benefits in the Charged Assets (as such term is defined therein), and (d) that certain Israeli law-governed Floating Charge Debenture (Unlimited in Amount), dated as of the Effective Date, by and between Parent and the Collateral Agent, for the benefit of Lenders and the other Secured Parties, pursuant to which Parent grants the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first ranking floating charge over all of Parent's rights, title, interest and benefits in the Charged Assets (as such term is defined therein).

"JELMYTO®" is defined in the definition of Product.

"JELMYTO® Revenue Forecast" means that certain Jelmyto Revenue Forecast included in the Project Upside Confidential Investor Model dated December 2021, made available by or on behalf of Parent to the Collateral Agent and Lenders on the Debtdomain virtual deal site for Project Upside and included in Schedule 5.17 of the Disclosure Letter.

"Knowledge" means, with respect to any Person, the actual knowledge, after reasonable investigation, of the Responsible Officers of such Person.

"Lender" means each Person signatory hereto as a "Lender" and its successors and assigns.

"Lender Expenses" means, collectively:

(a) all reasonable and documented out-of-pocket fees and expenses of the Collateral Agent and, as applicable, each Lender (and their respective successors and assigns) and their respective Related Parties (including the reasonable and documented out-of-pocket fees, expenses and disbursements of any legal counsel, manufacturing consultants or intellectual property experts (it being agreed that such consultant or expert fees, expenses and disbursements shall be limited to one such consultant and one such expert for the Collateral Agent, Lenders and such Related Parties, taken as a whole and in the case of an actual or perceived conflict of interest, one additional legal counsel for such affected Indemnified Person) therefor, (i) incurred in connection with developing, preparing, negotiating, syndicating, executing and delivering, and interpreting, investigating and administering, the Loan Documents (or any term or provision thereof), any commitment, proposal letter, letter of intent or term sheet therefor or any other document prepared in connection therewith, (ii) incurred in connection with the consummation and administration of any transaction contemplated therein, (iii) incurred in connection with the performance of any obligation or agreement contemplated therein, (iv) incurred in connection with any modification or amendment of any term or provision of, or any supplement to, or the termination (in whole or in part) of, any Loan Document, (v) incurred in connection with internal audit reviews and Collateral audits, or (vi) otherwise incurred with respect to the Credit Parties in connection with the Loan Documents, including any filing or recording fees and expenses; and

(b) all reasonable and documented out-of-pocket costs and expenses incurred by the Collateral Agent and each Lender (and their respective successors and assigns) and their respective Related Parties (including the reasonable and documented out-of-pocket fees, expenses and disbursements of any legal counsel therefor for the Collateral Agent, Lenders and such Related Parties taken as a whole and in the case of an actual or perceived conflict of interest, one additional legal counsel for such affected Indemnified Person) in connection with (i) any refinancing or restructuring of the credit arrangements provided hereunder in the nature of a "work-out," (ii) the enforcement or protection or preservation of any right or remedy under any Loan Document, any Obligation, with respect to any of the Collateral or any other related right or remedy, or (iii) the commencement, defense, conduct of, intervention in, or the taking of any other action with respect to, any proceeding (including any Insolvency Proceeding) related to any Credit Party or any Subsidiary of any Credit Party in respect of any Loan Document or Obligation, or otherwise in connection with any Loan Document or Obligation (or the response to and preparation for any subpoena or request for document production relating thereto); provided, that, except with respect to an Insolvency Proceeding, to the extent such enforcement entails the Collateral Agent or any Lender commencing legal action of any sort against Borrower, any fees and expenses incurred in connection therewith shall only be payable by Borrower to the extent the Collateral Agent or any Lender is successful in such legal action.

"Lender Transfer" is defined in Section 11.1(b).

"Lien" means a claim, mortgage, deed of trust, levy, charge, pledge, security interest or other encumbrance of any kind or assignment for security purposes, whether voluntarily incurred or arising by operation of law or otherwise against any property or assets.

"Loan Documents" means, collectively, this Agreement, the Disclosure Letter, the Term Loan Notes, the Security Agreement, the Israeli Security Agreement, the RTW Intercreditor Agreement, the IP Agreements, the Perfection Certificate, any Control Agreement, any Collateral Access Agreement, any other Collateral Document, any guaranties executed by a Guarantor in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties in connection with this Agreement, and any other present or future agreement between or among a Credit Party, the Collateral Agent and any Lender in connection with this Agreement, including in each case, for the avoidance of doubt, any annexes, exhibits or schedules thereto.

"Makewhole Amount" means the Tranche A Makewhole Amount or the Tranche B Makewhole Amount or the Tranche C Makewhole Amount or the Tranche D Makewhole Amount (as applicable) or the combination thereof, as the context dictates.

"Managed Care Plans" means all health maintenance organizations, preferred provider organizations, individual practice associations, competitive medical plans and similar arrangements.

"Manufacturing Agreement" means (a) any contract or agreement entered into on or prior to the Effective Date by any Credit Party or any of its Subsidiaries with third parties for (i) the clinical or commercial manufacture or in-bound supply in the Territory of Product for any indication, or (ii) for the commercial manufacture or in-bound supply of the active pharmaceutical ingredient incorporated therein that was included in the NDA for Product (with the Manufacturing Agreements in effect as of the Effective Date being set forth in Schedule 12.1 of the Disclosure Letter), and (b) any future contract or agreement entered into after the Effective Date by any Credit Party or any of its Subsidiaries with third parties for (i) the clinical or commercial manufacture or in-bound supply in the Territory of Product for any indication or (ii) for the commercial manufacture or in-bound supply of the active ingredient incorporated therein.

"Margin Stock" means "margin stock" within the meaning of Regulations U and X of the Federal Reserve Board as now and from time to time hereafter in effect.

"Material Adverse Change" means any material adverse change in or material adverse effect on: (a) the business, financial condition, properties or assets (including all or any portion of the Collateral that is material to the exclusivity of JELMYTO®), liabilities (actual or contingent), operations or performance of the Credit Parties, taken as a whole, since December 31, 2020; (b) without limiting the generality of clause (a) above, (i) the rights of the Credit Parties, taken as a whole, in or related to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of JELMYTO® in the Specified Territory, (ii) any rights that are material to the business and operations of the Credit Parties and their Subsidiaries, taken as a whole, under any Material Contract, or (iii) the period of regulatory exclusivity granted by the FDA for JELMYTO® (including Orphan Drug exclusivity); (c) the ability of the Credit Parties, taken as a whole, to fulfill the payment or performance obligations under this Agreement or any other Loan Document; or (d) the binding nature or validity of, or the ability of the Collateral Agent or any Lender to enforce, the Loan Documents or any of its rights or remedies under the Loan Documents (except to the extent resulting from any act or omission to act on the part of

the Collateral Agent or any Lender); provided, however, that, for purposes of clauses (a) and (b) above, the parties hereto agree that no single clinical or regulatory failure shall, in and of itself, constitute or be deemed to constitute a Material Adverse Change hereunder. Notwithstanding the foregoing, none of the following events shall, in and of itself, constitute or be deemed to constitute a Material Adverse Change if and only so long as, in each case of sub-clauses (i) through (iv) below, such event does not involve or relate to JELMYTO®: (i) adverse results or delays in any nonclinical or clinical trial; (ii) the failure to achieve any clinical or non-clinical trial goals or objectives, including the failure to demonstrate the desired safety or efficacy of any drug or companion diagnostic; (iii) any denial, delay or limitation of approval of the FDA (or foreign equivalents) or any other Governmental Authority; or (iv) a change in or discontinuation of a strategic partnership or other collaboration or license arrangement.

"Material Contract" means any contract or other arrangement to which any Credit Party or any of its Subsidiaries is a party (other than the Loan Documents) or by which any of its assets or properties are bound, in each case, relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory, for which the breach of, default or nonperformance under, cancellation or termination of or the failure to renew could reasonably be expected to result in a Material Adverse Change under clauses (a), (b)(i), (b)(iii), (c) or (d) of the definition thereof. For the avoidance of doubt, each Manufacturing Agreement and each Company IP Agreement is a Material Contract and the Pre-Paid Forward Contract and each other PPFC Document is a Material Contract. For the avoidance of doubt, the following agreements are not Material Contracts: (a) any customer contracts, (b) any purchase orders or statements of work entered into from time to time in the ordinary course of business pursuant to Manufacturing Agreements, (c) agreements or other contractual arrangements in connection with capital expenditures in the ordinary course of business, (d) agreements or other contractual arrangements entered into in the ordinary course of business in connection with the purchase of materials or the sale of third party products for further distribution and (e) distribution agreements entered into in the ordinary course of business with third parties for the sale of Product in a specific territory outside of the United States.

"Medicaid" means the health care assistance program established by Title XIX of the SSA (42 U.S.C. 1396 et seq.).

"Medicare" means the health insurance program for the aged and disabled established by Title XVIII of the SSA (42 U.S.C. 1395 et seq.).

"Mortgage" means any deed of trust, leasehold deed of trust, mortgage, leasehold mortgage, deed to secure debt, leasehold deed to secure debt or other document creating a Lien on real estate or any interest in real estate.

"Multiemployer Plan" means a multiemployer plan within the meaning of Section 4001(a)(3) or Section 3(37) of ERISA (a) to which Parent or its Subsidiaries or their respective ERISA Affiliates is then making or accruing an obligation to make contributions; (b) to which Parent or its Subsidiaries or their respective ERISA Affiliates has within the preceding five (5) plan years made contributions; or (c) with respect to which Parent or its Subsidiaries could incur material liability.

"NDA" means a new drug application, submitted to the FDA pursuant to 21 U.S.C. § 355 seeking authorization to market a new drug in the United States.

"Net Sales" means, as of any date of determination, the net consolidated product revenue (consistent with the calculation of same in Parent's financial statements) of Parent and its Subsidiaries of JELMYTO® for the twelve (12) months prior to such date (excluding, for the avoidance of doubt, any (i) upfront or milestone payments received by Parent or any of its Subsidiaries, (ii) advancements, payments or reimbursements of expenses of Parent or any of its Subsidiaries, and (iii) any other non-sales-based revenue or proceeds received by Parent or any of its Subsidiaries), determined on a consolidated basis in accordance with Applicable Accounting Standards as set forth in Parent's financial statements or as otherwise evidenced in a manner reasonably satisfactory to the Required Lenders.

"Note Register" is defined in Section 2.8(a).

"Obligations" means, collectively, the Credit Parties' obligations to pay when due any and all debts, principal, interest, Lender Expenses, the Additional Consideration, the Makewhole Amount, the Prepayment Premium and any other fees, expenses, indemnities and amounts any Credit Party owes any Lender or the Collateral Agent now or later, under this Agreement or any other Loan Document, including interest accruing after Insolvency Proceedings begin (whether or not allowed), and to perform Borrower's (or Parent's, as applicable) duties under the Loan Documents.

"OFAC" is defined in Section 4.18(c).

"Operating Documents" means, collectively with respect to any Person, such Person's formation and constitutional documents and, (a) if such Person is a corporation, its bylaws (or similar organizational regulations), (b) if such Person is an exempted company or a company limited by shares, its memorandum and articles of association (or similar organizational regulations), (c) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (d) if such Person is a partnership, its partnership agreement (or similar agreement), in each case including all amendments, restatements, supplements and modifications thereto.

"ordinary course of business" means, in respect of any transaction involving any Person, the ordinary course of such Person's business, undertaken by such Person in good faith and not for purposes of evading any covenant, prepayment obligation or restriction in any Loan Document.

"Orphan Drug" means a drug that meets the definition for "orphan drug" provided in 21 C.F.R. § 316.3(b)(10), which has been granted an orphan drug designation by the Secretary of Health and Human Services or the FDA under 21 U.S.C. § 360bb.

"Other Connection Taxes" means, with respect to any Lender, Taxes imposed as a result of a present or former connection between such Lender and the jurisdiction imposing such Tax (other than connections arising solely from such Lender having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Term Loan or Loan Document).

"Other Taxes" means all present or future stamp, court or documentary, intangible, recording, excise, filing, value added Taxes, mortgage or property Taxes, charges or similar levies or similar Taxes that arise from any payment made hereunder, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to a Lender Transfer.

"Participant Register" is defined in Section 11.1(d).

"Patents" means all patents and patent applications (including any improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications), any patent issued with respect to any of the foregoing patent applications, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign and international counterparts of any of the foregoing. For the avoidance of doubt, patents and patent applications under this definition include individual patent claims and include all patents and patent applications filed with the U.S. Patent and Trademark Office or which could be nationalized in the United States.

"Patriot Act" is defined in Section 3.1(h).

"Payment Date" means, with respect to the Term Loans and as the context dictates: (a) the first Interest Date occurring in the calendar quarter immediately following the Tranche A Closing Date; (b) thereafter, each succeeding Interest Date; and (c) the Term Loan Maturity Date.

"Perfection Certificate" is defined in Section 4.6.

"Periodic Term SOFR Determination Day" has the meaning specified in the definition of Term SOFR.

"Permitted Acquisition" means any Acquisition, so long as:

(a) no Default or Event of Default shall have occurred and be continuing as of, or could reasonably be expected to result from, the consummation of such Acquisition;

(b) the properties or assets being acquired or licensed, or the Person whose Equity Interests are being acquired, are useful in or engaged in, as applicable, (i) the same, similar or related line of business as that then-conducted by Parent and its Subsidiaries, or (ii) a line of business that is related or ancillary to or in furtherance of a line of business as that then-conducted by Parent and its Subsidiaries;

(c) in the case of any Asset Acquisition, any and all assets are being acquired or licensed in such Acquisition by a Credit Party and, within the timeframes expressly set forth in Section 5.12 with respect to all such assets constituting Collateral, such Credit Party shall have executed and delivered or authorized, as applicable, any and all joinders, security agreements, financing statements and any other documentation, and made such other deliveries, required by Section 5.12 or reasonably requested by the Collateral Agent in order to include such newly acquired or licensed assets within the Collateral, in each case to the extent required by Section 5.12;

(d) in the case of any Stock Acquisition, any and all Equity Interests are being acquired in such Acquisition directly by a Credit Party and, within the timeframes expressly set forth in Section 5.13, such Credit Party shall have complied with its obligations under Section 5.13, in each case to the extent such Equity Interests are subject thereto; and

(e) any Indebtedness or Liens assumed in connection with such Acquisition are otherwise permitted under Section 6.4 or 6.5, respectively.

"Permitted Convertible Indebtedness" means Indebtedness of the Parent or any Subsidiary of Parent that is a Credit Party having a feature which entitles the holder thereof in certain circumstances to convert or exchange all or a portion of such Indebtedness into Equity Interests in Parent or such Subsidiary (or other securities or property following a merger event or other change of the common stock of Parent or such Subsidiary), cash or any combination of cash and such Equity Interests (or such other securities or property) based on the market price of such Equity Interests (or such other securities or property); provided, however, that (a) such Indebtedness shall be unsecured, (b) such Indebtedness shall not be guaranteed by any Subsidiary of Parent, (c) such Indebtedness shall bear interest at a rate per annum not to exceed five percent (5.0%), (d) such Indebtedness shall not include covenants and defaults (other than covenants and defaults customary for convertible indebtedness but not customary for loans, as determined by Parent in its good faith judgment) that are, taken as a whole, more restrictive on the Credit Parties than the provisions of this Agreement (as determined by Parent in its good faith judgment), (e) immediately prior to and after giving effect to the incurrence of such Indebtedness, no Default or Event of Default shall have occurred and be continuing or could reasonably be expected to occur as a result therefrom (after giving effect to this Agreement), (f) such Indebtedness shall not (i) mature or be mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, (ii) be redeemable at the option of the holder thereof, in whole or in part or (iii) provide for the scheduled payment of dividends or distributions (other than scheduled cash interest payments) in cash, in each case of the foregoing sub-clauses (i), (ii) and (iii), earlier than twelve (12) months after the Term Loan Maturity Date (it being understood, for the avoidance of doubt, that (w) a redemption right of Parent or such Subsidiary in respect of such Indebtedness, (x) conversion rights of holders in respect of such Indebtedness, (y) acceleration rights of holders of such Indebtedness upon the occurrence of an event of default specified in the agreement governing such Indebtedness and (z) the obligation to pay customary amounts to holders of such Indebtedness in connection with a "change of control" or "fundamental change", in each case, shall not be considered in connection with the determination of scheduled maturity date for purposes of this clause (f)); (g) immediately after giving effect to the creation, incurrence or assumption of any such Indebtedness, the amount of all Permitted Convertible Indebtedness then-outstanding shall not exceed $200,000,000 in the aggregate; (h) as of the date of pricing for, and as of the Trading Day immediately preceding the creation, incurrence or assumption of, any such Indebtedness, (i) Parent's market capitalization is greater than $750,000,000, and (ii) either (A) the trailing twelve-month Net Sales of JELMYTO® are greater than $150,000,000 or (B) the first FDA approval of UGN-102 has been obtained for marketing and distribution in the United States; and (h) Parent shall have delivered to the Collateral Agent a certificate of a Responsible Officer of Parent certifying as to the foregoing clauses (a) through (h) with respect to any such Indebtedness.

"Permitted Distributions" means, in each case subject to Section 6.8 if applicable:

(a) dividends, distributions or other payments by any Wholly-Owned Subsidiary of Parent on its Equity Interests to, or the redemption, retirement or purchase by any Wholly-Owned Subsidiary of Parent of its Equity Interests from, Parent or any other Wholly-Owned Subsidiary of Parent;

(b) dividends, distributions or other payments by any non-Wholly-Owned Subsidiary on its Equity Interests to, or the redemption, retirement or purchase by any non-Wholly-Owned Subsidiary of its Equity Interests from, Parent or any other Subsidiary or each other owner of such non-Wholly-Owned Subsidiary's Equity Interests based on their relative ownership interests of the relevant class of such Equity Interests;

(c) exchanges, redemptions or conversions by Parent in whole or in part any of its Equity Interests for or into another class of its Equity Interests or rights to acquire its Equity Interests or with proceeds from substantially concurrent equity contributions or issuances of new Equity Interests;

(d) any such payments arising from a Permitted Acquisition or other Permitted Investment by Parent or any of its Subsidiaries;

(e) the payment of dividends by Borrower solely in non-cash pay and non-redeemable capital stock (including, for the avoidance of doubt, dividends and distributions payable solely in Equity Interests);

(f) cash payments in lieu of the issuance of fractional shares arising out of stock dividends, splits or combinations or in connection with the exercise of warrants, options or other securities convertible into or exchangeable for Equity Interests;

(g) in connection with any Acquisition or other Investment by Parent or any of its Subsidiaries, (i) the receipt or acceptance of the return to Parent or any of its Subsidiaries of Equity Interests of Parent constituting a portion of the purchase price consideration in settlement of indemnification claims, or as a result of a purchase price adjustment (including earn-outs or similar obligations) and (ii) payments or distributions to equity holders pursuant to appraisal rights required under Requirements of Law;

(h) the distribution of rights pursuant to any shareholder rights plan or the redemption of such rights for nominal consideration in accordance with the terms of any shareholder rights plan;

(i) dividends, distributions or payments on its Equity Interests by any Subsidiary to any Credit Party;

(j) dividends, distributions or payments on its Equity Interests by any Subsidiary that is not a Credit Party to any other Subsidiary that is not a Credit Party;

(k) purchases of Equity Interests of Parent or its Subsidiaries in connection with the exercise of stock options by way of cashless exercise, or in connection with the satisfaction of withholding tax obligations;

(l) issuance to directors, officers, employees or contractors of Borrower of common stock of Borrower upon the vesting of restricted stock, restricted stock units, or other rights to acquire common stock of Borrower, in each case pursuant to plans or agreements approved by Borrower's Board of Directors or stockholders;

(m) the repurchase, retirement or other acquisition or retirement for value of Equity Interests of Parent or any of its Subsidiaries held by any future, present or former employee, consultant, officer or director (or spouse, ex-spouse or estate of any of the foregoing or trust for the benefit of any of the foregoing or any lineal descendants thereof) of Parent or any of its Subsidiaries pursuant to any management equity plan or stock option plan or any other management or employee benefit plan or agreement, or any stock subscription or shareholder agreement or employment agreement; provided, however, that the aggregate payments made under this clause (m) do not exceed in any calendar year the sum of (i) $3,000,000 plus (ii) the amount of any payments received in such calendar year under key-man life insurance policies;

(n) dividends or distributions on its Equity Interests by Parent or any of its Subsidiaries payable solely in additional shares of its common stock; and

(o) solely in connection with Permitted Convertible Indebtedness and any Refinancing Convertible Debt relating thereto, the Credit Parties or its Subsidiaries may enter into Permitted Equity Derivatives (and may settle, terminate or unwind any such Permitted Equity Derivatives in connection with any refinancing, early conversion or maturity of such Permitted Convertible Indebtedness).

"Permitted Equity Derivative" means any call or capped option (or substantively equivalent equity derivative transaction) or call spread transaction relating to the Equity Interests of Parent or any other Credit Party purchased by Parent or such Credit Party in connection with the issuance of Permitted Convertible Indebtedness and any Refinancing Convertible Debt relating thereto by Parent or such other Credit Party, provided, that the purchase price for such call or capped option does not exceed the net cash proceeds received by Parent or such other Credit Party from the issuance of such Permitted Convertible Indebtedness or Refinancing Convertible Debt.

"Permitted Indebtedness" means:

(a) Indebtedness of the Credit Parties to Secured Parties under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and shown on Schedule 12.2 of the Disclosure Letter;

(c) Permitted Convertible Indebtedness not to exceed $200,000,000 in the aggregate at any time outstanding; provided that Permitted Convertible Indebtedness will not be deemed to be outstanding, to the extent that in connection with the issuance of any Refinancing Convertible Debt, the Permitted Convertible Indebtedness to be refinanced is cancelled within three (3) Business Days of the incurrence of such Refinancing Convertible Debt;

(d) Indebtedness not to exceed $5,000,000 in the aggregate at any time outstanding, consisting of (i) Indebtedness incurred to finance the purchase, construction, repair, or improvement of fixed assets and (ii) Capital Lease Obligations;

(e) Indebtedness in connection with trade credit, corporate credit cards, purchasing cards or bank card products, provided, that any such Indebtedness that is secured shall not exceed $1,000,000 in the aggregate at any time outstanding;

(f) guarantees of Permitted Indebtedness;

(g) Indebtedness consisting of indemnity obligations and royalty payments or sales milestones based on net sales incurred in connection with any Permitted Acquisition, Permitted Transfer, Permitted Investment or any in-licensing or any collaboration, co-promotion or co-marketing arrangement; in each instance only if such Indebtedness is due and payable upon the occurrence of an event or the performance of an act (and not solely with the passage of time);

(h) Indebtedness of Parent or any of its Subsidiaries with respect to letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments outstanding and to the extent secured, secured solely by cash or Cash Equivalents, in each case entered into in the ordinary course of business;

(i) Indebtedness owed: (i) by a Credit Party to another Credit Party; (ii) by a Subsidiary of Parent that is not a Credit Party to another Subsidiary of Parent that is not a Credit Party; (iii) by a Credit Party to a Subsidiary of Parent that is not a Credit Party; or (iv) by a Subsidiary of Parent that is not a Credit Party to a Credit Party, not to exceed $5,000,000 in the aggregate at any time outstanding;

(j) Indebtedness consisting of Contingent Obligations described in clause (a) of the definition thereof: (i) of a Credit Party of Permitted Indebtedness of another Credit Party (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder); (ii) of a Subsidiary of Parent which is not a Credit Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of another Subsidiary of Parent which is not a Credit Party; (iii) of a Subsidiary of Parent which is not a Credit Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of a Credit Party; or (iv) of a Credit Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of a Subsidiary of Parent which is not a Credit Party not to exceed $10,000,000 in the aggregate at any time outstanding;

(k) Indebtedness not to exceed $5,000,000 in the aggregate at any time outstanding *plus* any additional amounts payable in Equity Interests and cash in lieu of fractional shares consisting of earn-outs and other obligations in respect of deferred purchase price of assets, property, services or rights, incurred in connection with any Permitted Acquisition, Permitted Transfer, Permitted Investment or any in-licensing or any collaboration, co-promotion or co-marketing arrangement;

(l) Indebtedness of any Person that becomes a (direct or indirect) Subsidiary of Parent (or of any Person not previously a Subsidiary that is merged or consolidated with or into a Subsidiary of Parent in a transaction permitted hereunder) after the Effective Date; provided, that all such Indebtedness is at all times Subordinated Debt;

(m) (i) Indebtedness with respect to workers' compensation claims, payment obligations in connection with health, disability or other types of social security benefits, unemployment or other insurance obligations, reclamation and statutory obligations or (ii) Indebtedness related to employee benefit plans, including annual employee bonuses, accrued wage increases and 401(k) plan matching obligations; in each case, incurred in the ordinary course of business;

(n) Indebtedness in respect of performance bonds, bid bonds, appeal bonds, surety bonds and completion guarantees and similar obligations arising in the ordinary course of business;

(o) Indebtedness in respect of netting services, overdraft protection and other cash management services, in each case in the ordinary course of business;

(p) Indebtedness consisting of the financing of insurance premiums in the ordinary course of business;

(q) Indebtedness consisting of guarantees resulting from endorsement of negotiable instruments for collection by any Credit Party in the ordinary course of business;

(r) unsecured Indebtedness incurred in connection with any items of Permitted Distributions in clause (m) of the definition of "Permitted Distributions";

(s) other unsecured Indebtedness in an aggregate amount not to exceed $5,000,000 at any time outstanding; and

(t) subject to the proviso immediately below, extensions, refinancings, renewals, modifications, amendments, restatements and, in the case of any items of Permitted Indebtedness in clause (b) of the definition thereof or Permitted Indebtedness constituting notes governed by an indenture (including Permitted Convertible Indebtedness), exchanges, of any items of Permitted Indebtedness in clauses (a) through (s) above, provided, that in the case of clause (b) above, the principal amount thereof is not increased (other than by any reasonable amount of premium (if any), interest (including post-petition interest), fees, expenses, charges or additional or contingent interest reasonably incurred in connection with the same and the terms thereof); provided, further, that in the case of any Indebtedness permitted under clause (c) of the definition thereof, (x) the maturity thereof is not shortened to before the Term Loan Maturity Date, (y) the amount of such Indebtedness at the time of, and taking into effect, such extension, refinancing, renewal, modification, amendment, restatement or exchange, together with all other Permitted Convertible Indebtedness then-outstanding, does not exceed $200,000,000 in the aggregate, and (z) there is no change to or addition of any direct or indirect obligor with respect thereto.

Notwithstanding the foregoing, "Permitted Indebtedness" shall not include any Hedging Agreements.

Notwithstanding the foregoing or anything in this Agreement to the contrary, no direct or indirect synthetic royalty or similar financing transaction involving the sale of revenues or royalties entered into after the Tranche A Closing Date and, except to the extent incurred in connection with any Permitted Acquisitions, Permitted Investments, in-licensing agreements or any collaboration, co-promotion or co-marketing arrangements, in each case entered into by any Credit Party or any of its Subsidiaries, no Indebtedness constituting royalty payments or sales milestones based on net sales that is, directly or indirectly, created, incurred, assumed or guaranteed after the Tranche A Closing Date by a Credit Party or any of its Subsidiaries, shall in any instance be permitted under this Agreement without the prior written consent of the Collateral Agent or the Required Lenders.

"Permitted Investments" means:

(a) Investments (including Investments in Subsidiaries) existing on the Effective Date and shown on Schedule 12.3 of the Disclosure Letter, including any extensions, renewals or reinvestments thereof;

(b) Investments consisting of cash and Cash Equivalents;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business;

(d) subject to Section 5.5, Investments consisting of deposit accounts or securities accounts;

(e) Investments in connection with Permitted Transfers;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of accounts receivable of, or prepaid royalties and other credit extensions or advances, to customers, suppliers or manufacturers who are not Affiliates, in the ordinary course of business or otherwise to support capacity demand; provided that this clause (h) shall not apply to Investments of any Credit Party in any of its Subsidiaries;

(i) joint ventures or strategic alliances consisting of the licensing or development of technology or the providing of technical support;

(j) Investments (i) required in connection with a Permitted Acquisition (including the formation of any Subsidiary for the purpose of effectuating such Permitted Acquisition, the capitalization of such Subsidiary whether by capital contribution or intercompany loans to the extent otherwise permitted by the terms of this Agreement, related Investments in Subsidiaries necessary to consummate such Permitted Acquisition and the receipt of any non-cash consideration in such Permitted Acquisition) and (ii) consisting of earnest money or escrow deposits required in connection with a Permitted Acquisition or other acquisition of properties or assets not otherwise prohibited hereunder;

(k) Investments constituting the formation of any Subsidiary for the purpose of consummating a merger or acquisition transaction permitted by Section 6.3(a)(i) through (iv) hereof, which such transaction is otherwise a Permitted Investment;

(l) Investments of any Person that (i) becomes a Subsidiary of Parent (or of any Person not previously a Subsidiary of Parent that is merged or consolidated with or into a Subsidiary of Parent in a transaction permitted hereunder) after the Effective Date, or (ii) are assumed after the Effective Date by Parent or any Subsidiary of Parent in connection with an acquisition of assets from such Person by Parent or such Subsidiary, in either case, in a Permitted Acquisition; provided, that in each case, any such Investment (x) exists at the time such Person becomes a Subsidiary of Parent (or is merged or consolidated with or into a Subsidiary of Parent) or such assets are acquired, (y) was not made in contemplation of or in connection with such Person becoming a Subsidiary of Parent (or merging or consolidating with or into a Subsidiary of Parent) or such acquisition of assets, and (z) could not reasonably be expected to result in a Default or an Event of Default;

(m) Investments arising as a result of the licensing of Intellectual Property in the ordinary course of business and not prohibited under this Agreement;

(n) to the extent constituting an Investment, any Permitted Equity Derivative, including the payment of premiums in connection therewith;

(o) Investments by: (i) any Credit Party in any other Credit Party; (ii) any Subsidiary of Parent which is not a Credit Party in another Subsidiary of Parent which is not a Credit Party; (iii) any Subsidiary of Parent which is not a Credit Party in any Credit Party; (iv) any Credit Party in a Subsidiary of Parent which is not a Credit Party, not to exceed $5,000,000 in the aggregate outstanding at any time; and (v) Parent and its Subsidiaries consisting of Equity Interests in their respective Subsidiaries existing on (x) the Tranche A Closing Date and (y) each other Closing Date, in each case of this sub-clause (y), only if the formation or acquisition of, or merger or consolidation resulting in a Person becoming, a Subsidiary is not prohibited hereunder;

(p) Repurchases of capital stock of Parent or any of its Subsidiaries deemed to occur upon the exercise of options, warrants or other rights to acquire capital stock of Parent or such Subsidiary solely to the extent that shares of such capital stock represent a portion of the exercise price of such options, warrants or such rights;

(q) Investments consisting of non-cash consideration received for any Permitted Transfer;

(r) Investments consisting of acquisitions from third parties of inventory, equipment, office supplies, software and other similar assets in the ordinary course of business;

(s) Investments consisting of in-licensing agreements, provided that no Indebtedness that is not Permitted Indebtedness is incurred or assumed in connection therewith;

(t) [Reserved]; and

(u) other Investments in an aggregate amount not to exceed $5,000,000 outstanding at any time;

(v) provided, however, that, none of the foregoing Investments shall be a "Permitted Investment" if any Indebtedness or Liens assumed in connection with such Investment are not otherwise permitted under Section 6.4 or 6.5, respectively.

Notwithstanding the foregoing, other than in connection with clause (n) above, "Permitted Investments" shall not include any Hedging Agreements.

"Permitted Licenses" means, collectively: (a) any non-exclusive license or covenant not to sue in any geography within the Territory, of or with respect to any Intellectual Property (including, for clarity, any Company IP); (b) any exclusive license or covenant not to sue as to any geography within the Territory other than the U.S., of or with respect to any Intellectual Property (including, for clarity, any Company IP); (c) any non-exclusive grant or covenant not to sue in any geography within the Territory, or any exclusive grant or covenant not to sue as to any geography within the Territory other than the U.S., of development, manufacturing, production, commercialization, marketing, co-promotion, distribution, sale, lease or similar commercial rights with respect to Product; and (d) any intercompany license, covenant not to sue, or other similar arrangement (i) in any geography within the Territory, between or among Credit Parties, and (ii) in any geography within the Territory other than the U.S., between or among Credit Parties and their respective Subsidiaries. Notwithstanding the foregoing or any other provision of this Agreement, no Excluded License entered into after the Tranche A Closing Date shall be a "Permitted License" hereunder without the prior written consent of the Collateral Agent or the Required Lenders.

"Permitted Liens" means:

(a) Liens in favor and for the benefit of any Lender and the other Secured Parties securing the Obligations pursuant to any Loan Document;

(b) Liens existing on the Effective Date and set forth on Schedule 12.4 of the Disclosure Letter;

(c) Liens for Taxes, assessments or governmental charges incurred in the ordinary course of business and which are not yet due and payable or if due and payable, (i) are being contested in good faith and by appropriate proceedings promptly instituted and diligently conducted and (ii) for which adequate reserves therefor have been set aside on the books of the applicable Person and maintained in conformity with Applicable Accounting Standards, if required;

(d) Pledges or deposits made in the ordinary course of business (other than Liens imposed by ERISA) in connection with workers' compensation, payroll taxes, employment insurance, unemployment insurance, old-age pensions, or other similar social security legislation, (ii) pledges or deposits made in the ordinary course of business securing liability for reimbursement or indemnification obligations of (including obligations in respect of letters of credit or bank guarantees for the benefit of) insurance carriers providing property, casualty or liability insurance to Parent or any of its Subsidiaries, (iii) subject to Section 6.2(b), statutory or common law Liens of landlords, (iv) Liens otherwise arising by operation of law in favor of the owner or sublessor of leased premises and confined to the property rented, (v) Liens that are restrictions on transfer of securities imposed by applicable securities laws, (vi) Liens resulting from a filing by a lessor as a precautionary filing for a true lease, and (vii) pledges or deposits to secure performance of tenders, bids, leases, statutory or regulatory obligations, surety and appeal bonds, government contracts, performance and return-of-money bonds and other obligations of like nature, in each case other than for borrowed money and entered into in the ordinary course of business;

(e) Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting an Event of Default under either Section 7.4 or 7.7;

(f) Liens (including the right of set-off) in favor of banks or other financial institutions incurred on deposits made in accounts held at such institutions in the ordinary course of business; provided that such Liens (i) are not given in connection with the incurrence of any Indebtedness, (ii) relate solely to obligations for administrative and other banking fees and expenses incurred in the ordinary course of business in connection with the establishment or maintenance of such accounts and (iii) are within the general parameters customary in the banking industry;

(g) Liens that are contractual rights of set-off (i) relating to pooled deposit or sweep accounts of Parent or any of its Subsidiaries to permit satisfaction of overdraft or similar obligations incurred in the ordinary course of business or (ii) relating to purchase orders and other agreements entered into with customers of Parent or any of its Subsidiaries in the ordinary course of business, including vendors' liens to secure payment arising under Article 2 of the Code or similar provisions of Requirements of Law in the ordinary course of business, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses;

(h) Liens solely on any cash earnest money deposits made by Parent or any of its Subsidiaries in connection with any Permitted Acquisition, Permitted Investment or other acquisition of assets or properties not otherwise prohibited under this Agreement;

(i) Liens existing on assets or properties at the time of its acquisition or existing on the assets or properties of any Person at the time such Person becomes a Subsidiary of Parent, in each case after the Effective Date; provided that (i) neither such Lien was created nor the Indebtedness secured thereby was incurred in contemplation of such acquisition or such Person becoming a Subsidiary of Parent, (ii) such Lien does not extend to or cover any other assets or properties (other than the proceeds or products thereof and other than after-acquired assets or properties subject to a Lien securing Indebtedness and other obligations incurred prior to such time and which Indebtedness and other obligations are permitted hereunder that requires, pursuant to its terms and conditions in effect at such time, a pledge of after-acquired assets or properties, it being understood that such requirement shall not be permitted to apply to any assets or properties to which such requirement would not have applied but for such acquisition), (iii) the Indebtedness and other obligations secured thereby is permitted under Section 6.4 hereof and (iv) such Liens are of the type otherwise permitted under Section 6.5 hereof;

(j) Liens securing Indebtedness permitted under clause (d) of the definition of "Permitted Indebtedness" (including any extensions, refinancings, modifications, amendments or restatements of such Indebtedness permitted under clause (t) of the definition of "Permitted Indebtedness"); provided, that such Lien does not extend to or cover any assets or properties other than those that are (i) subject to such Capital Lease Obligations or (ii) acquired with or otherwise financed or refinanced by such Indebtedness;

(k) servitudes, easements, rights-of-way, restrictions and other similar encumbrances on real property imposed by Requirements of Law and encumbrances consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor defects or other irregularities in title which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any Credit Party or any Subsidiary of any Credit Party;

(l) to the extent constituting a Lien, escrow arrangements securing indemnification obligations associated with any Permitted Acquisition or Permitted Investment;

(m) (i) leases or subleases of real property granted in the ordinary course of business (including, if referring to a Person other than a Credit Party or a Subsidiary, in the ordinary course of such Person's business), (ii) licenses, sublicenses, leases or subleases of personal property (other than Intellectual Property) granted to third parties in the ordinary course of business, in each case which do not interfere in any material respect with the operations of the business of any Credit Party or any of its Subsidiaries and do not prohibit granting the Collateral Agent a security interest in any Credit Party's personal property held at such location for the benefit of the Lenders and other Secured Parties, (iii) Permitted Licenses, and (iv) retained interests of lessors or licensors or similar party under any in-licenses;

(n) Liens on cash or other current assets pledged to secure (i) Indebtedness in respect of corporate credit cards, purchasing cards or bank card products, provided, that such Liens shall not secure more than $1,000,000 of such Indebtedness in the aggregate at any time, or (ii) Indebtedness in the form of letters of credit or bank guarantees;

(o) Liens on any properties or assets of Parent or any of its Subsidiaries which do not constitute Collateral under the Loan Documents, other than (i) any Company IP that does not constitute Collateral under the Loan Documents but is related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory and (ii) Equity Interests of any Subsidiary;

(p) Liens on any properties or assets of Parent or any of its Subsidiaries imposed by law or regulation which were incurred in the ordinary course of business, including landlords', carriers', warehousemen's, mechanics', materialmen's, contractors', suppliers of materials', architects' and repairmen's Liens, and other similar Liens arising in the ordinary course of business; provided that such Liens (i) do not materially detract from the value of such properties or assets subject thereto or materially impair the use of such properties or assets subject thereto in the operations of the business of Parent or such Subsidiary or (ii) are being contested in good faith by appropriate proceedings which conclusively operate to stay the sale or forfeiture of

any portion of such properties or assets subject thereto, and for which adequate reserves have been set aside on the books of the applicable Person and maintained in conformity with Applicable Accounting Standards, if required;

(q) Liens in favor of customs and revenue authorities arising as a Requirement of Law which were incurred in the ordinary course of business, to secure payment of customs duties in connection with the importation of goods in the ordinary course of business;

(r) Liens on any goods sold to Parent or any of its Subsidiaries in the ordinary course of business in favor of the seller thereof, but only to the extent securing the unpaid purchase price for such goods and any related expenses; and

(s) subject to the provisos immediately below, the modification, replacement, extension or renewal of the Liens described in clauses (a) through (r) above; provided, however, that any such modification, replacement, extension or renewal must (i) be limited to the assets or properties encumbered by the existing Lien (and any additions, accessions, parts, improvements and attachments thereto and the proceeds thereof) and (ii) not increase the principal amount of any Indebtedness secured by the existing Lien (other than by any reasonable premium or other reasonable amount paid and fees and expenses reasonably incurred in connection therewith); provided, further, that to the extent any of the Liens described in clauses (a) through (r) above secure Indebtedness of a Credit Party, such Liens, and any such modification, replacement, extension or renewal thereof, shall constitute Permitted Liens if and only to the extent that such Indebtedness is permitted under Section 6.4 hereof.

"Permitted Negative Pledges" means:

(a) prohibitions or limitations with regard to specific properties or assets encumbered by Permitted Liens, if and only to the extent each such prohibition or limitation applies only to such properties or assets;

(b) prohibitions or limitations set forth in any lease, license or other similar agreement entered into in the ordinary course of business;

(c) prohibitions or limitations relating to Permitted Indebtedness, in the case of each relevant agreement, document or instrument if and only to the extent such prohibitions or limitations, taken as a whole, are not materially more restrictive than the prohibitions and limitations set forth in this Agreement and the other Loan Documents, taken as a whole (as reasonably determined by a Responsible Officer of Parent in good faith);

(d) customary provisions restricting assignments, subletting, sublicensing or other transfer of properties or assets subject thereto set forth in leases, subleases, licenses (including Permitted Licenses) and other similar agreements that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such restriction applies only to the properties or assets subject to such leases, subleases, licenses or agreements, and customary provisions restricting assignment, pledges or transfer of any agreement entered into in the ordinary course of business;

(e) prohibitions or limitations imposed by Requirements of Law;

(f) prohibitions or limitations that exist as of the Effective Date under Indebtedness existing on the Effective Date;

(g) customary prohibitions or limitations arising in connection with any Permitted Transfer or contained in any agreement relating to any Permitted Transfer pending the consummation of such Permitted Transfer;

(h) customary provisions in shareholders' agreements, joint venture agreements, Operating Documents or similar binding agreements relating to, or any agreement evidencing Indebtedness of, any joint venture entity or non-Wholly-Owned Subsidiary and applicable solely to such joint venture entity or non-Wholly-Owned Subsidiary and the Equity Interests issued thereby;

(i) customary net worth provisions set forth in real property leases entered into by Subsidiaries of Borrower, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Parent in good faith);

(j) customary net worth provisions set forth in customer agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Parent in good faith);

(k) restrictions on cash or other deposits (including escrowed funds) imposed by agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document;

(l) prohibitions or limitations set forth in any agreement in effect at the time any Person becomes a Subsidiary (but not any amendment, modification, restatement, renewal, extension, supplement or replacement expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary and each such prohibition or limitation does not apply to Borrower or any other Subsidiary (other than such Person and any other Person that is a Subsidiary of such first Person at the time such first Person becomes a Subsidiary);

(m) prohibitions or limitations imposed by any Loan Document;

(n) customary provisions set forth in joint venture agreements or agreements governing minority investments that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to the joint venture entity or minority investment that is the subject of such agreement;

(o) limitations imposed with respect to any license acquired in a Permitted Acquisition;

(p) customary provisions restricting assignments or other transfer of properties or assets subject thereto set forth in any agreement entered into in the ordinary course of business, if and only to the extent each such restriction applies only to the properties or assets subject to such agreement;

(q) prohibitions or limitations imposed by any agreement evidencing any Permitted Indebtedness of the type described in clause (d) of the definition of "Permitted Indebtedness"; and

(r) prohibitions or limitations imposed by any amendments, modifications, restatements, renewals, extensions, supplements or replacements of any of the agreements referred to in clauses (a) through (q) above, except to the extent that any such amendment, modification, restatement, renewal, extension, supplement or replacement expands the scope of any such prohibition or limitation.

"Permitted Subsidiary Distribution Restrictions" means, in each case notwithstanding Section 6.8:

(a) prohibitions or limitations with regard to specific properties or assets encumbered by Permitted Liens, if and only to the extent each such prohibition or limitation applies only to such properties or assets;

(b) prohibitions or limitations set forth in any lease, license or other similar agreement entered into in the ordinary course of business;

(c) prohibitions or limitations relating to Permitted Indebtedness, in the case of each relevant agreement, document or instrument if and only to the extent such prohibitions or limitations, taken as a whole, are not materially more restrictive than the prohibitions and limitations set forth in this Agreement and the other Loan Documents, taken as a whole (as reasonably determined by a Responsible Officer of Parent in good faith);

(d) customary provisions restricting assignments, subletting, sublicensing or other transfer of properties or assets subject thereto set forth in leases, subleases, licenses (including Permitted Licenses) and other similar agreements that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such restriction applies only to the properties or assets subject to such leases, subleases, licenses or agreements, and customary provisions restricting assignment, pledges or transfer of any agreement entered into in the ordinary course of business;

(e) prohibitions or limitations on the transfer or assignment of any properties, assets or Equity Interests set forth in any agreement entered into in the ordinary course of business that is not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to such properties, assets or Equity Interests;

(f) prohibitions or limitations imposed by Requirements of Law;

(g) prohibitions or limitations that exist as of the Effective Date under Indebtedness existing on the Effective Date;

(h) customary prohibitions or limitations arising in connection with any Permitted Transfer or contained in any agreement relating to any Permitted Transfer pending the consummation of such Permitted Transfer;

(i) customary provisions in shareholders' agreements, joint venture agreements, Operating Documents or similar binding agreements relating to, or any agreement evidencing Indebtedness of, any joint venture entity or non-Wholly-Owned Subsidiary and applicable solely to such joint venture entity or non-Wholly-Owned Subsidiary and the Equity Interests issued thereby;

(j) customary net worth provisions set forth in real property leases entered into by Subsidiaries of Borrower, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Parent in good faith);

(k) customary net worth provisions set forth in customer agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Parent in good faith);

(l) restrictions on cash or other deposits (including escrowed funds) imposed by agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document;

(m) prohibitions or limitations set forth in any agreement in effect at the time any Person becomes a Subsidiary (but not any amendment, modification, restatement, renewal, extension, supplement or replacement expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary and each such prohibition or limitation does not apply to Borrower or any other Subsidiary (other than such Person and any other Person that is a Subsidiary of such first Person at the time such first Person becomes a Subsidiary);

(n) prohibitions or limitations imposed by any Loan Document;

(o) customary provisions set forth in joint venture agreements or agreements governing minority investments that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to the joint venture entity or minority investment that is the subject of such agreement;

(p) customary provisions restricting assignments or other transfer of properties or assets subject thereto set forth in any agreement entered into in the ordinary course of business, if and only to the extent each such restriction applies only to the properties or assets subject to such agreement;

(q) prohibitions or limitations imposed by any agreement evidencing any Permitted Indebtedness of the type described in clause (d) of the definition of "Permitted Indebtedness"; and

(r) prohibitions or limitations imposed by any amendments, modifications, restatements, renewals, extensions, supplements or replacements of any of the agreements referred to in clauses (a) through (q) above, except to the extent that any such amendment, modification, restatement, renewal, extension, supplement or replacement expands the scope of any such prohibition or limitation.

"Permitted Transaction" is defined in Section 2.2(c)(iii).

"Permitted Transfers" means:

(a) Transfers of any properties or assets which do not constitute Collateral under the Loan Documents, other than any Company IP that does not constitute Collateral under the Loan Documents but is related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Specified Territory (other than, for the avoidance of doubt, any such Company IP Transferred pursuant to any Permitted License);

(b) Transfers of Inventory in the ordinary course of business;

(c) Transfers of surplus, damaged, worn out or obsolete equipment that is, in the reasonable judgment of a Responsible Officer of Parent exercised in good faith, no longer economically practicable to maintain or useful in the ordinary course of business, and Transfers of other properties or assets in lieu of any pending or threatened institution of any proceedings for the condemnation or seizure of such properties or assets or for the exercise of any right of eminent domain;

(d) Transfers made in connection with Permitted Liens, Permitted Acquisitions or Permitted Investments;

(e) Transfers of cash and Cash Equivalents made in connection with Permitted Distributions or otherwise in the ordinary course of business for equivalent value and in a manner that is not prohibited under this Agreement or the other Loan Documents;

(f) Transfers (i) between or among Credit Parties, provided that, with respect to any properties or assets constituting Collateral under the Loan Documents, any and all steps as may be required to be taken in order to create and maintain a first priority security interest in and Lien upon such properties and assets in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties are taken contemporaneously with the completion of any such Transfer, and (ii) between or among non-Credit Parties;

(g) (i) the sale or issuance of Equity Interests of any Subsidiary of Parent to any Credit Party or Subsidiary, provided, that any such sale or issuance by a Credit Party shall be to another Credit Party; and (ii) the sale, transfer, issuance or other disposition of a *de minimis* number of shares of the Equity Interests of any Subsidiary of Parent in order to qualify members of the governing body of such Subsidiary if required by Requirements of Law;

(h) the discount without recourse or sale or other disposition of unpaid and overdue accounts receivable arising in the ordinary course of business in connection with the compromise, collection or settlement thereof and not part of a financing transaction;

(i) any abandonment, disclaimer, forfeiture, dedication to the public, cancellation, non-renewal or discontinuance of use or maintenance of Company IP that a Responsible Officer of Parent reasonably determines in good faith (i) is no longer economically practicable to maintain or useful in the ordinary course of business and that (ii) could not reasonably be expected to be adverse to the rights, remedies and benefits available to, or conferred upon, the Collateral Agent or any Lender under any Loan Document in any material respect;

(j) Transfers by Parent or any of its Subsidiaries pursuant to any Permitted License;

(k) intercompany licenses or grants of rights of distribution, co-promotion or similar commercial rights (i) between or among the Credit Parties, or (ii) between or among the Credit Parties and Subsidiaries that are not Credit Parties entered into prior to the Effective Date, and renewals, replacements and extensions thereof (including additional licenses or grants in relation to new territories) on comparable terms in the ordinary course of business;

(l) licenses, sublicenses, leases or subleases, in each case other than relating to any Company IP, granted to third parties in the ordinary course of business and not material to the research, development, manufacture, production, use (by any Credit Party or its Subsidiaries), commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory;

(m) the abandonment disclaimer, forfeiture, dedication to the public, or other disposition of any Company IP that is (i) not material to the research, development, manufacture, production, use (by any Credit Party or its Subsidiaries), commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory or (ii) no longer used or useful in any material respect in any Product line of business of Parent and its Subsidiaries;

(n) any involuntary disposition or any sale, lease, license or other disposition of property (other than, for the avoidance of doubt, any Company IP) in settlement of, or to make payment in satisfaction of, any property or casualty insurance;

(o) sales, leases, licenses, transfers or other dispositions of property to the extent that (i) such property is exchanged for credit against the purchase price of similar replacement property or (ii) the proceeds of such sale, lease, license, transfer or other disposition are promptly applied to the purchase price of similar replacement property;

(p) any early unwind, settlement or termination of any Permitted Equity Derivative; and

(q) other Transfers made in the ordinary course of business on commercially reasonable arm's length terms.

"Person" means any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, exempted company, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"Personal Data" means information protected as "personal data," "personal information," "personally identifiable information," "protected health information," "identifiable private information," or any similar terms under applicable Data Protection Laws.

"Plan" means any employee pension benefit plan (other than a Multiemployer Plan) subject to the provisions of Title IV of ERISA or Section 412 of the IRC or Section 302 of ERISA which is maintained or contributed to by Borrower or its Subsidiaries or their respective ERISA Affiliates or with respect to which Borrower or its Subsidiaries have any liability (including under Section 4069 of ERISA).

"PPFC Documents" means, collectively, the Pre-Paid Forward Contract and each other "Transaction Document" (as such term is defined in the Pre-Paid Forward Contract).

"Pre-Paid Forward Contract" means that certain Pre-Paid Forward Contract, dated as of March 18, 2021 and amended as of April 30, 2021, by and between Parent and RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2).

"Prepayment Premium" means the Tranche A Prepayment Premium or the Tranche B Prepayment Premium or the Tranche C Prepayment Premium or the Tranche D Prepayment Premium (as applicable) or the combination thereof, as the context dictates.

"Prior Effective Date" is defined in the preamble hereof.

"Product" means: (a)(i) the pharmaceutical product known as JELMYTO® (mitomycin) (and foreign-named equivalents) for pyelocalyceal solution and any successors thereto (collectively, "**JELMYTO®**"), (ii) any pharmaceutical product for the treatment of upper tract urothelial cancer in a hydrogel formulation that contains any radioisomer, stereoisomer, racemates, solvates, salt forms, bases, anhydrides, hydrates, polymorphs, metabolites, ester forms deuterated forms or pro-drugs of mitomycin, and (iii) any pharmaceutical product that contains any of the foregoing, including an active ingredient thereof, in each case of sub-clauses (a)(i) – (a)(iii) above, in any dosage form, dosing regimen, strength or route of administration; (b)(i) the pharmaceutical product known as UGN-102 (mitomycin) for intravesical solution and any successors thereto, (ii) any pharmaceutical product for the treatment of bladder cancer in a hydrogel formulation that contains any radioisomer, stereoisomer, racemates, solvates, salt forms, bases, anhydrides, hydrates, polymorphs, metabolites, ester forms deuterated forms or pro-drugs of mitomycin, and (iii) any pharmaceutical product that contains any of the foregoing, including an active ingredient thereof, in each case of sub-clauses (b)(i) – (b)(iii) above, in any dosage form, dosing regimen, strength or route of administration; and (c) the pharmaceutical products known as UGN-301 (anti-CTLA-4) and UGN-201 (TLR 7 agonist) and any successors thereto, alone or in combination with each other, in any dosage form, dosing regimen, strength or route of administration for the treatment of bladder cancer).

"Refinancing Convertible Debt" is defined in Section 2.2(c)(iii).

"Registered Organization" means any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"Regulatory Agency" means a U.S. or foreign Governmental Authority with responsibility for the approval or licensure of the marketing and sale of pharmaceuticals or other regulation of pharmaceuticals, or otherwise having authority to regulate Product, including the FDA.

"Regulatory Approval" means all approvals (including orphan-drug exclusive approval under 21 C.F.R. § 316.34), designations (including orphan-drug designation under 21 C.F.R. § 316.24), licensures, product or establishment licenses, registrations or authorizations of any Regulatory Agency necessary for the manufacture, use, import, export, storage, transport, offer for sale, or distribution or sale of Product.

"Regulatory Submission Material" means all regulatory filings, submissions, approvals, licensures, and authorizations related to any research, development, manufacture, production, use, commercialization, post-approval or post-licensure monitoring and reporting, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory, including all data and information provided in, and used to develop, any of the foregoing.

"Related Parties" means, with respect to any Person, such Person's Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of such Person and of such Person's Affiliates.

"Release" means any release, spill, emission, leaking, pumping, pouring, injection, escaping, deposit, disposal, discharge, dispersal, dumping, leaching or migration of any Hazardous Material into the indoor or outdoor environment (including the abandonment or disposal of any barrels, containers or other closed receptacles containing any Hazardous Material), including the movement of any Hazardous Material through the air, soil, surface water or groundwater.

"Relevant Governmental Body" means the Board of Governors of the Federal Reserve System or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Board of Governors of the Federal Reserve System or the Federal Reserve Bank of New York, or any successor thereto.

"Required Lenders" means, (a) prior to the Tranche A Closing Date, Lenders obligated with respect to greater than fifty percent (50%) of the Term Loan Commitments and (b), as of any date of determination thereafter, Lenders representing greater than fifty percent (50%) of the principal amount of the Term Loans outstanding as of such date.

"Requirements of Law" means, as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, order, policy, rule or regulation or determination of an arbitrator or a court or other Governmental Authority (including Environmental Laws, Health Care Laws, Data Protection Laws and FDA Laws, and all applicable statutes, rules, regulations, standards, guidelines, policies and orders administered or issued by any foreign Governmental Authority) in each case, applicable to and binding upon such Person or any of its assets or properties or to which such Person or any of its assets or properties are subject, including, with respect to Borrower, the rules or requirements of any applicable U.S. national securities exchange applicable to Borrower or any of its Equity Interests.

"Responsible Officers" means, with respect to any Credit Party: (a) collectively, for purposes of determining the Persons with Knowledge with respect to such Credit Party, each of the Chief Executive Officer, Chief Financial Officer, General Counsel, Chief Medical Officer, Chief Commercial Officer, Chief Business Officer, Executive Vice-President, Research and Development and Technical Operations and Executive Vice-President, Regulatory Affairs and Quality of such Credit Party or, in each case, if none, of Parent; and (b) collectively, for purposes of determining the Persons authorized to provide the certifications of a Responsible Officer of such Credit Party required under the Loan Documents, each of the Chief Executive Officer, Chief Financial Officer and General Counsel of such Credit Party or, in each case, if none, of Parent.

"Restricted License" any material license or other material agreement of the kind or nature subject or purported to be subject from time to time to a Lien under any Collateral Document, with respect to which a Credit Party is the licensee and pursuant to which such Credit Party controls the Company IP, (a) that prohibits or otherwise restricts such Credit Party from granting a security interest in its interest therein to the Collateral Agent, for the benefit of Lenders and the other Secured Parties (other than as a result of customary anti-assignment provisions) in a manner enforceable under Requirements of Law, or (b) for which a breach of or default under could reasonably be expected to interfere with the Collateral Agent's or any Lender's right to sell any Collateral. For the avoidance of doubt, software, open source code, application programming interfaces and/or trademarks, copyrights or patents of others that are commercially available to the public under the shrinkwrap licenses, clickwrap licenses, online terms of service or other terms of use or similar agreements and intellectual property rights of customers used by Borrower in the course of providing service to third parties in the ordinary course of business shall not constitute a Restricted License.

"RTW Intercreditor Agreement" means that certain New York law-governed intercreditor agreement, dated as of the Tranche A Closing Date, among Parent, RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2) and the Collateral Agent (for the benefit of Lenders and the other Secured Parties), in form and substance consistent with the parameters of an "Applicable Intercreditor Agreement" set forth in the definition thereof in Section 1.1 of the Pre-Paid Forward Contract and otherwise satisfactory to the Collateral Agent.

"Sanctioned Person" an individual or entity that is, or is owned or controlled by individuals or entities that are: (i) the subject or target of any sanctions administered or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control ("**OFAC**"), the U.S. Department of State, the U.S. Department of Commerce, the United Nations Security Council, the European Union, the United Kingdom or other relevant sanctions authority (collectively, "**Sanctions**"); or (ii) located, organized or resident in a country or territory that is the subject of comprehensive Sanctions, including currently, Crimea, Cuba, Iran, North Korea and Syria.

"Sanctions" is defined in Section 4.18(c).

"SEC" shall mean the Securities and Exchange Commission and any analogous Governmental Authority.

"Secretary's Certificate" means, with respect to any Person, a certificate of such Person executed by its Secretary, authorized signatory or director certifying as to the various matters set forth therein.

"Section 5 of the FTC Act" means the Section 5(a) of the U.S. Federal Trade Commission Act (15 U.S.C. § 45), which prohibits unfair and deceptive acts or practices in or affecting commerce and serves as the primary basis for U.S. Federal Trade Commission authority on privacy and security.

"Secured Parties" means each Lender, each other Indemnified Person and each other holder of any Obligation of a Credit Party.

"Securities Account" means any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"Security Agreement" means the Guaranty and Security Agreement, dated as of the Tranche A Closing Date, by and among the Credit Parties and the Collateral Agent, in form and substance substantially similar to Exhibit C attached hereto or in such form or substance as the Credit Parties and the Collateral Agent may otherwise agree.

"Sensitive Information" means, collectively, (a) any Personal Data that is subject to any Data Protection Law, (b) any information in which Parent or any of its Subsidiaries have IP Ancillary Rights or any other Intellectual Property rights (including Company IP), (c) any information with respect to which Parent or any of its Subsidiaries have contractual non-disclosure obligations, and (d) nonpublic Regulatory Submission Materials.

"SOFR" means a rate equal to the secured overnight financing rate as administered by the SOFR Administrator.

"SOFR Administrator" means the Federal Reserve Bank of New York (or a successor administrator of the secured overnight financing rate).

"Software" means "Software", as such term is defined in the Security Agreement.

"Solvent" means, with respect to any Person as of any date of determination, that, as of such date, (a) the value of the assets (including goodwill minus disposition costs) of such Person (both at fair value and present fair saleable value) is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such Person, (b) such Person is able to generally pay all liabilities (including trade debt) of such Person as such liabilities become absolute and mature in the ordinary course of business and (c) such Person does not have unreasonably small capital after giving due consideration to the prevailing practice in the industry in which it is engaged or will be engaged. In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

"Specified Territory" means the United States, United Kingdom, Germany, France, Italy and Israel.

"SSA" means the Social Security Act of 1935, codified at Title 42, Chapter 7, of the United States Code.

"Stock Acquisition" means the purchase or other acquisition by Parent or any of its Subsidiaries of any of the Equity Interests (by merger, stock purchase or otherwise) in any other Person.

"Subordinated Debt" means any Indebtedness in the form of or otherwise constituting term debt incurred by any Credit Party or any Subsidiary thereof (including any Indebtedness incurred in connection with any Acquisition or other Investment) that: (a) is subordinated in right of payment to the Obligations at all times until all of the Obligations have been paid, performed or discharged in full and Borrower has no further right to obtain any Credit Extension hereunder pursuant to a subordination, intercreditor or other similar agreement that is in form and substance reasonably satisfactory to the Collateral Agent (which agreement shall include turnover provisions that are reasonably satisfactory to the Collateral Agent); (b) except as permitted by clause (d) below, is not subject to scheduled amortization, redemption (mandatory), sinking fund or similar payment and does not have a final maturity, in each case, before a date that is at least 120 days following the Term Loan Maturity Date; (c) does not include covenants (including financial covenants) and agreements (excluding agreements with respect to maturity, amortization, pricing and other economic terms) that, taken as a whole, are more restrictive or onerous on the Credit Parties in any material respect than the comparable covenants and agreements, taken as a whole, in the Loan Documents (as reasonably determined by a Responsible Officer of such Credit Party in good faith); (d) is not subject to repayment or prepayment, including pursuant to a put option exercisable by the holder of any such Indebtedness, prior to a date that is at least 120 days following the final maturity thereof except in the case of an event of default or change of control (or, in each case, the equivalent thereof, however described); and (e) does not provide or otherwise include provisions having the effect of providing that a default or event of default (or the equivalent thereof, however described) under or in respect of such Indebtedness shall exist, or such Indebtedness shall otherwise become due prior to its scheduled maturity or the holder or holders thereof or any trustee or agent on its or their behalf shall be permitted (with or without the giving of notice, the lapse of time or both) to cause any such Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity, in any such case upon the occurrence of a Default or Event of Default hereunder unless and until the Obligations have been declared, or have otherwise automatically become, immediately due and payable pursuant to Section 8.1(a). Notwithstanding the foregoing, Permitted Convertible Indebtedness and Indebtedness under the Pre-Paid Forward Contract and other PPFC Documents shall not constitute Subordinated Debt.

"Subsidiary" means, with respect to any Person, a corporation, partnership, limited liability company or other entity of which more than fifty percent (50.0%) of whose shares of stock or other ownership interests having ordinary voting power (other than stock or such other ownership interests having such power only by reason of the happening of a contingency) to elect a majority of the Board of Directors (or similar body, if applicable) of such corporation, partnership or other entity are at the time owned, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of a Credit Party.

"Systems" is defined in Section 4.22(a).

"Tax" means any taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges of any nature or hereafter imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"Term Loan" means each of the Tranche A Loan or the Tranche B Loan, as applicable, and "**Term Loans**" means, collectively, the Tranche A Loan and the Tranche B Loan, as the context dictates.

"Term Loan Commitment" mean each of the Tranche A Commitment, the Tranche B Commitment, the Tranche C Commitment or the Tranche D Commitment, as applicable, and "**Term Loan Commitments**" means, collectively, the Tranche A Commitment, the Tranche B Commitment, the Tranche C Commitment and the Tranche D Commitment, as the context dictates.

"Term Loan Maturity Date" means the 5th-year anniversary of the Tranche A Closing Date; provided, however, that upon the satisfaction of the Tranche D Approval Condition, the Term Loan Maturity Date means the 6th-year anniversary of the Tranche A Closing Date.

"Term Loan Note" means each of the Tranche A Note or the Tranche B Note (as applicable), and "**Term Loan Notes**" means, collectively, the Tranche A Notes and the Tranche B Notes, as the context dictates.

"Term Loan Rate" is defined in Section 2.3(a)(i).

"Term SOFR" means, for any day in any calendar month, the Term SOFR Reference Rate for a tenor of three (3) months on the day (such day, the "**Periodic Term SOFR Determination Day**") that is two (2) U.S. Government Securities Business Days' prior to the first day of such Interest Period, as such rate is published by the Term SOFR Administrator; provided, however, that if as of 5:00 p.m. (New York City time) on any Periodic Term SOFR Determination Day the Term SOFR Reference Rate for the applicable tenor has not been published by the Term SOFR Administrator and a Benchmark Replacement Date with respect to the Term SOFR Reference Rate has not occurred, then Term SOFR will be the Term SOFR Reference Rate for such tenor as published by the Term SOFR Administrator on the first preceding U.S. Government Securities Business Day for which such Term SOFR Reference Rate for such tenor was published by the Term SOFR Administrator so long as such first preceding U.S. Government Securities Business Day is not more than three (3) U.S. Government Securities Business Days prior to such Periodic Term SOFR Determination Day.

"Term SOFR Adjustment" means a percentage equal to 0.26161% *per annum*.

"Term SOFR Administrator" means CME Group Benchmark Administration Limited (CBA) (or a successor administrator of the Term SOFR Reference Rate selected by the Collateral Agent in its reasonable discretion).

"Term SOFR Reference Rate" means the forward-looking term rate based on SOFR.

"Territory" means anywhere in the world.

"Third Party IP" is defined in Section 4.6(l).

"Trademarks" means (a) all trademarks, trade names, corporate names, company names, business names, fictitious business names, service marks, elements of package or trade dress of goods or services, logos and other source or business identifiers, together with the goodwill associated therewith, including all registrations and recordings thereof, and all applications in connection therewith, in the United States Patent and Trademark Office or in any similar office or agency of the United States or any state thereof or in any similar office or agency anywhere in the world in which foreign counterparts are registered or issued, and (b) all renewals thereof.

"Trading Day" means a day on which exchanges in the United States are open for the buying and selling of securities.

"Tranche A/B Additional Consideration" is defined in Section 2.7(a).

"Tranche A Closing Date" means the date on which the Tranche A Loan is advanced by Lenders, which is March 16, 2022.

"Tranche A Commitment" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche A Loan on the Tranche A Closing Date in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto.

"Tranche A Loan" is defined in Section 2.2(a)(i).

"Tranche A Loan Amount" means an original principal amount equal to Seventy-Five Million Dollars ($75,000,000.00).

"Tranche A Makewhole Amount" means, as of any date of prepayment of the Tranche A Loan occurring prior to the 2nd-year anniversary of the Tranche A Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 2nd-year anniversary of the Tranche A Closing Date on the amount of principal prepaid; provided, however, that if the Tranche D Approval Condition is satisfied prior to the 2nd-year anniversary of the Tranche A Closing Date, "Tranche A Makewhole Amount" means, as of any date of prepayment of the Tranche A Loan occurring prior to the 3rd-year anniversary of the Tranche A Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 3rd-year anniversary of the Tranche A Closing Date on the amount of principal prepaid; provided, further, that if the Tranche D Approval Condition is satisfied on or after the 2nd-year anniversary of the Tranche A Closing Date, "Tranche A Makewhole Amount" means, as of any date of prepayment of the Tranche A Loan occurring prior to the one-year anniversary of the date on which the Tranche D Approval Condition is satisfied, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the one-year anniversary of the date on which the Tranche D Approval Condition is satisfied on the amount of principal prepaid. For purposes of calculating the Tranche A Makewhole Amount: (a) the date of determination shall be such date of prepayment, using the interest rate as in effect on such date and (b) the Default Rate shall not apply to any interest that would have accrued and been payable from and after such date of determination.

"Tranche A Note" means a promissory note in substantially the form attached hereto as Exhibit B-1, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Tranche A Prepayment Premium" means, with respect to any prepayment of the Tranche A Loan by Borrower (x) pursuant to Section 2.2(c) or (y) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), an amount equal to the product of the amount of any principal so prepaid, multiplied by:

(a) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs prior to the 3rd-year anniversary of the Tranche A Closing Date, 0.03;

(b) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs on or after the 3rd-year anniversary of the Tranche A Closing Date but prior to the 4th-year anniversary of the Tranche A Closing Date, 0.02; and

(c) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs on or after the 4th-year anniversary of the Tranche A Closing Date but prior to the Term Loan Maturity Date, 0.01.

For the avoidance of doubt, no Tranche A Prepayment Premium shall be due and owing for any payment of principal of the Tranche A Loan made on the Term Loan Maturity Date.

"Tranche B Closing Date" means the date on which the Tranche B Loan is advanced by Lenders, which is December 16, 2022.

"Tranche B Commitment" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche B Loan on the Tranche B Closing Date in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto; provided, however, that the parties hereto agree that such commitment, and any obligations of such Lender hereunder with respect thereto, shall terminate automatically without any further action by any party hereto and be of no further force and effect if (x) any prepayment of principal amount of any Tranche A Loan is made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a) on or before the Tranche B Closing Date or (y) the Tranche B Closing Date does not occur on or before December 31, 2022 (in either of which case, for purposes of this Agreement, such Lender's Tranche B Commitment equals zero).

"Tranche B Loan" is defined in Section 2.2(a)(ii).

"Tranche B Loan Amount" means an original principal amount of Twenty-Five Million Dollars ($25,000,000.00); provided, that if either of the events described clauses (x) or (y) in the proviso to the definition of Tranche B Commitment occurs, the Tranche B Loan Amount, for purposes of this Agreement, equals zero.

"Tranche B Makewhole Amount" as of any date of prepayment of the Tranche B Loan occurring prior to the 2nd-year anniversary of the Tranche B Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 2nd-year anniversary of the Tranche B Closing Date on the amount of principal prepaid; provided, however, that if the Tranche D Approval Condition is satisfied prior to the 2nd-year anniversary of the Tranche B Closing Date, "Tranche B Makewhole Amount" means, as of any date of prepayment of the Tranche B Loan occurring prior to the 3rd-year anniversary of the Tranche B Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 3rd-year anniversary of the Tranche B Closing Date on the amount of principal prepaid; provided, further, that if the Tranche D Approval Condition is satisfied on or after the 2nd-year anniversary of the Tranche B Closing Date, "Tranche B Makewhole Amount" means, as of any date of prepayment of the Tranche B Loan occurring prior to the one-year anniversary of the date on which the Tranche D Approval Condition is satisfied, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the one-year anniversary of the date on which the Tranche D Approval Condition is satisfied on the amount of principal prepaid. For purposes of calculating the Tranche B Makewhole Amount: (a) the date of determination shall be such date of prepayment, using the interest rate as in effect on such date, and (b) the Default Rate shall not apply to any interest that would have accrued and been payable from and after such date of determination.

"Tranche B Note" means a promissory note in substantially the form attached hereto as Exhibit B-2, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Tranche B Prepayment Premium" means, with respect to any prepayment of the Tranche B Loan by Borrower (x) pursuant to Section 2.2(c) or (y) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), an amount equal to the product of the amount of any principal so prepaid, multiplied by:

(a) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs prior to the 3rd-year anniversary of the Tranche A Closing Date, 0.03;

(b) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs on or after the 3rd-year anniversary of the Tranche A Closing Date but prior to the 4th-year anniversary of the Tranche A Closing Date, 0.02; and

(c) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs on or after the 4th-year anniversary of the Tranche A Closing Date but prior to the Term Loan Maturity Date, 0.01.

For the avoidance of doubt, no Tranche B Prepayment Premium shall be due and owing for any payment of principal of the Tranche B Loan made on the Term Loan Maturity Date.

"Tranche C Additional Consideration" is defined in Section 2.7(b).

"Tranche C Closing Date" means the date on which the Tranche C Loan is advanced by Lenders, which, subject to the satisfaction of the conditions precedent to the Tranche C Loan set forth in Section 3.3, Section 3.5, Section 3.6 and Section 3.7, shall be thirty (30) days following the delivery by Borrower to the Collateral Agent of a completed Advance Request Form for the Tranche C Loan and in no event later than September 30, 2024.

"Tranche C Commitment" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche C Loan on the Tranche C Closing Date in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto; provided, however, that the parties hereto agree that such commitment, and any obligations of such Lender hereunder with respect thereto, shall terminate

automatically without any further action by any party hereto and be of no further force and effect if (x) any prepayment of principal amount of any Term Loan is made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a) on or before the Tranche C Closing Date or (y) the Tranche C Closing Date does not occur on or before September 30, 2024 (in either of which case, for purposes of this Agreement, such Lender's Tranche C Commitment equals zero).

"Tranche C Loan" is defined in Section 2.2(a)(iii).

"Tranche C Loan Amount" means an original principal amount equal to Twenty-Five Million Dollars ($25,000,000.00).

"Tranche C Makewhole Amount" means, (a) as of any date of prepayment of the Tranche C Loan occurring prior to the 2nd-year anniversary of the Tranche C Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 2nd-year anniversary of the Tranche C Closing Date; (b) without any duplication of the amounts in clause (a) above or clause (c) below, in the event the Tranche C Loan is not then-funded, as of any date of prepayment of the Term Loans occurring for any reason on or prior to September 30, 2024, an amount equal to the sum of all interest that would have accrued and been payable on the Tranche C Loan (as if it had it been funded in full) from such date of prepayment through the 2nd-year anniversary thereof; and (c) upon a prepayment pursuant Section 2.2(e)(iii)(C) following the occurrence of an Event of Default under Section 7.2(c) (including in the case where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero), an amount equal to the sum of all interest that would have accrued and been payable on the Tranche C Loan (as if it had it been funded in full) from September 30, 2024 through September 30, 2026. For purposes of calculating the Tranche C Makewhole Amount: (x) the date of determination shall be such date of prepayment, using the interest rate as in effect on such date, and (b) the Default Rate shall not apply to any interest that would have accrued and been payable from and after such date of determination.

"Tranche C Note" means a promissory note in substantially the form attached hereto as Exhibit B-3, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Tranche C Prepayment Premium" means, (x) with respect to any prepayment of the Tranche C Loan by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), an amount equal to the product of the amount of any principal so prepaid, (y) without any duplication with sub-clause (z) below, in the event the Tranche C Loan is not then-funded, with respect to any prepayment of the Term Loans by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in either case on or prior to September 30, 2024, an amount equal to the product of the Tranche C Loan Amount (as if the Tranche C Loan had been funded in full, including in the case where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero) and (z) upon the occurrence of an Event of Default under Section 7.2(c) (including in the case where the Tranche C Closing Date does not timely occur and the Tranche C Commitments are reduced to zero), an amount equal to the product of the Tranche C Loan Amount (as if the Tranche C Loan had been funded in full), in each case of sub-clause (x), (y) and (z) above, multiplied by:

(a) if such prepayment or acceleration (in the case of clause (x) or clause (y) above) or Event of Default (in the case of clause (z) above) occurs prior to the 2nd-year anniversary of the Effective Date, 0.03;

(b) if such prepayment or acceleration (in the case of clause (x) above) occurs on or after the 2nd-year anniversary of the Effective Date but prior to 3rd-year anniversary of the Effective Date, 0.02; and

(c) if such prepayment or acceleration (in the case of clause (x) above) occurs on or after the 3rd-year anniversary of the Effective Date but prior to the Term Loan Maturity Date, 0.01.

For the avoidance of doubt, no Tranche C Prepayment Premium shall be due and owing for any payment of principal of the Tranche C Loan made on the Term Loan Maturity Date.

"Tranche D Additional Consideration" is defined in Section 2.7(c).

"Tranche D Approval Condition" means FDA approval of an NDA for UGN-102 (mitomycin) shall have been obtained, by or on behalf of Parent, for the introduction or delivery for introduction into interstate commerce of UGN-102 (mitomycin) in the United States on or before June 30, 2025.

"Tranche D Closing Date" means the date on which the Tranche D Loan is advanced by Lenders, which, subject to the satisfaction of the conditions precedent to the Tranche D Loan set forth in Section 3.4, Section 3.5, Section 3.6 and Section 3.7, shall be sixty (60) days following the delivery by Borrower to the Collateral Agent of a completed Advance Request Form for the Tranche D Loan and, in no event, later than August 29, 2025.

"Tranche D Commitment" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche D Loan on the Tranche D Closing Date in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto; provided, however, that the parties hereto agree that such commitment, and any obligations of such Lender hereunder with respect thereto, shall terminate automatically without any further action by any party hereto and be of no further force and effect if (x) the Tranche C Loan is not advanced by Lenders for any reason, (y) any prepayment of principal amount of any Term Loan is made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a) on or before the Tranche D Closing Date or (z) the Tranche D Closing Date does not occur on or before August 29, 2025 (in each of which case, for purposes of this Agreement (other than the proviso in Section 2.7(c)), such Lender's Tranche D Commitment equals zero).

"Tranche D Loan" is defined in Section 2.2(a)(iv).

"Tranche D Loan Amount" means an original principal amount equal to Seventy-Five Million Dollars ($75,000,000.00).

"Tranche D Makewhole Amount" means, as of any date of prepayment of the Tranche D Loan occurring prior to the 2nd-year anniversary of the Tranche D Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 2nd-year anniversary of the Tranche D Closing Date on the amount of principal prepaid. For purposes of calculating the Tranche D Makewhole Amount: (x) the date of determination shall be such date of prepayment, using the interest rate as in effect on such date, and (y) the Default Rate shall not apply to any interest that would have accrued and been payable from and after such date of determination.

"Tranche D Note" means a promissory note in substantially the form attached hereto as Exhibit B-4, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Tranche D Prepayment Premium" means, with respect to any prepayment of the Tranche D Loan by Borrower (x) pursuant to Section 2.2(c) or (y) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), an amount equal to the product of the amount of any principal so prepaid, multiplied by:

(a) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs prior to the 2nd-year anniversary of the Effective Date, 0.03;

(b) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs on or after the 2nd-year anniversary of the Effective Date but prior to 3rd-year anniversary of the Effective Date, 0.02; and

(c) if such prepayment (in the case of clause (x) above) or acceleration (in the case of clause (y) above) occurs on or after the 3rd-year anniversary of the Effective Date but prior to the Term Loan Maturity Date, 0.01.

For the avoidance of doubt, no Tranche D Prepayment Premium shall be due and owing for any payment of principal of the Tranche D Loan made on the Term Loan Maturity Date.

"Transfer" is defined in Section 6.1.

"Treasury Regulations" mean those regulations promulgated pursuant to the IRC.

"TRICARE" means, collectively, a program of medical benefits covering former and active members of the uniformed services and certain of their dependents, financed and administered by the United States Departments of Defense, Health and Human Services and Transportation, and all laws applicable to such programs.

"UKBA" is defined in Section 4.18(a).

"Unadjusted Benchmark Replacement" means the applicable Benchmark Replacement excluding the related Benchmark Replacement Adjustment.

"United States" or "**U.S.**" means the United States of America, its fifty (50) states, the District of Columbia, Puerto Rico and any other jurisdiction within the United States of America.

"U.S. Government Securities Business Day" means any day except for (a) a Saturday, (b) a Sunday or (c) a day on which the Securities Industry and Financial Markets Association recommends that the fixed income departments of its members be closed for the entire day for purposes of trading in United States government securities.

"Wholly-Owned Subsidiary" means, with respect to any Person, a Subsidiary of such Person, all of the Equity Interests of which (other than directors' qualifying shares or nominee or other similar shares required pursuant to Requirements of Law) are owned by such Person or another Wholly-Owned Subsidiary of such Person. Unless the context otherwise requires, each reference to a Wholly-Owned Subsidiary herein shall be a reference to a Wholly-Owned Subsidiary of a Credit Party.

"Withdrawal Liability" means liability to a Multiemployer Plan as a result of a complete or partial withdrawal from such Multiemployer Plan, as such terms are defined in Part I of Subtitle E of Title IV of ERISA.

"Withholding Agent" is defined in Section 2.6(b).

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

UROGEN PHARMA, INC.,
as Borrower and a Credit Party

By_____

Name:_____

Title:_____

UROGEN PHARMA LTD.,
as Parent and a Credit Party

By_____

Name:_____

Title:_____

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BPCR LIMITED PARTNERSHIP,
as a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP,
as Lender

By: BioPharma Credit Investments V GP LLC,
its General Partner

By: Pharmakon Advisors, LP,
its Investment Manager

By_____
Name: Pedro Gonzalez de Cosio
Title: CEO and Managing Member

EXHIBIT A – LOAN ADVANCE REQUEST FORM

Reference is made to that certain Amended and Restated Loan Agreement, dated as of March 13, 2024, by and among UROGEN PHARMA, INC., a Delaware corporation ("**Borrower**"), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "**Parent**" and a Credit Party), the other Guarantors signatory thereto or otherwise party thereto from time to time, as additional Credit Parties, BIOPHARMA CREDIT PLC (in its capacity as "**Collateral Agent**"), BPCR LIMITED PARTNERSHIP (a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP (a "**Lender**"), acting by its general partner, BioPharma Credit Investments V GP LLC (the "**Loan Agreement**"); with any capitalized term not otherwise defined herein having the meaning ascribed to such term in the Loan Agreement. This Loan Advance Request is being delivered pursuant to Section 3.5 of the Loan Agreement.

The undersigned, being the duly elected and acting _____ of Borrower does hereby certify to each Lender and the Collateral Agent, solely in his/her capacity as an authorized officer of Borrower and not in his/her personal capacity, that, on [the Tranche A Closing Date] [[_____, 20__] (the "**Tranche B Closing Date**")] [[_____, 20__] (the "**Tranche C Closing Date**")] [[_____, 20__] (the "**Tranche D Closing Date**")]:

1. Borrower hereby requests a borrowing of [the Tranche A Loan] [the Tranche B Loan] [the Tranche C Loan] [the Tranche D Loan];

2. the representations and warranties made by the Credit Parties in Section 4 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects, unless any such representation or warranty is stated to relate to a specific earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (it being understood that any representation or warranty that is qualified as to "materiality," "Material Adverse Change," or similar language shall be true and correct in all respects on the Tranche [A][B][C][D] Closing Date or as of such earlier date, as applicable);

3. no Default or Event of Default has occurred since the [Effective Date] [Tranche A Closing Date] [Tranche B Closing Date] or [Tranche C Closing Date] or is occurring as of the date hereof;

4. each of the Credit Parties is in compliance with the covenants and requirements contained in Sections 5 and 6 of the Loan Agreement;

4. all conditions referred to in Section 3 of the Loan Agreement to the making of the Tranche [A][B][C][D] Loan to be made on the Tranche [A][B][C][D] Closing Date have been satisfied (or waived in writing by the Required Lenders);

5. no Material Adverse Change has occurred since the [Effective Date] [Tranche A Closing Date] [Tranche B Closing Date] [Tranche C Closing Date];

6. the undersigned is a Responsible Officer of Borrower; and

7. the proceeds of the [Tranche A Loan] [Tranche B Loan] [Tranche C Loan] [Tranche D Loan] shall be disbursed as set forth on Attachment A hereto.

Dated: _____, 202_

[Signature page follows]

UROGEN PHARMA, INC.,
as Borrower

By_____

Name:_____

Title:_____

EXHIBIT B-1

THIS TRANCHE A NOTE HAS BEEN ISSUED WITH "ORIGINAL ISSUE DISCOUNT" (WITHIN THE MEANING OF SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED). HOLDERS OF THIS TRANCHE A NOTE SHOULD CONTACT DON KIM, CHIEF FINANCIAL OFFICER, UROGEN PHARMA, 400 ALEXANDER PARK DRIVE, PRINCETON, NEW JERSEY 08540 IN WRITING TO OBTAIN (1) THE ISSUE PRICE AND ISSUE DATE OF THIS TRANCHE A NOTE, (2) THE AMOUNT OF ORIGINAL ISSUE DISCOUNT ON THIS TRANCHE A NOTE AND (3) THE YIELD TO MATURITY OF THIS TRANCHE A NOTE.

SECOND AMENDED AND RESTATED SECURED TRANCHE A LOAN PROMISSORY NOTE

$37,500,000.00 Dated: March 13, 2024

FOR VALUE RECEIVED, the undersigned, UROGEN PHARMA, INC., a private limited company incorporated under the laws of England and Wales and limited by shares ("**Borrower**"), HEREBY PROMISES TO PAY to [BPCR LIMITED PARTNERSHIP] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of THIRTY-SEVEN MILLION FIVE HUNDRED THOUSAND DOLLARS AND NO CENTS ($37,500,000.00), plus interest on the aggregate unpaid principal amount of this Second Amended and Restated Secured Tranche A Loan Promissory Note (this "**Tranche A Note**") at a *per annum* rate equal to Adjusted Term SOFR *plus* the Applicable Margin, and in accordance with the terms of the Amended and Restated Loan Agreement dated as of March 13, 2024 by and among Borrower, Lender, BioPharma Credit PLC, as Collateral Agent, the other Lenders from time to time party thereto and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date. This Second Amended and Restated Secured Tranche A Loan Promissory Note amends and restates in its entirety that certain Amended and Restated Secured Tranche A Loan Promissory Note, dated June 29, 2023, in the aggregate principal amount of Thirty-Seven Million and Five Hundred Thousand Dollars and Zero Cents ($37,500,000.00). Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Borrower shall make four (4) equal quarterly payments of principal of each Term Loan commencing on the Payment Date occurring in the second calendar quarter of 2026 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, however, that upon the satisfaction of the Tranche D Approval Condition, the quarterly payments of principal payable pursuant to this Section 2.2(b)(i) will instead commence on the Payment Date occurring in the second calendar quarter of 2027 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, further, that if any such date is not a Business Day, the applicable principal shall be due and payable on the first Business Day immediately following such date. All unpaid principal with respect to the Tranche A Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date. Interest shall accrue on this Tranche A Note commencing on, and including, the date of this Tranche A Note, and shall accrue on this Tranche A Note, or any portion thereof, for the day on which this Tranche A Note or such portion is paid. Interest on this Tranche A Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche A Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche A Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche A Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche A Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche A Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche A Note are hereby waived.

THIS TRANCHE A NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche A Note shall be registered on a record of ownership maintained by Borrower pursuant to Section 2.8(a) of the Loan Agreement. Notwithstanding anything else in this Tranche A Note to the contrary, the right to the principal of, and stated interest on, this Tranche A Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche A Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche A Note on the part of any other Person.

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IN WITNESS WHEREOF, Borrower has caused this Second Amended and Restated Tranche A Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

UROGEN PHARMA, INC.,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT B-2

SECOND AMENDED AND RESTATED SECURED TRANCHE B LOAN PROMISSORY NOTE

$12,500,000.00 Dated: March 13, 2024

FOR VALUE RECEIVED, the undersigned, UROGEN PHARMA, INC., a private limited company incorporated under the laws of England and Wales and limited by shares ("**Borrower**"), HEREBY PROMISES TO PAY to [BPCR LIMITED PARTNERSHIP] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of TWELVE MILLION FIVE HUNDRED THOUSAND DOLLARS AND NO CENTS ($12,500,000.00), plus interest on the aggregate unpaid principal amount of this Second Amended and Restated Secured Tranche B Loan Promissory Note (this "**Tranche B Note**") at a *per annum* rate equal to Adjusted Term SOFR *plus* the Applicable Margin, and in accordance with the terms of the Amended and Restated Loan Agreement dated as of March 13, 2024 by and among Borrower, Lender, BioPharma Credit PLC, as Collateral Agent, the other Lenders from time to time party thereto and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date. This Second Amended and Restated Secured Tranche B Loan Promissory Note amends and restates in its entirety that certain Amended and Restated Secured Tranche B Loan Promissory Note, dated June 29, 2023, in the aggregate principal amount of twelve million five hundred thousand dollars and zero cents ($12,500,000.00). Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Borrower shall make four (4) equal quarterly payments of principal of each Term Loan commencing on the Payment Date occurring in the second calendar quarter of 2026 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, however, that upon the satisfaction of the Tranche D Approval Condition, the quarterly payments of principal payable pursuant to this Section 2.2(b)(i) will instead commence on the Payment Date occurring in the second calendar quarter of 2027 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, further, that if any such date is not a Business Day, the applicable principal shall be due and payable on the first Business Day immediately following such date. All unpaid principal with respect to the Tranche B Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date.. Interest shall accrue on this Tranche B Note commencing on, and including, the date of this Tranche B Note, and shall accrue on this Tranche B Note, or any portion thereof, for the day on which this Tranche B Note or such portion is paid. Interest on this Tranche B Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche B Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche B Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche B Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche B Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche B Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche B Note are hereby waived.

THIS TRANCHE B NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche B Note shall be registered on a record of ownership maintained by Borrower pursuant to Section 2.8(a) of the Loan Agreement. Notwithstanding anything else in this Tranche B Note to the contrary, the right to the principal of, and stated interest on, this Tranche B Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche B Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche B Note on the part of any other Person.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Second Amended and Restated Tranche B Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

UROGEN PHARMA, INC.,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT B-3

THIS TRANCHE C NOTE HAS BEEN ISSUED WITH "ORIGINAL ISSUE DISCOUNT" (WITHIN THE MEANING OF SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED). HOLDERS OF THIS TRANCHE C NOTE SHOULD CONTACT DON KIM, CHIEF FINANCIAL OFFICER, UROGEN PHARMA, 400 ALEXANDER PARK DRIVE, PRINCETON, NEW JERSEY 08540 IN WRITING TO OBTAIN (1) THE ISSUE PRICE AND ISSUE DATE OF THIS TRANCHE C NOTE, (2) THE AMOUNT OF ORIGINAL ISSUE DISCOUNT ON THIS TRANCHE C NOTE AND (3) THE YIELD TO MATURITY OF THIS TRANCHE C NOTE.

SECURED TRANCHE C LOAN PROMISSORY NOTE

$25,000,000.00 Dated: _____, 202_

FOR VALUE RECEIVED, the undersigned, UROGEN PHARMA, INC., a private limited company incorporated under the laws of England and Wales and limited by shares ("**Borrower**"), HEREBY PROMISES TO PAY to BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP ("**Lender**"), or its registered assignees, the principal amount of TWENTY-FIVE MILLION DOLLARS AND NO CENTS ($25,000,000.00), plus interest on the aggregate unpaid principal amount of this Secured Tranche C Loan Promissory Note (this "**Tranche C Note**") at a *per annum* rate equal to Adjusted Term SOFR *plus* the Applicable Margin, and in accordance with the terms of the Amended and Restated Loan Agreement dated as of March 13, 2024 by and among Borrower, Lender, BioPharma Credit PLC, as Collateral Agent, the other Lenders from time to time party thereto and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Borrower shall make four (4) equal quarterly payments of principal of each Term Loan commencing on the Payment Date occurring in the second calendar quarter of 2026 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, however, that upon the satisfaction of the Tranche D Approval Condition, the quarterly payments of principal payable pursuant to this Section 2.2(b)(i) will instead commence on the Payment Date occurring in the second calendar quarter of 2027 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, further, that if any such date is not a Business Day, the applicable principal shall be due and payable on the first Business Day immediately following such date. All unpaid principal with respect to the Tranche C Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date.. Interest shall accrue on this Tranche C Note commencing on, and including, the date of this Tranche C Note, and shall accrue on this Tranche C Note, or any portion thereof, for the day on which this Tranche C Note or such portion is paid. Interest on this Tranche C Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche C Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche C Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche C Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche C Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche C Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche C Note are hereby waived.

THIS TRANCHE C NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche C Note shall be registered on a record of ownership maintained by Borrower pursuant to Section 2.8(a) of the Loan Agreement. Notwithstanding anything else in this Tranche C Note to the contrary, the right to the principal of, and stated interest on, this Tranche C Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche C Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche C Note on the part of any other Person.

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IN WITNESS WHEREOF, Borrower has caused this Tranche C Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

UROGEN PHARMA, INC.,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT B-4

THIS TRANCHE D NOTE HAS BEEN ISSUED WITH "ORIGINAL ISSUE DISCOUNT" (WITHIN THE MEANING OF SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED). HOLDERS OF THIS TRANCHE D NOTE SHOULD CONTACT DON KIM, CHIEF FINANCIAL OFFICER, UROGEN PHARMA, 400 ALEXANDER PARK DRIVE, PRINCETON, NEW JERSEY 08540 IN WRITING TO OBTAIN (1) THE ISSUE PRICE AND ISSUE DATE OF THIS TRANCHE D NOTE, (2) THE AMOUNT OF ORIGINAL ISSUE DISCOUNT ON THIS TRANCHE D NOTE AND (3) THE YIELD TO MATURITY OF THIS TRANCHE D NOTE.

SECURED TRANCHE D LOAN PROMISSORY NOTE

$75,000,000.00 Dated: _____, 202_

FOR VALUE RECEIVED, the undersigned, UROGEN PHARMA, INC., a private limited company incorporated under the laws of England and Wales and limited by shares ("**Borrower**"), HEREBY PROMISES TO PAY to BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP ("**Lender**"), or its registered assignees, the principal amount of SEVENTY-FIVE MILLION DOLLARS AND NO CENTS ($75,000,000.00), plus interest on the aggregate unpaid principal amount of this Secured Tranche D Loan Promissory Note (this "**Tranche D Note**") at a *per annum* rate equal to Adjusted Term SOFR *plus* the Applicable Margin, and in accordance with the terms of the Amended and Restated Loan Agreement dated as of March 13, 2024 by and among Borrower, Lender, BioPharma Credit PLC, as Collateral Agent, the other Lenders from time to time party thereto and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Borrower shall make four (4) equal quarterly payments of principal of each Term Loan commencing on the Payment Date occurring in the second calendar quarter of 2026 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, however, that upon the satisfaction of the Tranche D Approval Condition, the quarterly payments of principal payable pursuant to this Section 2.2(b)(i) will instead commence on the Payment Date occurring in the second calendar quarter of 2027 and continuing quarterly thereafter through the Term Loan Maturity Date; provided, further, that if any such date is not a Business Day, the applicable principal shall be due and payable on the first Business Day immediately following such date. All unpaid principal with respect to the Tranche D Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date.. Interest shall accrue on this Tranche D Note commencing on, and including, the date of this Tranche D Note, and shall accrue on this Tranche D Note, or any portion thereof, for the day on which this Tranche D Note or such portion is paid. Interest on this Tranche D Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche D Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche D Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche D Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche D Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche D Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche D Note are hereby waived.

THIS TRANCHE D NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche D Note shall be registered on a record of ownership maintained by Borrower pursuant to Section 2.8(a) of the Loan Agreement. Notwithstanding anything else in this Tranche D Note to the contrary, the right to the principal of, and stated interest on, this Tranche D Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche D Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche D Note on the part of any other Person.

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IN WITNESS WHEREOF, Borrower has caused this Tranche D Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

UROGEN PHARMA, INC.,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT C

FORM OF SECURITY AGREEMENT

GUARANTY AND SECURITY AGREEMENT

Dated as of March , 2022

by

UROGEN PHARMA, INC.

(as *Borrower* and a *Grantor*),

UROGEN PHARMA LTD.

(as *Parent* and a *Grantor*),

and

EACH OTHER GRANTOR FROM TIME TO TIME PARTY HERETO

in favor of

BIOPHARMA CREDIT PLC

(as *Collateral Agent* on behalf of Lenders and the other Secured Parties)

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GUARANTY AND SECURITY AGREEMENT, dated as of March , 2022, by UROGEN PHARMA, INC., a Delaware corporation ("Borrower" and a Grantor), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "Parent" and a Grantor) and each other Person that becomes a party hereto in the capacity of a Grantor hereunder pursuant to Section 8.6, in favor of BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales (as the "Collateral Agent") on behalf of Lenders and each other Secured Party.

W I T N E S S E T H:

WHEREAS, pursuant to the Loan Agreement dated as of March 7, 2022 (as the same may be amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement") by and among Borrower, the Collateral Agent and the other parties thereto, Lenders have agreed to make extensions of credit to Borrower upon the terms and subject to the conditions set forth therein;

WHEREAS, each Grantor other than Borrower agrees to guaranty, jointly and severally, the Obligations (as defined in the Loan Agreement) of Borrower;

WHEREAS, each Grantor will derive substantial direct and indirect benefits from the making of the extensions of credit under the Loan Agreement; and

WHEREAS, it is a condition precedent to the obligation of Lenders to make Term Loans to Borrower under the Loan Agreement that the Grantors shall have executed and delivered this Agreement to the Collateral Agent and each Lender for the benefit of Lenders and the other Secured Parties.

NOW, THEREFORE, in consideration of the mutual promises herein contained and for valuable consideration the receipt and sufficiency of which is hereby acknowledged and to induce each of the Collateral Agent, Lenders and the Credit Parties to enter into the Loan Agreement and to induce each Lender to make extensions of credit to Borrower thereunder, each Grantor hereunder hereby agrees with the Collateral Agent, each intending to be legally bound, as follows:

ARTICLE 1

DEFINED TERMS

Section 1.1 **Definitions**

. Capitalized terms used herein without definition are used as defined in the Loan Agreement.

(a) The following terms have the meanings given to them in the Code and terms used herein without definition that are defined in the Code have the meanings given to them in the Code (such meanings to be equally applicable to both the singular and plural forms of the terms defined): "account", "account debtor", "as-extracted collateral", "certificated security", "chattel paper", "check", "commercial tort claim", "commodity account", "commodity contract", "documents", "deposit account", "electronic chattel paper", "encumbrance", "entitlement holder", "equipment", "farm products", "financial asset", "fixture", "general intangible", "goods", "health-care-insurance receivable", "instruments", "inventory", "investment property", "letter of credit", "letter-of-credit right", "money", "proceeds", "promissory note", "record", "securities account", "security", "security entitlement", "supporting obligation", "tangible chattel paper" and "uncertificated security".

(b) The following terms shall have the following meanings:

"Agreement" means this Guaranty and Security Agreement, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Applicable IP Office" means, as applicable, the United States Patent and Trademark Office or the United States Copyright Office or any similar offices or agencies in such other jurisdictions as required by and pursuant to Section 5.12(e) of the Loan Agreement.

"Collateral" has the meaning specified in Section 3.1.

"Collateral Agent" means BioPharma Credit PLC, together with its successors and permitted assigns.

"Excluded Property" means, collectively:

(i) any "intent-to-use" application for registration of a United States Trademark for which a "Statement of Use" pursuant to Section 1(d) of the Lanham Act, 15 U.S.C. § 1051 (or any successor provision) or an "Amendment to Allege Use" pursuant to Section 1(c) of the Lanham Act, 15 U.S.C. § 1051 (or any successor provision) has not been filed with and accepted by the Applicable IP Office, solely to the extent, if any, that, and only during the period, if any, in which, the grant of a security interest therein would impair the validity or enforceability of any registration that issues from such intent-to-use United States Trademark application under Requirements of Law; provided, however, that upon filing and acceptance by the Applicable IP Office of such statement of use or amendment to allege use (as applicable), such intent-to-use application shall be considered Collateral for all purposes under the Loan Documents;

(ii) any rights or interests in any permit, lease, license, contract, instrument or other agreement held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure

the Obligations (and any guaranty thereof) are prohibited by the terms thereof, but only, in each case, to the extent, and for so long as, such prohibition is not terminated or rendered unenforceable or otherwise deemed ineffective by the Code (including Sections 9-406(d), 9-407(a), 9-408(a) and 9-409 of the Code) or by any applicable Requirements of Law;

(iii) any rights or interests in any permit, lease, license, contract, instrument or other agreement held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien thereupon, and the pledge to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) require the consent, authorization, approval or waiver of any Governmental Authority or other third party (other than Borrower or an Affiliate of Borrower) and such consent, authorization, approval or waiver has not been obtained by such Grantor or Parent following their respective commercially reasonable efforts to obtain the same;

(iv) any other asset or property subject or purported to be subject to a Lien under any Collateral Document held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien thereupon, and the pledge to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) require the consent, authorization, approval or waiver of any Governmental Authority or other third party (other than Borrower or an Affiliate of Borrower) and such consent, authorization, approval or waiver has not been obtained by such Grantor or Parent following their respective commercially reasonable efforts to obtain the same;

(v) any property or asset subject or purported to be subject to a Lien under any Collateral Document held by any Grantor that is a non-Wholly-Owned Subsidiary with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, the Operating Documents of, the joint venture agreement or shareholder agreement with respect to, or any other contract with such third party relating to such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Documents, joint venture agreement, shareholder agreement or other contract is in effect;

(vi) any asset or property subject or purported to be subject to a Lien under any Collateral Document held by any Grantor with respect to which, the cost, difficulty, burden or consequences (including adverse Tax consequences) of granting the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, a security interest therein and Lien thereupon, and pledging to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to Secured Parties thereby;

(vii) any rights under any Federal or state governmental license, permit, franchise or authorization to the extent that the granting of a security interest therein is specifically prohibited or restricted by any Requirements of Law;

(viii) any asset or property subject to a Permitted Lien to the extent the documents governing such Permitted Lien or the Permitted Indebtedness secured thereby validly prohibit other Liens on such assets or property, but only, in each case, to the extent, and for so long as, such prohibition is not terminated or rendered unenforceable or otherwise deemed ineffective by the Code (including Sections 9-406(d), 9-407(a), 9-408(a) and 9-409 of the Code) or by any applicable Requirements of Law;

(ix) leasehold interests in real property;

(x) fee interests in real property with a fair market value (reasonably determined in good faith by a Responsible Officer of Parent) less than $5,000,000;

(xi) Vehicles;

(xii) any letter of credit with an amount less than $500,000 and all letter-of-credit rights with respect thereto to the extent not perfected by the filing of a UCC-1 financing statement;

(xiii) commercial tort claims with a predicted value of less than $500,000 (as reasonably determined by a Responsible Officer of Parent in good faith and based upon reasonable assumptions)

(xiv) Excluded Equity Interests;

(xv) Excluded Accounts; and

(xvi) any other asset or property held by any Grantor (including any asset or property not located in the United States) with respect to which Borrower and Collateral Agent reasonably determine by mutual written agreement that the grant to Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) are specifically prohibited by Requirements of Law, but only, in each such case, to the extent, and for so long as, such prohibition is not rendered or deemed ineffective by the Code (or any other applicable Requirements of Law) notwithstanding such prohibition;

provided, however, that "Excluded Property" shall not include any proceeds, products, substitutions or replacements of Excluded Property unless such proceeds, products, substitutions or replacements would otherwise constitute Excluded Property.

"Fraudulent Transfer Laws" has the meaning set forth in Section 2.2.

"Grantor" means each of the Borrower and each other Person that becomes a party hereto in the capacity as a "Grantor" pursuant to Section 8.6, and "Grantors" means, collectively, Borrower and each other such Person.

"Guaranteed Obligations" has the meaning set forth in Section 2.1.

"Guarantor" means Parent and each other Grantor other than Borrower.

"Guaranty" means the guaranty of the Guaranteed Obligations made by Guarantors as set forth in this Agreement.

"IP License" means all express and implied grants or rights to make, have made, use, sell, reproduce, distribute, modify, or otherwise exploit any Intellectual Property in the U.S., as well as all covenants not to sue and co-existence agreements (and all related IP Ancillary Rights) relating to any Intellectual Property in the U.S.

"IP Security Agreement" means an intellectual property security agreement in the form attached hereto as Annex 3, and "IP Security Agreements" means, collectively, all such intellectual property security agreements.

"Maximum Guaranteed Amount" has the meaning set forth in Section 2.2.

"NDA" means a new drug application filed with the FDA pursuant to Section 505(b) of the U.S. Federal Food, Drug, and Cosmetic Act, along with all supplements and amendments thereto.

"Pledged Certificated Stock" means all of the Equity Interests (other than Excluded Equity Interests) in any Subsidiary evidenced by a certificate or instrument or other document of title (in each case, as defined in the Code), in each case owned by any Grantor, including a Grantor's right, title and interest resulting from its ownership of any such Equity Interests as a limited or general partner in any partnership that has issued Pledged Certificated Stock or as a member of any limited liability company that has issued Pledged Certificated Stock, and a Grantor's right, title and interest resulting from its ownership of any such Equity Interests in, to and under any Operating Document or shareholder agreement of any corporation, partnership or limited liability company to which it is a party, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including all certificated Equity Interests listed on Schedule 1 of the Security Disclosure Letter. "Pledged Certificated Stock" includes, for the avoidance of doubt, any Pledged Uncertificated Stock that subsequently becomes certificated.

"Pledged Collateral" means, collectively, the Pledged Stock and the Pledged Debt Instruments.

"Pledged Debt Instruments" means all right, title and interest of any Grantor in instruments evidencing any Indebtedness owed to such Grantor or other obligations owed to such Grantor, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including all Indebtedness described on Schedule 3 of the Security Disclosure Letter, issued by the obligors named therein. "Pledged Debt Instruments" excludes any Excluded Property.

"Pledged Investment Property" means any investment property of any Grantor, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, other than any Pledged Stock or Pledged Debt Instruments. "Pledged Investment Property" excludes any Excluded Property.

"Pledged Stock" means all Pledged Certificated Stock and all Pledged Uncertificated Stock.

"Pledged Uncertificated Stock" means all of the Equity Interests (other than Excluded Equity Interests) in any Subsidiary that is not Pledged Certificated Stock, in each case owned by any Grantor, including Grantor's right, title and interest resulting from its ownership of any such Equity Interests as a limited or general partner in any partnership not constituting Pledged Certificated Stock or as a member of any limited liability company not constituting Pledged Certificated Stock, a Grantor's right, title and interest resulting from its ownership of any such Equity Interests in, to and under any Operating Document or shareholder agreement of any partnership or limited liability company to which it is a party, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including in each case those interests set forth on Schedule 1 of the Security Disclosure Letter, to the extent such interests are not certificated.

"Secured Obligations" has the meaning set forth in Section 3.2.

"Security Disclosure Letter" means the security agreement disclosure letter, dated as of the date hereof, delivered by the Grantors to the Collateral Agent and each Lender.

"Vehicles" means rolling stock, motor vehicles, vessels, aircraft and other assets subject to certificates of title.

Section 1.2 **Certain Other Terms**

.

(a) For the purposes of and as used in this Agreement: (i) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (ii) each authorization herein shall be deemed irrevocable and coupled with an interest; and (iii) where the context requires, provisions relating to any Collateral when used in relation to a Grantor shall refer to such Grantor's Collateral or any relevant part thereof.

(b) Other Interpretive Provisions.

(i) Defined Terms. Unless otherwise specified herein or therein, all terms defined in this Agreement shall have the defined meanings when used in any certificate or other document made or delivered pursuant hereto.

(ii) This Agreement. The words "hereof", "herein", "hereunder" and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

(iii) Certain Common Terms. The words "include", "included" and "including" are not limiting and mean "including without limitation." The word "or" has the inclusive meaning represented by the phrase "and/or". The word "shall" is mandatory. The word "may" is permissive. The singular includes the plural and the plural includes the singular.

(iv) Performance; Time. Whenever any performance obligation hereunder (other than a payment obligation) shall be stated to be due or required to be satisfied on a day other than a Business Day, such performance shall be made or satisfied on the next succeeding Business Day. In the computation of periods of time from a specified date to a later specified date, the word "from" means "from and including"; the words "to" and "until" each mean "to but excluding", and the word "through" means "to and including." If any provision of this Agreement refers to any action taken or to be taken by any Person, or which such Person is prohibited from taking, such provision shall be interpreted to encompass any and all means, direct or indirect, of taking, or not taking, such action.

(v) Contracts. Except as the context otherwise requires (including to the extent otherwise expressly provided herein), references to any contract, agreement, instrument or other document, including this Agreement and the other Loan Documents, shall be deemed to include any and all amendments, supplements or modifications thereto or restatements or substitutions thereof, in each case which are in effect from time to time, but only to the extent such amendments, supplements, modifications, restatements or substitutions are not prohibited by the terms of any Loan Document.

(vi) Laws. Except as the context otherwise requires (including to the extent otherwise expressly provided herein), references to any law, statute, treaty, order, policy, rule or regulation include any amendments, supplements and successors thereto, and references to any law, statute, treaty, order, policy, rule or regulation are to be construed as including all statutory and regulatory provisions related thereto or consolidating, amending, replacing, supplementing or interpreting such law, statute, treaty, order, policy, rule or regulation.

(vii) Excluded Property. Notwithstanding anything to the contrary herein, the representations, warranties and covenants set forth herein in relation to the assets of the Grantors shall not apply to any Excluded Property.

ARTICLE 2

GUARANTY

Section 2.1 **Guaranty**

. To induce Lenders to make the Term Loans to Borrower in accordance with the terms and conditions of the Loan Agreement, each Guarantor, jointly and severally with each other Guarantor, absolutely, unconditionally and irrevocably guarantees, as primary obligor and not merely as surety, the full and punctual payment when due, whether at stated maturity or earlier, by reason of acceleration, mandatory prepayment or otherwise in accordance with any Loan Document, of all the Obligations of Borrower existing on the date hereof or hereinafter incurred or created (the "Guaranteed Obligations"). This Guaranty by each Guarantor hereunder constitutes a guaranty of payment and not of collection. Each Guarantor hereby acknowledges and agrees that the Guaranteed Obligations, at any time and from time to time, may exceed the Maximum Guaranteed Amount of such Guarantor and may exceed the aggregate of the Maximum Guaranteed Amounts of all Guarantors, in each case without discharging, limiting or otherwise affecting the obligations of any Guarantor hereunder or the rights, powers and remedies of any Secured Party hereunder or under any other Loan Document.

Section 2.2 **Limitation of Guaranty**

. Any term or provision of this Guaranty or any other Loan Document to the contrary notwithstanding, the maximum aggregate amount for which any Guarantor shall be liable hereunder (the "Maximum Guaranteed Amount") shall not exceed the maximum amount for which such Guarantor can be liable without rendering this Guaranty or any other Loan Document, as it relates to such Guarantor, subject to avoidance under (a) applicable Requirements of Law relating to fraudulent conveyance or fraudulent transfer (including the Uniform Fraudulent Conveyance Act, the Uniform Fraudulent Transfer Act and Section 548 of title 11 of the United States Code or any applicable provisions of comparable Requirements of Law) (collectively, "Fraudulent Transfer Laws") and (b) the Israeli Guarantee Law, 5727-1967. Any analysis of the provisions of this Guaranty for purposes of Fraudulent Transfer Laws shall take into account the right of contribution established in Section 2.7 below and, for purposes of such analysis, give effect to any discharge of intercompany debt as a result of any payment made under the Guaranty.

Section 2.3 **Authorization; Other Agreements**

. The Collateral Agent, on behalf of Lenders and the other Secured Parties, is hereby authorized, without notice to or demand upon any Guarantor and without discharging or otherwise affecting the obligations of any Guarantor hereunder and without incurring any liability hereunder, from time to time, to do each of the following but subject in all cases to the terms and conditions of the other Loan Documents:

(a) subject to compliance with Section 11.5 of the Loan Agreement and Section 8.5 hereof (as applicable), (i) modify, amend, supplement or otherwise change, (ii) accelerate or otherwise change the time of payment or (iii) waive or otherwise consent to noncompliance with, any Guaranteed Obligation or any Loan Document;

(b) apply to the Guaranteed Obligations any sums by whomever paid or however realized to any Guaranteed Obligation in such order as provided in the Loan Documents;

(c) refund at any time any payment received by any Secured Party in respect of any Guaranteed Obligation;

(d) in accordance with the terms of the Loan Documents: (i) sell, exchange, enforce, waive, substitute, liquidate, terminate, release, abandon, fail to perfect, subordinate, accept, substitute, surrender, exchange, affect, impair or otherwise alter or release any Collateral for any Guaranteed Obligation or any other guaranty therefor in any manner, (ii) receive, take and hold additional Collateral to secure any Guaranteed Obligation, (iii) add, release or substitute any one or more other Guarantors, makers or endorsers of any Guaranteed Obligation or any part thereof and (iv) otherwise deal in any manner with Borrower or any other Guarantor, maker or endorser of any Guaranteed Obligation or any part thereof; and

(e) subject to Section 11.1 of the Loan Agreement, settle, release, compromise, collect or otherwise liquidate the Guaranteed Obligations.

Section 2.4 **Guaranty Absolute and Unconditional**

. Each Guarantor hereby waives and agrees not to assert any defense (other than the absolute, unconditional and irrevocable payment in full of the Guaranteed Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), whether arising in connection with or in respect of any of the following clauses (a) through (f) or otherwise, and hereby agrees that its obligations under this Guaranty are irrevocable, absolute and unconditional and shall not be discharged as a result of or otherwise affected by any of the following clauses (a) through (f) (which may not be pleaded and evidence of which may not be introduced in any proceeding with respect to this Guaranty, in each case except as otherwise agreed in writing by the Collateral Agent):

(a) the invalidity or unenforceability of any obligation of Borrower or any other Guarantor under any Loan Document or any other agreement or instrument relating thereto (including any amendment, consent or waiver thereto), or any security for, or other guaranty of, any Guaranteed Obligation or any part thereof, or the lack of perfection or continuing perfection or failure of priority of any security for the Guaranteed Obligations or any part thereof;

(b) the absence of (i) any attempt to collect any Guaranteed Obligation or any part thereof from Borrower or any other Guarantor or other action to enforce the same or (ii) any action to enforce any Loan Document or any Lien thereunder;

(c) the failure by any Person to take any steps to perfect and maintain any Lien on, or to preserve any rights with respect to, any Collateral;

(d) any workout, insolvency, bankruptcy proceeding, reorganization, arrangement, liquidation or dissolution by or against Borrower, any other Guarantor or any of Borrower's other Subsidiaries or any procedure, agreement, order, stipulation, election, action or omission thereunder, including any discharge or disallowance of, or bar or stay against collecting, any Guaranteed Obligation (or any interest thereon) in or as a result of any such proceeding;

(e) any foreclosure, whether or not through judicial sale, and any other sale or other disposition of any Collateral or any election following the occurrence of an Event of Default and during the continuance thereof by the Collateral Agent, on behalf of Lenders and any other Secured Party, to proceed separately against any Collateral in accordance with the Collateral Agent's rights and the rights of any Lender or other Secured Party under any applicable Requirements of Law; or

(f) any other defense, setoff, counterclaim or any other circumstance that might otherwise constitute a legal or equitable discharge of Borrower, any other Guarantor or any other Subsidiary of Borrower, in each case other than the absolute, unconditional and irrevocable payment in full of the Guaranteed Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted).

Section 2.5 **Waivers**

. Except, in each case, as otherwise expressly required in any of the Loan Documents, to the fullest extent permitted by Requirements of Law, each Guarantor hereby unconditionally and irrevocably waives and agrees not to assert any claim, defense, setoff or counterclaim based on diligence, promptness, presentment, requirements for any demand or notice hereunder, including any of the following: (a) any demand for payment or performance and protest and notice of protest; (b) any notice of acceptance; (c) any presentment, demand, protest or further notice or other requirements of any kind with respect to any Guaranteed Obligation (including any accrued but unpaid interest thereon) becoming immediately due and payable; and (d) any other notice in respect of any Guaranteed Obligation or any part thereof, and any defense arising by reason of any disability or other defense of Borrower or any other Guarantor. Until the absolute, unconditional and irrevocable payment in full of the Guaranteed Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), each Guarantor further unconditionally and irrevocably agrees not to (x) enforce or otherwise exercise any right of subrogation or any right of reimbursement or contribution or similar right against Borrower or any other Guarantor by reason of any Loan Document or any payment made thereunder or (y) assert any claim, defense, setoff or counterclaim it may have against any other Credit Party or set off any of its obligations to such other Credit Party against obligations of such Credit Party to such Guarantor. No obligation of any Guarantor hereunder shall be discharged other than by complete performance.

Section 2.6 **Reliance**

. Each Guarantor hereby assumes responsibility for keeping itself informed of the financial condition of Borrower, each other Guarantor and any other guarantor, maker or endorser of any Guaranteed Obligation or any part thereof, and of all other circumstances bearing upon the risk of nonpayment of any Guaranteed Obligation or any part thereof that reasonable and diligent inquiry would reveal, and each Guarantor hereby agrees that neither the Collateral Agent nor any Lender or other Secured Party shall have any duty to advise any Guarantor of information known to it regarding such condition or any such circumstances. In the event the Collateral Agent, in its sole discretion, undertakes at any time or from time to time to provide any such information to any Guarantor, such Person shall be under no obligation to (a) undertake any investigation not a part of its regular business routine, (b) disclose any information that any Lender or other Secured Party, pursuant to accepted or reasonable commercial finance or banking practices, wishes to maintain confidential or (c) make any future disclosures of such information or any other information to any Guarantor.

Section 2.7 **Contribution**

. To the extent that any Guarantor shall be required hereunder to pay any portion of any Guaranteed Obligation exceeding the greater of (a) the amount of the value actually received by such Guarantor and its Subsidiaries from the Term Loans and other Obligations and (b) the amount such Guarantor would otherwise have paid if such Guarantor had paid the aggregate amount of the Guaranteed Obligations (excluding the amount thereof repaid by Borrower) in the same proportion as such Guarantor's net worth on the date enforcement is sought hereunder bears to the aggregate net worth of all Guarantors on such date, then such Guarantor shall be reimbursed by such other Guarantors for the amount of such excess, *pro rata*, based on the respective net worth of such other Guarantors on such date.

ARTICLE 3

GRANT OF SECURITY INTEREST

Section 3.1 **Collateral**

. For the purposes of this Agreement, the following tangible and intangible assets and property now owned or at any time hereafter acquired, developed or created by a Grantor or in which a Grantor now has or at any time in the future may acquire any right, title or interest, in each case, wherever located, is collectively referred to as the "Collateral":

(a) all accounts;

(b) all as-extracted collateral;

(c) all chattel paper, including electronic chattel paper or tangible chattel paper;

(d) all checks;

(e) all deposit accounts;

(f) all documents;

(g) all encumbrances;

(h) all equipment;

(i) all fixtures;

(j) all general intangibles (including all Current Company IP Agreements, Manufacturing Agreements and any other agreements or contracts of any kind);

(k) all goods;

(l) all Intellectual Property and IP Licenses (including any IP Licenses under the Current Company IP Agreements to which a Grantor is a party and the rights of such Grantor thereunder, and all of a Grantor's right, title and interest in, to and under any Internet Domain Names and Software), including any similar or equivalent rights to those set forth in any of clauses (a) through (g) of the definition of "Intellectual Property");

(m) all instruments (including all promissory notes and similar instruments);

(n) all right, title and interest in, to and under any NDA relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution, sale or lease of Product in the Territory;

(o) all inventory;

(p) all investment property (including Pledged Collateral, Pledged Investment Property, Equity Interests, securities, securities accounts and security entitlements with respect thereto and financial assets carried therein, and all commodity accounts and commodity contracts);

(q) all money (including cash and cash equivalents);

(r) all letters of credit, letter-of-credit rights and supporting obligations;

(s) all commercial tort claims with a predicted value of $500,000 or more (as reasonably determined by a Responsible Officer of Parent in good faith and based upon reasonable assumptions described on Schedule 4 of the Security Disclosure Letter);

(t) all books, records, ledger cards, files, correspondence, customer lists, blueprints, technical specifications, manuals, computer software, computer printouts, tapes, disks and other electronic storage media and related data processing software and similar items that at any time pertain to or evidence or contain information relating to any of the other property described in this Section 3.1;

(u) all property of such Grantor held by the Collateral Agent for the benefit of Lenders and any other Secured Party, including all property of every description, in the custody of or in transit to the Collateral Agent for the benefit of Lenders and any other Secured Party for any purpose, including safekeeping, collection or pledge, for the account of such Grantor or as to which such Grantor may have any right or power, including cash;

(v) all proceeds, products, accessions, rents and profits of or in respect of any of the foregoing;

(w) to the extent not otherwise included, all personal property of such Grantor, whether tangible or intangible and wherever located, and all proceeds, products, accessions, rents, issues and profits of any and all of the foregoing and all collateral security, supporting obligations and guarantees given by any Person with respect to any of the foregoing; and

(x) to the extent not otherwise included, all other properties or assets of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Collateral Document;

excluding, however, in all cases, all Excluded Property.

Section 3.2 **Grant of Security Interest in Collateral**

. Without limiting any other security interest granted to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, each Grantor, as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Obligations of such Grantor (the "Secured Obligations"), hereby pledges, hypothecates and grants to the Collateral Agent, in favor and for the benefit of Lenders and the other Secured Parties, to secure the payment and performance in full of all of the Obligations for the benefit of Lenders and the other Secured Parties, a first priority Lien (subject only to Permitted Liens) on and continuing security interest in, all of its right, title and interest in, to and under the Collateral of such Grantor, wherever located, whether now owned or hereafter acquired or arising; provided, however, notwithstanding the foregoing, no Lien or security interest is hereby granted on, and "Collateral" shall not include, any Excluded Property; provided, further, that if and when any property or asset shall cease to be Excluded Property, a first priority Lien (subject only to Permitted Liens) on and security interest in such property or asset shall be deemed granted therein and, therefore, "Collateral" shall then include any such property or asset.

ARTICLE 4

REPRESENTATIONS AND WARRANTIES

To induce each of the Collateral Agent and Lenders to enter into the Loan Documents, each Grantor, jointly and severally with each other Grantor, represents and warrants each of the following to the Collateral Agent, each Lender and the other Secured Parties:

Section 4.1 **Title; No Other Liens**

. Except for the Lien granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties pursuant to this Agreement and any other Permitted Liens under any Loan Document (including Section 4.2 hereof), such Grantor owns or otherwise has the rights it purports to have in each item of the Collateral, free and clear of any and all Liens or claims of others. Such Grantor (a) is the record and beneficial owner of the Collateral pledged by it hereunder constituting instruments or certificates and (b) except for Permitted Subsidiary Distribution Restrictions, has rights in or the power to transfer each other item of Collateral in which a Lien is granted by it hereunder, free and clear of any other Lien other than any Permitted Liens.

Section 4.2 **Perfection and Priority**

. Other than in respect of money and other Collateral subject to Section 9-311(a)(1) of the Code, the security interest granted to the Collateral Agent pursuant to this Agreement constitutes a valid and continuing first priority perfected security interest (subject, in the case of priority only, to Permitted Liens that are expressly permitted (if at all) by the terms of the Loan Agreement or this Agreement to, or that by operation of law, have superior priority to the Lien and security interest granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties) in favor of and for the benefit of Lenders and the other Secured Parties in all Collateral, subject, for the following Collateral, to the occurrence of the following: (a) in the case of all Collateral in which a security interest may be perfected by filing a financing statement under the Code, the completion of the filings and other actions specified on Schedule 2 of the Security Disclosure Letter (which, in the case of all filings and other documents referred to on such schedule, have been duly authorized by the applicable Grantor); (b) with respect to any account over which a Control Agreement is required pursuant to Section 5.5 of the Loan Agreement, the execution of Control Agreements; (c) in the case of all United States Trademarks, Patents and Copyrights for which Code filings are insufficient to effectuate perfection, all appropriate filings having been made with the Applicable IP Office, as applicable; (d) in the case of all Pledged Certificated Stock, Pledged Debt Instruments and Pledged Investment Property, the delivery to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of such Pledged Certificated Stock, Pledged Debt Instruments and Pledged Investment Property consisting of instruments and certificates, in each case, properly endorsed for transfer to the Collateral Agent or in blank; (e) in the case of all Pledged Uncertificated Stock, the delivery to the Collateral Agent, for the benefit of the Lenders and the other Secured Parties, of an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent in the form attached as Annex 4 hereto; (f) in the case of letter-of-credit rights that are not supporting obligations of Collateral, the execution of a contractual obligation granting control to Collateral Agent, for the benefit of the Lenders and the other Secured Parties, over such letter-of-credit rights; (g) in the case of electronic chattel paper, the completion of all steps necessary to grant control to Collateral Agent, for the benefit of the Lenders and the other Secured Parties, over such electronic chattel paper; and (h) in the case of all other instruments that are not Pledged Stock, if any, the delivery thereof to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of such instruments. Such Lien on and security interest in Pledged Stock shall be prior to all other Liens on such Collateral, subject to Permitted Liens having priority over the Collateral Agent's Lien by operation of law or as and to the extent expressly permitted (if at all) by any Loan Document. Subject to Section 3.2 and this Section 4.2 above, except to the extent expressly not required pursuant to the terms of the Loan Agreement or this Agreement, all actions by each Grantor necessary or desirable under the Code to protect and perfect the first priority Lien on and security interest in the Collateral granted hereunder have been duly taken.

Section 4.3 **Pledged Stock**

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(a) The Pledged Stock issued by any Subsidiary of any Grantor pledged by such Grantor hereunder (i) consist of the number and types of Equity Interests listed on Schedule 1 of the Security Disclosure Letter (or any update thereof or supplement thereto permitted to be made pursuant to the Loan Agreement and received by the Collateral Agent in accordance with the Loan Agreement) and constitutes that percentage of the issued and outstanding equity of all classes of each issuer thereof as set forth on Schedule 1 of the Security Disclosure Letter, (ii) has been duly authorized, validly issued and is fully paid and nonassessable (other than Pledged Stock in limited liability companies and partnerships), and (iii) if and to the extent applicable, constitutes the legal, valid and binding obligation of the issuer thereof with respect thereto, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law). As of the date any Joinder Agreement or Pledge Amendment is delivered pursuant to Section 8.6, the Pledged Stock pledged by each applicable Grantor thereunder (x) is listed on the applicable schedule attached to such Joinder Agreement or Pledge Amendment, as applicable, and constitutes that percentage of the issued and outstanding equity of all classes of each issuer thereof as set forth on such schedule, (y) has been duly authorized, validly issued and is fully paid and non-assessable (other than Pledged Stock in limited liability companies and partnerships) and (z) if and to the extent applicable, constitutes the legal, valid and binding obligation of the issuer thereof with respect thereto, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law).

(b) All Pledged Certificated Stock has been delivered to (or otherwise in accordance with the written direction of) the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a), and (ii) with respect to all Pledged Uncertificated Stock, uncertificated stock control agreements in the form attached as Annex 4 hereto have been delivered to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a).

(c) Upon the occurrence and during the continuance of an Event of Default, the Collateral Agent for the benefit of Lenders and the other Secured Parties shall be entitled to exercise all of the rights of the Grantor granting the security interest in any Pledged Stock, and a transferee or assignee of such Pledged Stock shall become a holder of such Pledged Stock to the same extent as such Grantor and, upon the transfer of the entire interest of such Grantor, such Grantor shall, by operation of law, cease to be a holder of such Pledged Stock.

Section 4.4 **Pledged Debt Instruments**

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(a) (i) All Pledged Debt Instruments constituting Indebtedness owed to such Grantor by a Subsidiary has been duly authorized, authenticated or issued and delivered by such Subsidiary, is the legal, valid and binding obligation of such Subsidiary and such Subsidiary is not in default thereunder and (ii) to the Knowledge of such Grantor, all other Pledged Debt Instruments not otherwise covered in clause (i) above constituting Indebtedness owed to such Grantor has been duly authorized, authenticated or issued and delivered by the issuer of such Indebtedness, is the legal, valid and binding obligation of such issuer and such issuer is not in default thereunder.

(b) Except as set forth on Schedule 3 of the Security Disclosure Letter (or any update thereof or supplement thereto permitted to be made pursuant to the Loan Agreement and received by the Collateral Agent in accordance with the Loan Agreement), none of the Pledged Debt Instruments constituting Indebtedness owed to such Grantor is subordinated in right of payment to any other Indebtedness or subject to the terms of an indenture (or similar agreement or instrument).

(c) All Pledged Debt Instruments constituting Indebtedness owed to such Grantor have been delivered to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a).

ARTICLE 5

COVENANTS

Each Grantor agrees with the Collateral Agent to the following, until the absolute, unconditional and irrevocable payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) and unless the Collateral Agent, on behalf of Lenders and the other Secured Parties, otherwise consents in writing:

Section 5.1 **Maintenance of Perfected Security Interest; Further Documentation and Consents**

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(a) Except as otherwise (i) mutually agreed in writing between Borrower and the Collateral Agent not to be required under this Agreement or the other Loan Documents, (ii) mutually agreed in writing between Borrower and the Collateral Agent to be effected solely by filings of financing statements under the Code or amendments thereto to be made by the Collateral Agent or any Lender or its Related Party pursuant to Section 7.2, or (iii) as otherwise expressly provided in Section 5.14 of the Loan Agreement, such Grantor, in order to grant and maintain a security interest to the Collateral Agent pursuant to this Agreement which constitutes a valid and continuing first priority perfected security interest as described in Section 4.2 (subject only to Permitted Liens), shall promptly:

(i) after the creation or acquisition of any U.S. deposit account over which a Control Agreement is required pursuant to Section 5.5 of the Loan Agreement but prior to the movement of any cash or other funds into such account (except as may be expressly provided in Section 5.14 of the Loan Agreement), execute and deliver to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.5 of the Loan Agreement, Control Agreements in form and substance reasonably satisfactory to the Collateral Agent;

(ii) in accordance with the requirements in Section 5.3 (as applicable), with respect to any Trademarks, Patents and Copyrights or any IP Rights, execute and deliver to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, all appropriate IP Security Agreements, in form and substance reasonably satisfactory to the Collateral Agent, for the filing thereof by the Collateral Agent or its Related Party, and such Grantor hereby duly authorizes the Collateral Agent and its Related Party to file such IP Security Agreements with the Applicable IP Office;

(iii) with respect to any Pledged Certificated Stock, deliver to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Pledged Certificated Stock consisting of instruments and certificates, in each case, properly endorsed for transfer to the Collateral Agent or in blank and in form and substance reasonably satisfactory to the Collateral Agent;

(iv) with respect to any Pledged Uncertificated Stock, deliver to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent in the form attached as Annex 4 hereto (and otherwise in form and substance reasonably satisfactory to the Collateral Agent), pursuant to which, *inter alia*, such issuer agrees to comply with the Collateral Agent's instructions with respect to such Pledged Uncertificated Stock without further consent by such Grantor; and

(v) maintain the security interest created by this Agreement as a first priority perfected security interest as described in Section 4.2 (subject to Permitted Liens) and shall take reasonable efforts to warrant and defend the Collateral covered by such security interest and such priority (subject to Permitted Liens) against the claims and demands of all Persons (other than Secured Parties).

(b) Such Grantor shall furnish to the Collateral Agent at any time and from time to time statements and schedules further identifying and describing the Collateral and such other documents in connection with the Collateral as the Collateral Agent may reasonably request in writing, in all cases in reasonable detail and in form and substance reasonably satisfactory to the Collateral Agent (including in the case of any commercial tort claim constituting Collateral, for the avoidance of doubt, reasonable detail identifying the specific claims subject to the security interest granted in such commercial tort claims to the Collateral Agent pursuant to this Agreement).

(c) At any time and from time to time, upon the reasonable written request of the Collateral Agent, such Grantor shall, for the purpose of obtaining or preserving the full benefits of this Agreement and the other Collateral Documents and of the rights and powers herein and therein granted, (i) promptly and duly execute and deliver, and have recorded, such further documents, including an authorization to file (or, as applicable, the filing) of any financing statement or amendment under the Code (or other filings under similar Requirements of Law) in effect in the U.S. or any other jurisdiction with respect to the security interest created hereby and (ii) take such further action as the Collateral Agent may reasonably request in writing that is consistent with the requirements hereof and of the other Loan Documents, including executing and delivering any Control Agreements required by Section 5.5 of the Loan Agreement with respect to the Collateral Accounts, in each case of sub-clause (i) and (ii) above, subject to the terms of Section 5.12(e) of the Loan Agreement.

Section 5.2 **Pledged Collateral and Pledged Investment Property**

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(a) Delivery of Pledged Collateral and Pledged Investment Property. Without limitation to Section 1 above, such Grantor shall promptly, and no later than thirty (30) days after, acquiring any Pledged Collateral not owned on the Closing Date:

(i) deliver to the Collateral Agent, properly endorsed, in blank or otherwise in suitable form for transfer and in form and substance reasonably satisfactory to the Collateral Agent, (A) all such Pledged Stock that is Pledged Certificated Stock, (B) each Pledged Debt Instrument evidencing Indebtedness or other monetary obligations in an amount, individually or together with one or more other Pledged Debt Instruments, exceeding $500,000 (as reasonably determined by a Responsible Officer of Parent in good faith) and (C) all certificates and instruments evidencing Pledged Investment Property with a fair market value, individually or together with one or more other such certificates or instruments, exceeding $500,000 (as reasonably determined by a Responsible Officer of Parent in good faith);

(ii) subject all Collateral Accounts required to be subject to a Control Agreement pursuant to Section 5.5 of the Loan Agreement to a Control Agreement;

(iii) cause the issuer of any such Pledged Stock that is Pledged Uncertificated Stock to execute an uncertificated stock control agreement in the form attached hereto as Annex 4, pursuant to which, *inter alia*, such issuer agrees to comply with the Collateral Agent's instructions with respect to such Pledged Uncertificated Stock without further consent by such Grantor, and, for the avoidance of doubt, if any such Pledged Uncertificated Stock becomes certificated, promptly (but in any event within thirty (30) days thereof) deliver to the Collateral Agent, in suitable form for transfer and in form and substance reasonably satisfactory to the Collateral Agent, all such certificates, instruments or other similar documents (as defined in the Code).

(b) Event of Default. During the continuance of any Event of Default and in connection with the exercise of rights or remedies hereunder or under any other Loan Document, the Collateral Agent shall have the right, at any time in its discretion and without prior notice to any Grantor, to (i) transfer to or to register in its name or in the name of its nominees any Pledged Stock and (ii) exchange any certificate or instrument representing or evidencing any Pledged Stock for certificates or instruments of smaller or larger denominations.

(c) Cash Distributions with respect to Pledged Collateral and Pledged Investment Property. Except as provided in Article VI and subject to any limitations set forth in the Loan Agreement, such Grantor shall be entitled to receive all cash distributions paid in respect of the Pledged Collateral and the Pledged Investment Property.

(d) Voting Rights. Except as provided in Article VI, such Grantor shall be entitled to exercise all voting, consent and corporate, partnership, limited liability company and similar rights with respect to the Pledged Collateral and Pledged Investment Property; provided, however, that no vote shall be cast, consent, waiver or ratification given or right exercised (or failed to be exercised) or other action taken (or failed to be taken) by such Grantor in any manner that would reasonably be expected to (i) violate or be inconsistent with any of the terms of this Agreement or any other Loan Document or (ii) have the effect of materially impairing such Collateral or the position of any Secured Party or their rights or interests in such Collateral.

Section 5.3 **Intellectual Property**

. If such Grantor shall at any time after the date hereof acquire any Copyright, Trademark or Patent or any IP License that constitutes Collateral, such Grantor shall, within thirty (30) days after delivery of financial statements pursuant to Section 5.2(a) of the Loan Agreement, execute and deliver to the Collateral Agent, in form and substance reasonably acceptable to the Collateral Agent and suitable for filing in the Applicable IP Office, the IP Security Agreement(s) in the form attached hereto as Annex 3, or in any other form, as required by the Applicable IP Office or other registry in the applicable jurisdiction, in each case, in respect of any such newly-acquired Copyright(s), Trademark(s) or Patent(s) or any such newly-acquired IP Licenses (as applicable) of such Grantor registered in the Applicable IP Office.

ARTICLE 6

REMEDIAL PROVISIONS

Section 6.1 **Code and Other Remedies**

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(a) Code Remedies. During the continuance of an Event of Default, the Collateral Agent, on behalf of Lenders and the other Secured Parties, may exercise, in addition to all other rights and remedies granted to it in this Agreement, any IP Agreement, any other Loan Document or in any other instrument or agreement securing, evidencing or relating to any Secured Obligation, all rights, powers and remedies of a secured party under the Code or any other Requirements of Law or in equity.

(b) Disposition of Collateral. During the continuance of an Event of Default, without limiting the generality of the foregoing, the Collateral Agent may (personally or through its agents or attorneys), without demand of performance or other demand, presentment, protest, advertisement or notice of any kind (except any notice required by Requirements of Law referred to below) to or upon any Grantor or any other Person (all and each of which demands, defenses, advertisements and notices are hereby waived): (i) enter upon the premises where any Collateral is located, without any obligation to pay rent, through self-help, without judicial process, without first obtaining a final judgment or giving Grantor or any other Person notice or opportunity for a hearing on the Collateral Agent's or any Lender's claim or action; (ii) collect, receive, appropriate and realize upon any Collateral; (iii) store, process, repair or recondition the Collateral or otherwise prepare any Collateral for disposition in any manner to the extent the Collateral Agent deems appropriate; and (iv) sell, assign, license out, convey, transfer, grant option or options to purchase or license and deliver any Collateral (or enter into contractual obligations to do any of the foregoing), in one or more parcels at public or private sale or sales, at any exchange, broker's board or office of the Collateral Agent or any Lender or other Secured Party or elsewhere upon such terms and conditions as it may deem advisable and at such prices as it may deem best, for cash or on credit or for future delivery without assumption of any credit risk. The Collateral Agent, on behalf of Lenders and the other Secured Parties, shall have the right, upon any such public sale or sales and, to the extent permitted by the Code and other Requirements of Law, upon any such private sale or sales, to purchase or license the whole or any part of the Collateral so sold or licensed, free of any right or equity of redemption of any Grantor, which right or equity is hereby waived and released. The Collateral Agent, as representative of all Lenders and other Secured Parties, shall be entitled, for the purpose of bidding and making settlement or payment of the purchase price for all or any portion of the Collateral sold at any such sale made in accordance with the Code, to use and apply any of the Secured Obligations as a credit on account of the purchase price for any Collateral payable by the Collateral Agent on behalf of Lenders and the other Secured Parties, at such sale. If the Collateral Agent on behalf of any Lender sells any of the Collateral upon credit, Grantor will be credited only with payments actually made by purchaser and received by such Lender and applied to indebtedness of the purchaser. In the event the purchaser fails to pay for the Collateral, the Collateral Agent may resell the Collateral and Grantor shall be credited with proceeds of the sale. Neither the Collateral Agent nor any Lender shall have an obligation to marshal any of the Collateral.

(c) Management of the Collateral. Each Grantor further agrees, that, during the continuance of any Event of Default, (i) at the Collateral Agent's request, it shall assemble the Collateral and make it available to the Collateral Agent at places that the Collateral Agent shall reasonably select, whether at such Grantor's premises or elsewhere, (ii) without limiting the foregoing, the Collateral Agent also has the right to require that such Grantor store and keep any Collateral pending further action by the Collateral Agent and, while any such Collateral is so stored or kept, provide such guards and maintenance services as shall be necessary to protect the same and to preserve and maintain such Collateral in good condition, normal wear and tear excepted, (iii) until the Collateral Agent is able to sell, assign, license out, convey or transfer any Collateral, the Collateral Agent shall have the right to hold or use such Collateral to the extent that it deems appropriate for the purpose of preserving the Collateral or its value or for any other purpose deemed appropriate by the Collateral Agent and (iv) the Collateral Agent may, if it so elects, seek the appointment of a receiver or keeper to take possession of any Collateral and to enforce any of the Collateral Agent's or any Lender's remedies, with respect to such appointment without any prior written notice or hearing as to such appointment. The Collateral Agent shall not have any obligation to any Grantor to maintain or preserve the rights of any Grantor as against other Persons with respect to any Collateral while such Collateral is in the possession of the Collateral Agent.

(d) Application of Proceeds. The Collateral Agent shall apply the cash proceeds received by it in respect of any sale of, any collection from, or other realization upon all or any part of the Collateral, after deducting all reasonable costs and expenses of every kind incurred in connection therewith or incidental to the care or safekeeping of any Collateral or in any way relating to the Collateral or the rights of Lenders and the other Secured Parties, including reasonable and documented out-of-pocket attorneys' fees and disbursements, to the payment in whole or in part of the Secured Obligations, as set forth in the Loan Agreement and, if and only to the extent applicable thereunder, the RTW Intercreditor Agreement, and only after such application and after the payment by the Collateral Agent or Lenders of any other amount required by any Requirements of Law, need the Collateral Agent or any Lender account for the surplus, if any, to any Grantor.

(e) Direct Obligation. Neither the Collateral Agent nor any Lender or other Secured Party shall be required to make any demand upon, or pursue or exhaust any right or remedy against, any Grantor or any other Person with respect to the payment of the Obligations or to pursue or exhaust any right or remedy with respect to any Collateral therefor or any direct or indirect guaranty thereof. All of the rights and remedies of the Collateral Agent and Lenders and any other Secured Party shall be cumulative, may be exercised individually or concurrently and not exclusive of any other rights or remedies provided by any Requirements of Law. To the extent it may lawfully do so, each Grantor absolutely and irrevocably waives and relinquishes the benefit and advantage of, and covenants not to assert against the Collateral Agent, Lenders or any other Secured Party, any valuation, stay, appraisement, extension, redemption or similar laws and any and all rights or defenses it may have as a surety, now or hereafter existing, arising out of the exercise by any of them of any rights or remedies hereunder. If any notice of a proposed sale (public or private) or other disposition of any Collateral shall be required by Requirements of Law, such notice shall be deemed reasonable and proper if given at least ten (10) days before such sale or other disposition.

(f) Commercially Reasonable. To the extent that applicable Requirements of Law impose duties on the Collateral Agent or any Lender or other Secured Party to exercise remedies in a commercially reasonable manner, each Grantor acknowledges and agrees that it is not commercially unreasonable for the Collateral Agent or any Lender to do any of the following:

(i) fail to incur significant costs, expenses or other liabilities reasonably deemed as such by the Collateral Agent or such Lender to prepare any Collateral for disposition or otherwise to complete raw material or work in process into finished goods or other finished products for disposition;

(ii) fail to obtain permits, licenses or other consents for access to any Collateral to sell or license or for the collection or sale or licensing of any Collateral, or, if not required by other Requirements of Law, fail to obtain permits, licenses or other consents for the collection or disposition of any Collateral;

(iii) fail to exercise remedies against account debtors or other Persons obligated on any Collateral or to remove Liens on any Collateral or to remove any adverse claims against any Collateral;

(iv) advertise dispositions of any Collateral through publications or media of general circulation, whether or not such Collateral is of a specialized nature, or to contact other Persons, whether or not in the same business as any Grantor, for expressions of interest in acquiring any such Collateral;

(v) exercise collection remedies against account debtors and other Persons obligated on any Collateral, directly or through the use of collection agencies or other collection specialists, hire one or more professional auctioneers to assist in the disposition of any Collateral, whether or not such Collateral is of a specialized nature, or, to the extent deemed appropriate by the Collateral Agent or such Lender, obtain the services of other brokers, investment bankers, consultants and other professionals to assist the Collateral Agent or such Lender in the collection or disposition of any Collateral, or utilize Internet sites that provide for the auction of assets of the types included in the Collateral or that have the reasonable capacity of doing so, or that match buyers and sellers of assets to dispose of any Collateral;

(vi) dispose of assets in wholesale rather than retail markets;

(vii) disclaim warranties, such as title, merchantability, possession, non-infringement or quiet enjoyment; or

(viii) purchase insurance or credit enhancements to insure the Collateral Agent or any Lender or other Secured Party against risks of loss, collection or disposition of any Collateral or to provide to the Collateral Agent and Lenders a guaranteed return from the collection or disposition of any Collateral.

(g) IP Licenses. To the extent permitted, and only for the purpose of enabling the Collateral Agent to exercise rights and remedies under this Section 6.1 or Section 8.1 of the Loan Agreement during the continuance of an Event of Default (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral) at such time as the Collateral Agent on behalf of Lenders and the other Secured Parties shall be lawfully entitled to exercise such rights and remedies, each Grantor hereby grants to the Collateral Agent: (i) an irrevocable, non-exclusive, assignable, royalty-free license or other right to use (and for its agents or representatives to use) in the Territory (exercisable without payment of royalty or other compensation to such Grantor), including the right to sublicense, use and practice, any and all Intellectual Property now owned or held or hereafter acquired or held by such Grantor and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; and (ii) an irrevocable license (without payment of rent or other compensation to such Grantor) to use, operate and occupy all real property owned, operated, leased, subleased or otherwise occupied by such Grantor; provided that, in each case of sub-clauses (i) and (ii) above, such license and sublicenses with respect to Trademarks will be subject to the maintenance of quality standards with respect to the goods and services on which such Trademarks are used sufficient to preserve the validity of such Trademarks; provided, further, that nothing in this clause (g) shall require a Grantor to grant any license that (x) violates the express terms of any license agreement between a Grantor and a third party governing such Grantor's use of such Intellectual Property or (y) is prohibited by applicable Requirement of Law.

Each Grantor acknowledges that the purpose of this Section 6.1 is to provide a non-exhaustive list of actions or omissions that are commercially reasonable when exercising remedies against any Collateral and that other actions or omissions by the Collateral Agent, Lenders or any other Secured Party shall not be deemed commercially unreasonable solely on account of not being indicated in this Section 6.1. Without limitation upon the foregoing, except as expressly provided in this Section 6.1, nothing contained in this Section 6.1 shall be construed to grant any rights to any Grantor or to impose any duties on the Collateral Agent or any Lender or other Secured Party that would not have been granted or imposed by this Agreement or by applicable Requirements of Law in the absence of this Section 6.1.

Section 6.2 **Accounts and Payments in Respect of General Intangibles**

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(a) In addition to, and not in substitution for, any similar requirement in the Loan Agreement, if required by the Collateral Agent at any time during the continuance of an Event of Default, any payment of accounts or payment in respect of general intangibles relating to the Collateral, when collected by any Grantor, shall promptly (and, in any event, within two (2) Business Days of such collection) be deposited by such Grantor in the exact form received (unless the Collateral Agent otherwise agrees in writing), duly indorsed by such Grantor to the Collateral Agent for the benefit of Lenders and the other Secured Parties, segregated from other funds of such Grantor (unless the Collateral Agent otherwise agrees in writing) in a Collateral Account, subject to withdrawal by the Collateral Agent as provided in Section 6.4. Until so turned over, such payment shall be held by such Grantor in trust for the Collateral Agent for the benefit of Lenders and the other Secured Parties, segregated from other funds of such Grantor. Each such deposit of proceeds of accounts and payments in respect of general intangibles relating to the Collateral shall, upon the Collateral Agent's request, be accompanied by a report identifying in reasonable detail the nature and source of the payments included in the deposit.

(b) At any time during the continuance of an Event of Default, in each case to the extent not prohibited under Section 8.1 of the Loan Agreement:

(i) each Grantor shall, upon the Collateral Agent's request, assemble and hold for the benefit of Lenders and the other Secured Parties all original and other documents evidencing, and relating to, the contractual obligations and transactions that gave rise to any account or any payment in respect of general intangibles, including all IP Licenses, original orders, invoices and shipping receipts and notify account debtors that the accounts or general intangibles have been collaterally assigned to the Collateral Agent for the benefit of Lenders and the other Secured Parties and that payments in respect thereof shall be made directly to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct; and

(ii) each Grantor shall take all actions, deliver all documents and provide all information necessary or reasonably requested by the Collateral Agent to ensure any Internet Domain Name is registered.

(c) Anything herein to the contrary notwithstanding, each Grantor shall remain liable under each account and each payment in respect of general intangibles included in the Collateral to observe and perform all the conditions and obligations to be observed and performed by it thereunder, all in accordance with the terms of any agreement giving rise thereto. Neither the Collateral Agent nor any Lender or other Secured Party shall have any obligation or liability under any agreement giving rise to an account or a payment in respect of a general intangible included in the Collateral by reason of or arising out of any Loan Document or the receipt by the Collateral Agent or any Lender or other Secured Party of any payment relating thereto, nor shall the Collateral Agent nor any Lender or other Secured Party be obligated in any manner to perform any obligation of any Grantor under or pursuant to any agreement giving rise to an account or a payment in respect of a general intangible included in the Collateral, to make any payment, to make any inquiry as to the nature or the sufficiency of any payment received by it or as to the sufficiency of any performance by any party thereunder, to present or file any claim, to take any action to enforce any performance or to collect the payment of any amounts that may have been assigned to it or to which it may be entitled at any time or times.

Section 6.3 **Pledged Collateral**

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(a) Voting Rights. During the continuance of an Event of Default, upon written notice from the Collateral Agent to the relevant Grantor(s), all rights of each Grantor to exercise or refrain from exercising the voting and other consensual rights which it would otherwise be entitled to exercise pursuant hereto shall cease and all such rights shall thereupon become vested in the Collateral Agent or a nominee on behalf of Lenders or the other Secured Parties, who shall thereupon have the sole right to exercise such voting and other consensual rights, including the right to exercise (i) any voting, consent, corporate and other right pertaining to the Pledged Collateral at any meeting of shareholders, partners or members, as the case may be, of the relevant issuer or issuers of Pledged Collateral or otherwise, and (ii) any right of conversion, exchange and subscription and any other right, privilege or option pertaining to the Pledged Collateral as if it were the absolute owner thereof (including the right to exchange at its discretion any Pledged Collateral upon the merger, amalgamation, consolidation, reorganization, recapitalization or other fundamental change in the corporate or equivalent structure of any issuer of Pledged Collateral, the right to deposit and deliver any Pledged Collateral with any committee, depositary, transfer agent, registrar or other designated agency upon such terms and conditions as the Collateral Agent (or such nominee) on behalf of Lenders or the other Secured Parties may determine), all without liability except to account for property actually received by it; provided, however, that the Collateral Agent (or such nominee) shall have no duty to any Grantor to exercise any such right, privilege or option and shall not be responsible for any failure to do so or delay in so doing; provided, further, that the failure of the Collateral Agent (or such nominee) to delivery such notice shall not limit, affect or diminish any right of the Collateral Agent or the Lenders hereunder.

(b) Proxies. During the continuance of an Event of Default, in order to permit the Collateral Agent on behalf of Lenders and the other Secured Parties to exercise the voting and other consensual rights that it may be entitled to exercise pursuant hereto and to receive all dividends and other distributions that it may be entitled to receive hereunder, (i) each Grantor shall promptly execute and deliver (or cause to be executed and delivered) to the Collateral Agent all such proxies, dividend payment orders and other instruments as the Collateral Agent may from time to time reasonably request in writing and (ii) without limiting the effect of clause (i) above, such Grantor hereby grants to the Collateral Agent for the benefit of Lenders and the other Secured Parties an irrevocable proxy to vote all or any part of the Pledged Collateral and to exercise all other rights, powers, privileges and remedies to which a holder of the Pledged Collateral would be entitled (including giving or withholding written consents of shareholders, partners or members, as the case may be, calling special meetings of shareholders, partners or members, as the case may be, and voting at such meetings), which proxy shall be effective, automatically and without the necessity of any action (including any transfer of any Pledged Collateral on the record books of the issuer thereof) by any other Person (including the issuer of such Pledged Collateral or any officer or agent thereof) during the continuance of an Event of Default and which proxy shall only terminate upon (A) the cure of any and all Events of Default or (B) the absolute, unconditional and irrevocable payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted).

(c) Authorization of Issuers. Each Grantor hereby expressly and irrevocably authorizes and instructs, without any further instructions from such Grantor, each issuer of any Pledged Collateral pledged hereunder by such Grantor to, and each Grantor that is an issuer of Pledged Collateral so pledged hereunder hereby agrees to: (i) comply with any instruction received by it from the Collateral Agent in writing that states that an Event of Default is continuing and is otherwise in accordance with the terms of this Agreement, and each Grantor agrees that such issuer shall be fully protected from liabilities to such Grantor in so complying; and (ii) during the continuance of such Event of Default, unless otherwise permitted hereby or by the Loan Agreement, pay any dividend or make any other payment with respect to the Pledged Collateral directly to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct.

Section 6.4 **Proceeds to be Turned over to and Held by Collateral Agent**

. Unless otherwise expressly provided in the Loan Agreement or this Agreement, during the continuance of an Event of Default and, upon written notice by the Collateral Agent to the relevant Grantor or Grantors, all proceeds of any Collateral received by any Grantor hereunder in cash or Cash Equivalents shall be held by such Grantor in trust for Lenders and the other Secured Parties, segregated from other funds of such Grantor (unless the Collateral Agent otherwise agrees in writing), and shall, promptly upon receipt by any Grantor, be turned over to the Collateral Agent for the benefit of Lenders and the other Secured Parties in the exact form received (unless the Collateral Agent otherwise agrees in writing), with any necessary endorsement. All such proceeds of Collateral and any other proceeds of any Collateral received by the Collateral Agent in cash or Cash Equivalents shall be held by the Collateral Agent for the benefit of itself and the other Secured Parties in a Collateral Account. All proceeds being held by the Collateral Agent in a Collateral Account (or by such Grantor in trust for Lenders and the other Secured Parties) shall continue to be held as collateral security for the Secured Obligations and shall not constitute payment thereof until applied as provided in the Loan Agreement.

Section 6.5 **Sale of Pledged Collateral**

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(a) Each Grantor recognizes that the Collateral Agent may be unable to effect a public sale of any Pledged Collateral by reason of certain prohibitions contained in the Securities Act and applicable state or foreign securities laws or otherwise or may determine that a public sale is impracticable, not desirable or not commercially reasonable and, accordingly, may resort to one or more private sales thereof to a restricted group of purchasers that shall be obliged to agree, among other things, to acquire such securities for their own account for investment and not with a view to the distribution or resale thereof. Each Grantor acknowledges and agrees that any such private sale may result in prices and other terms less favorable than if such sale were a public sale and, notwithstanding such circumstances, agrees that any such private sale shall be deemed to have been made in a commercially reasonable manner. The Collateral Agent shall be under no obligation to delay a sale of any Pledged Collateral for the period of time necessary to permit the issuer thereof to register such securities for public sale under the Securities Act or under applicable state securities laws even if such issuer would agree to do so.

(b) Each Grantor agrees to use commercially reasonable efforts to do or cause to be done all such other acts as may be reasonably necessary to make such sale or sales of any portion of the Pledged Collateral pursuant to Section 6.1, this Section 6.5 and Section 8.1 of the Loan Agreement valid and binding and in compliance with all applicable Requirements of Law. Each Grantor further agrees that a breach of any covenant contained herein will cause irreparable injury to the Collateral Agent, Lenders and the other Secured Parties, that the Collateral Agent, Lenders and the other Secured Parties have no adequate remedy at law in respect of such breach and, as a consequence, that each and every covenant contained herein shall be specifically enforceable against such Grantor, and such Grantor hereby waives and agrees not to assert any defense against an action for specific performance of such covenants except for a defense that no Event of Default has occurred and is continuing under the Loan Agreement or a defense of unconditional payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted). Each Grantor waives any and all rights of contribution or subrogation upon the sale or disposition of all or any portion of the Pledged Collateral by the Collateral Agent on behalf of Lenders and the other Secured Parties.

Section 6.6 **Deficiency**

. Each Grantor shall remain liable for any deficiency if the proceeds of any sale or other disposition of any Collateral are insufficient to pay the Secured Obligations and the reasonable and documented fees and disbursements of any attorney employed by the Collateral Agent or any Lender to collect such deficiency.

Section 6.7 **Collateral Accounts**

. If any Event of Default shall have occurred and be continuing, the Collateral Agent may apply the balance from any Collateral Account of a Grantor or instruct the bank at which any Collateral Account is maintained to pay the balance of any Collateral Account to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct, to be applied to the Secured Obligations in accordance with the terms hereof.

Section 6.8 **Directions, Notices or Instructions**

. Neither the Collateral Agent nor any Lender or any Related Party thereof or any other Secured Party shall take any action under or issue any directions, notice or instructions pursuant to any Control Agreement or similar agreement or any acknowledgement from a landlord or third party bailee with respect to any Collateral Access Agreement unless an Event of Default has occurred and is continuing.

ARTICLE 7

ADDITIONAL RIGHTS OF COLLATERAL AGENT

Section 7.1 **Collateral Agent's Appointment as Attorney-in-Fact**

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(a) Each Grantor hereby irrevocably constitutes and appoints the Collateral Agent and any Related Party thereof, with full power of substitution, as its true and lawful attorney-in-fact with full irrevocable power and authority in the place and stead of such Grantor and in the name of such Grantor or in its own name, for the purpose of carrying out the terms of the Loan Documents, to take any appropriate action and to execute any document or instrument that may be necessary or desirable to accomplish the purposes of the Loan Documents, in each case during the continuance of an Event of

Default, and, without limiting the generality of the foregoing, each Grantor hereby gives the Collateral Agent and its Related Party the power and right, on behalf of such Grantor, without notice to or assent by such Grantor, to do any of the following when an Event of Default shall be continuing:

(i) in the name of such Grantor, in its own name or otherwise, take possession of and indorse and collect any check, draft, note, acceptance or other instrument for the payment of moneys due under any account or general intangible or with respect to any other Collateral and file any claim or take any other action or proceeding in any court of law or equity or otherwise deemed appropriate by the Collateral Agent for the purpose of collecting any such moneys due under any account or general intangible or with respect to any other Collateral whenever payable;

(ii) in the case of any Intellectual Property (including any IP Ancillary Rights) or any IP Licenses included in the Collateral, execute, deliver and have recorded any document that the Collateral Agent may request to evidence, effect, publicize or record the Collateral Agent's security interest, in favor of and for the benefit of Lenders and the other Secured Parties, in such Intellectual Property or IP Licenses and the goodwill and general intangibles of such Grantor relating thereto or represented thereby and the Collateral Agent's (on behalf of Lenders and the other Secured Parties) rights and remedies with respect thereto;

(iii) pay or discharge taxes and Liens levied or placed on or threatened against any Collateral, effect any repair or obtain or pay any insurance called for by the terms of the Loan Agreement (including all or any part of the premiums therefor and the costs thereof);

(iv) execute, in connection with any sale provided for in Section 6.1 or 6.5, any document to effect or otherwise necessary or appropriate in relation to evidence the sale of any Collateral; or

(v) (A) direct any party liable for any payment under any Collateral to make payment of any moneys due or to become due thereunder directly to the Collateral Agent or as the Collateral Agent shall direct, (B) ask or demand for, and collect and receive payment of and receipt for, any moneys, claims and other amounts due or to become due at any time in respect of or arising out of any Collateral, (C) commence and prosecute any suit, action or proceeding at law or in equity in any court of competent jurisdiction to collect any Collateral and to enforce any other right in respect of any Collateral, (D) defend any actions, suits, proceedings, audits, claims, demands, orders or disputes brought against such Grantor with respect to any Collateral, (E) settle, compromise or adjust any such actions, suits, proceedings, audits, claims, demands, orders or disputes and, in connection therewith, give such discharges or releases as the Collateral Agent may deem appropriate, (F) assign or license any Intellectual Property included in the Collateral on such terms and conditions and in such manner as the Collateral Agent shall in its sole discretion determine, including the execution and filing of any document necessary to effectuate or record such assignment or license and (G) generally, sell, assign, license, convey, transfer or grant a Lien on, make any contractual obligation with respect to and otherwise deal with, any Collateral as fully and completely as though the Collateral Agent on behalf of Lenders and the other Secured Parties were the absolute owner thereof for all purposes and do, at the Collateral Agent's option, at any time or from time to time, all acts and things that the Collateral Agent deems necessary to protect, preserve or realize upon any Collateral and the Collateral Agent's, in favor of and for the benefit of Lenders and the other Secured Parties, security interests therein and to effect the intent of the Loan Documents, all as fully and effectively as such Grantor might do.

(vi) If any Grantor fails to perform or comply with any contractual obligation contained herein, the Collateral Agent, at its option, but without any obligation so to do, may perform or comply, or otherwise cause performance or compliance, with such contractual obligation.

(b) In accordance with, and without limiting the generality of, Section 2.4 of the Loan Agreement, each Grantor agrees to promptly pay or reimburse the Lender Expenses and any other reasonable and documented out-of-pocket expenses of the Collateral Agent and any Lender and other Secured Party incurred in connection with the taking of any actions pursuant to or as otherwise contemplated by this Section 7.1, together with, solely in the event any Grantor fails to pay any of the Obligations when due or upon the commencement and during the continuance of an Insolvency Proceeding of the Borrower or, at the election of the Required Lenders, upon the occurrence and during the continuance of any other Event of Default, interest thereon at the Default Rate from the date any such expenses were paid by the Collateral Agent or any Lender through the date such expenses are reimbursed by the relevant Grantor.

(c) Each Grantor hereby ratifies all that said attorneys shall lawfully do or cause to be done by virtue of this Section 7.1. All powers, authorizations and agencies contained in this Agreement are coupled with an interest and are irrevocable until the absolute, unconditional and irrevocable payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), this Agreement is terminated and the security interests created hereby are released

Section 7.2 **Authorization to File Financing Statements**

. Each Grantor authorizes the Collateral Agent and its Related Party, at any time and from time to time, without notice to any Grantor, to file or record financing statements and other filing or recording documents or instruments with respect to any Collateral, and amendments thereto, in each case in such form, in such jurisdictions and in such offices as the Collateral Agent reasonably determines appropriate to perfect or protect the security interests of

the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, under this Agreement or any other Loan Document (and the Collateral Agent's and each Lender's and each other Secured Party's rights in respect thereof), and such financing statements, documents and instruments, and amendments thereto, may describe the Collateral covered thereby as "all assets of the debtor" or words of similar effect and may include a notice that any disposition of the Collateral, by any Grantor or other Person, shall be deemed to violate the rights of the Collateral Agent and Lenders and other Secured Parties under the Code (or other Requirements of Law in the applicable jurisdiction) to the extent not permitted under this Agreement or any other Loan Document. Save as otherwise required by Requirements of Law, a photographic or other reproduction of this Agreement shall be sufficient as a financing statement or other filing or recording document or instrument for filing or recording in any jurisdiction. Notwithstanding anything to the contrary herein or in the Loan Agreement, Lender Expenses shall not include, and the Collateral Agent and Lenders shall be solely responsible for, any filing fees or other expenses incurred by the Collateral Agent or any Lender in connection with any filings, recordings or other actions taken in jurisdictions other than the United States, Israel and, with respect to any Grantor that is not a Domestic Subsidiary, the jurisdiction of such Grantor, and, upon the occurrence and during the continuance of an Event of Default, any such other jurisdiction pursuant to Section 5.12(e) of the Loan Agreement.

Section 7.3 **Authority of Collateral Agent**

. Each Grantor acknowledges that, as between the Collateral Agent and the Grantors, the Collateral Agent shall be conclusively presumed to be acting as agent for each Lender and all of the other Secured Parties with full and valid authority so to act or refrain from acting, and no Grantor shall be under any obligation or entitlement to make any inquiry respecting such authority.

Section 7.4 **Duty; Obligations and Liabilities**

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(a) Duty of Collateral Agent. The Collateral Agent's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in its possession shall be to deal with it in the same manner as it deals with similar property for its own account, but in no event in less than a commercially reasonable manner. The powers conferred on the Collateral Agent hereunder are solely to protect each Lender's and the other Secured Parties' interest in the Collateral and shall not impose any duty upon the Collateral Agent to exercise any such powers. The Collateral Agent shall be accountable only for amounts that it receives as a result of the exercise of such powers, and neither it nor any of its Related Parties shall be responsible to any Grantor for any act or failure to act hereunder, except for its or their own gross negligence, bad faith or willful misconduct as finally determined by a court of competent jurisdiction. In addition, the Collateral Agent shall not be liable or responsible for any loss or damage to any Collateral, or for any diminution in the value thereof, by reason of the act or omission of any warehousemen, carrier, forwarding agency, consignee or other bailee if such Person has been selected by the Collateral Agent in good faith.

(b) Obligations and Liabilities with respect to Collateral. Neither the Collateral Agent nor Lenders or any other Secured Parties nor any of their respective Related Parties shall be liable for failure to demand, collect or realize upon any Collateral or for any delay in doing so or shall be under any obligation to sell or otherwise dispose of any Collateral upon the request of any Grantor or any other Person or to take any other action whatsoever with regard to any Collateral.

ARTICLE 8

MISCELLANEOUS

Section 8.1 **Reinstatement**

. Each Grantor agrees that, if any payment made by any Credit Party or other Person and applied to the Secured Obligations is at any time annulled, avoided, set aside, rescinded, invalidated, declared to be fraudulent or preferential or otherwise required to be refunded or repaid, or the proceeds of any Collateral are required to be returned by any Secured Party to such Credit Party, its estate, trustee, receiver or any other party, including any Grantor, under any bankruptcy law, state or federal law, common law or equitable cause, in each case as finally determined by a court of competent jurisdiction, then, to the extent of such payment or repayment, any Lien or other Collateral securing such liability shall be and remain in full force and effect, as fully as if such payment had never been made. If, prior to any of the foregoing, (a) any Lien or other Collateral securing such Grantor's liability hereunder shall have been released or terminated by virtue of the foregoing or (b) any provision of the Guaranty hereunder shall have been terminated, cancelled or surrendered, such Lien, other Collateral or provision shall be reinstated in full force and effect and such prior release, termination, cancellation or surrender shall not diminish, release, discharge, impair or otherwise affect the obligations of such Grantor in respect of any Lien or other Collateral securing such obligation or the amount of such payment.

Section 8.2 **Release of Collateral and Guarantee Obligations**

.

(a) When all Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) have been absolutely, unconditionally and irrevocably paid in full, the Collateral shall be automatically released from the Lien created hereby and this Agreement and all obligations (other than those expressly stated to survive such termination) of each Lender and any other Secured Party and each Grantor and Guarantor hereunder shall automatically terminate, all without delivery of any instrument or performance of any act by any party (except as required hereunder), and all rights of the Collateral Agent, Lenders and any other Secured Parties to the Collateral shall automatically revert to the Grantors. Upon the sale, transfer or other disposition of any Collateral to any Person (other than a Credit Party) that is permitted under the Loan Documents or to which Required Lenders have otherwise consented (including the sale, transfer or other disposition of Pledged Stock of a Grantor to any Person (other than a Credit Party)), such Collateral shall be automatically released from the Lien created hereby. In connection with any Permitted License and any other licensing of Intellectual Property permitted pursuant to the Loan Agreement, the Collateral Agent, on behalf of the Lenders and Secured Parties, shall enter into customary non-disturbance and similar agreements, in each case in form and substance reasonably satisfactory to the Collateral Agent and the other party or parties thereto.

(b) In connection with any termination or release pursuant to this Section 8.2, the Collateral Agent shall, and to the extent required, each Secured Party hereby authorizes the Collateral Agent to, promptly execute and deliver to any Grantor all instruments, documents and agreements which such Grantor shall reasonably request in writing to evidence and confirm such termination or release (including termination statements under the Code and customary payoff letters), and will duly assign, transfer and deliver to such Grantor (or its designee), such of the Collateral that may be in the possession of the Collateral Agent, all without further consent or joinder of the Collateral Agent or any Lender or other Secured Party.

(c) Any termination or release pursuant to this Section 8.2 is subject to reinstatement as provided in Section 8.1.

(d) Upon the release of the Liens on any Collateral or of a Grantor from all of its obligations as a Credit Party under the Loan Agreement and as a Grantor hereunder, any representation, warranty or covenant contained in any Loan Document relating to any such Collateral or such Grantor, as applicable, shall no longer be deemed to be made.

(e) In accordance with, and without limiting the generality of, Section 2.4 of the Loan Agreement, each Grantor agrees to pay or reimburse promptly the Lender Expenses and any other reasonable and documented out-of-pocket expenses of the Collateral Agent and any Lender and other Secured Party incurred in connection with the taking of any actions pursuant to or as otherwise contemplated by this Section 8.2.

Section 8.3 **Independent Obligations**

. The obligations of each Grantor hereunder are independent of and separate from the Secured Obligations and the Guaranteed Obligations. Upon any Event of Default and during the continuance thereof, the Collateral Agent for the benefit of Lenders and the other Secured Parties may, at its sole election, proceed directly and at once, without notice, against any Grantor and any Collateral to collect and recover the full amount of any Secured Obligation or Guaranteed Obligation then due, without first proceeding against any other Grantor, any other Credit Party or any other Collateral and without first joining any other Grantor or any other Credit Party in any proceeding.

Section 8.4 **No Waiver by Course of Conduct**

. Neither the Collateral Agent nor any Secured Party shall by any act (except by a written instrument pursuant to Section 8.5), delay, indulgence, omission or otherwise be deemed to have waived any right or remedy hereunder or to have acquiesced in any Default or Event of Default. No failure to exercise, nor any delay in exercising, on the part of the Collateral Agent or any Secured Party, any right, power or privilege hereunder shall operate as a waiver thereof. No single or partial exercise of any right, power or privilege hereunder shall preclude any other or further exercise thereof or the exercise of any other right, power or privilege. A waiver by the Collateral Agent or any Secured Party of any right or remedy hereunder on any one occasion shall not be construed as a bar to any right or remedy that the Collateral Agent or any Secured Party would otherwise have on any future occasion.

Section 8.5 **Amendments in Writing**

. None of the terms or provisions of this Agreement may be waived, amended, supplemented or otherwise modified except in accordance with Section 11.5 of the Loan Agreement; provided, however, that annexes to this Agreement may be supplemented (but no existing provisions may be modified

and no Collateral may be released) through Pledge Amendments and Joinder Agreements, in substantially the form of Annex 1 and Annex 2 attached hereto, respectively, in each case, duly executed by the Collateral Agent and each Grantor directly affected thereby.

Section 8.6 **Additional Grantors and Guarantors; Additional Pledged Collateral**

.

(a) Joinder Agreements. If, at the option of Parent pursuant to Section 5.12 of the Loan Agreement or as otherwise required pursuant to Section 5.12 or Section 5.13 of the Loan Agreement, Parent shall cause any Subsidiary (other than an Excluded Subsidiary, unless Parent has elected to join such Excluded Subsidiary pursuant to Section 5.12 of the Loan Agreement) that is not a Grantor and Guarantor hereunder on the Closing Date to become a Grantor and Guarantor hereunder, such Subsidiary shall execute and deliver to the Collateral Agent a Joinder Agreement substantially in the form of Annex 2 attached hereto and shall thereafter for all purposes be a party hereto and have the same rights, benefits and obligations as a Grantor and Guarantor party hereto on the Closing Date.

(b) Pledge Amendments. To the extent any Pledged Collateral has not been delivered as of the Closing Date, each relevant Grantor shall, promptly after such Pledged Collateral is acquired, deliver a pledge amendment duly executed by such Grantor in substantially the form of Annex 1 attached hereto (each, a "Pledge Amendment"). Such Grantor authorizes the Collateral Agent to attach each Pledge Amendment to this Agreement.

Section 8.7 **Notices**

. All notices, requests and demands hereunder to or upon the Collateral Agent or any other party hereto shall be effected in the manner provided for in Section 9 of the Loan Agreement; provided, however, that any such notice, request or demand to or upon any Grantor hereunder shall be addressed to Borrower's notice address set forth in Section 9 of the Loan Agreement.

Section 8.8 **Successors and Assigns**

. This Agreement shall be binding upon the successors and assigns of each Grantor and shall inure to the benefit of the Collateral Agent and each Secured Party and their respective successors and assigns; provided, however, that no Grantor may assign, transfer or delegate any of its rights or obligations under this Agreement without the prior written consent of the Collateral Agent.

Section 8.9 **Counterparts**

. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or by electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Section 8.10 **Severability**

. Any provision of this Agreement being held illegal, invalid or unenforceable in any jurisdiction shall not affect any part of such provision not held illegal, invalid or unenforceable, any other provision of this Agreement or any part of such provision in any other jurisdiction.

Section 8.11 **Choice of Law**

. THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION), AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HERETO AND THERETO, SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE

APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT.

Section 8.12 **Jury Trial Waiver**

. TO THE FULLEST EXTENT PERMITTED BY REQUIREMENTS OF LAW, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ITS RIGHT TO A JURY TRIAL IN ANY CLAIM, SUIT, ACTION OR PROCEEDING WITH RESPECT TO, OR DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH, THIS AGREEMENT, ANY OTHER LOAN DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREIN AND THEREIN OR RELATED HERETO OR THERETO (WHETHER FOUNDED IN CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO OTHER PARTY AND NO RELATED PARTY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.2 AND (C) HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

THE TERMS OF SECTION 10 OF THE LOAN AGREEMENT ARE INCORPORATED HEREIN BY REFERENCE, *MUTATIS MUTANDIS*, AS IF SET FORTH IN FULL HEREIN AND THE PARTIES HERETO AGREE TO SUCH TERMS AND TO BE BOUND BY SUCH TERMS.

Section 8.13 **Intercreditor Agreement**

. NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, THE LIEN AND SECURITY INTEREST GRANTED TO THE COLLATERAL AGENT PURSUANT TO OR IN CONNECTION WITH THIS AGREEMENT, THE TERMS OF THIS AGREEMENT, AND THE EXERCISE OF ANY RIGHT OR REMEDY BY THE COLLATERAL AGENT HEREUNDER ARE SUBJECT TO THE PROVISIONS OF THE INTERCREDITOR AGREEMENT DATED AS OF MARCH 16, 2022 (AS MAY BE AMENDED, RESTATED, AMENDED AND RESTATED, SUPPLEMENTED OR OTHERWISE MODIFIED FROM TIME TO TIME, THE "INTERCREDITOR AGREEMENT") BY AND BETWEEN BIOPHARMA CREDIT PLC, AS COLLATERAL AGENT UNDER THE LOAN AGREEMENT AND RTW INVESTMENTS ICAV, FOR AND ON BEHALF OF RTW FUND 2, AS PAYER UNDER THE PRE-PAID FORWARD CONTRACT (AS DEFINED THEREIN) AND ACKNOWLEDGED AND AGREED BY UROGEN PHARMA, INC., AS BORROWER UNDER THE LOAN AGREEMENT, AND UROGEN PHARMA LTD., AS THE COUNTERPARTY UNDER THE PRE-PAID FORWARD CONTRACT AND PARENT AND A CREDIT PARTY UNDER THE LOAN AGREEMENT. IN THE EVENT OF ANY CONFLICT BETWEEN THE TERMS OF THE INTERCREDITOR AGREEMENT AND THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT, THE TERMS OF THE INTERCREDITOR AGREEMENT SHALL CONTROL.

Section 8.14 **Israeli Security Agreement**

. For the avoidance of doubt, it is hereby clarified that this Agreement is in addition to the Israeli Security Agreement (and in no manner in lieu thereof or replacement thereto), and each of this Agreement and the Israeli Security Agreement shall independently serve as aforesaid to secure the Secured Obligations in their entirety. Without derogating from the generality of the foregoing or from any other right of the Collateral Agent, the Collateral Agent shall have the right to act on this Agreement or on the Israeli Security Agreement, or on both, in each case in connection with the liens and security interests created by each (including, with respect to any and all assets, properties and rights subject to each of this Agreement and the Israeli Security Agreement); and no action or omission relating to any such liens and security interests shall prevent or stop the Collateral Agent from invoking such other liens and security interests, at the same time or subsequently.

[Signature Pages Follow]

IN WITNESS WHEREOF, each of the undersigned has caused this Guaranty and Security Agreement to be duly executed and delivered as of the date first above written.

UROGEN PHARMA, INC.,
as Borrower and a Grantor

By_____

Name:_____

Title:_____

UROGEN PHARMA LTD.,
as Parent and a Grantor

By_____

Name:_____

Title:_____

ACCEPTED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,

as Collateral Agent

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 1
TO GUARANTY AND SECURITY AGREEMENT

FORM OF PLEDGE AMENDMENT

This Pledge Amendment, dated as of _____, 20__, is delivered pursuant to Section 8.6 of the Guaranty and Security Agreement, dated as of March 16, 2022, by UROGEN PHARMA, INC., as Borrower, the undersigned Grantor and the other Persons from time to time party thereto as Grantors in favor of BIOPHARMA CREDIT PLC, as Collateral Agent on behalf of Lenders and each of the other Secured Parties (as such agreement may be amended, restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"). Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

The undersigned hereby agrees that this Pledge Amendment may be attached to the Guaranty and Security Agreement and that the Pledged Collateral listed on Annex 1-A to this Pledge Amendment shall be and become part of the Collateral referred to in the Guaranty and Security Agreement and shall secure all Secured Obligations of the undersigned.

[GRANTOR]

By: _____
Name:
Title:

Annex 1-A

PLEDGED STOCK

ISSUER	CLASS	CERTIFICATE NO(S).	PAR VALUE	NUMBER OF SHARES, UNITS OR INTERESTS

PLEDGED DEBT INSTRUMENTS

COMMERCIAL TORT CLAIMS

ACKNOWLEDGED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 2
TO
GUARANTY AND SECURITY AGREEMENT

FORM OF JOINDER AGREEMENT

This JOINDER AGREEMENT, dated as of _____ __, 20__, is delivered pursuant to Section 8.6 of the Guaranty and Security Agreement, dated as of March 16, 2022, by and among UROGEN PHARMA, INC. ("Borrower") and the other Persons from time to time party thereto as Grantors, in favor of BIOPHARMA CREDIT PLC (together with its successors and permitted assigns, the "Collateral Agent") on behalf of Lenders and each of the other Secured Parties, (as such agreement may be amended, restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"). Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

By executing and delivering this Joinder Agreement, the undersigned, as provided in Section 8.6 of the Guaranty and Security Agreement, (a) hereby becomes a party to the Guaranty and Security Agreement as a "Grantor" and "Guarantor" thereunder with the same force and effect as if originally named as a Grantor and Guarantor therein and, without limiting the generality of the foregoing, hereby assumes all obligations and liabilities of a Grantor and a Guarantor thereunder and (b) as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Secured Obligations of the undersigned, hereby pledges and hypothecates to the Collateral Agent for the benefit of Lenders and the other Secured Parties, and grants to the Collateral Agent for the benefit of Lenders and the other Secured Parties, a lien on and security interest in, all of its right, title and interest in, to and under the Collateral of the undersigned. The undersigned hereby agrees to be bound as a Grantor and a Guarantor for the purposes of the Guaranty and Security Agreement.

In connection with this Joinder Agreement, the undersigned has delivered to the Collateral Agent a completed Perfection Certificate duly executed by the undersigned. The information set forth in Annex 1-A is hereby added to the information set forth in Schedules 1 and 3 to the Security Disclosure Letter. By acknowledging and agreeing to this Joinder Agreement, the undersigned hereby agrees that this Joinder Agreement may be attached to the Guaranty and Security Agreement, the Perfection Certificate delivered herewith by the undersigned shall constitute a "Perfection Certificate" referred to in Section 4.6 of the Loan Agreement and that the Pledged Collateral listed on Annex 1-A to this Joinder Agreement shall be and become part of the Collateral referred to in the Guaranty and Security Agreement and shall secure all Secured Obligations of the undersigned.

The undersigned hereby represents and warrants that each of the representations and warranties contained in Article IV of the Guaranty and Security Agreement applicable to it is true and correct on and as the date hereof as if made on and as of such date.

In witness whereof, the undersigned has caused this Joinder Agreement to be duly executed and delivered as of the date first above written.

[Additional Grantor]

By: _____
Name:
Title:

ACKNOWLEDGED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 3
TO
GUARANTY AND SECURITY AGREEMENT

FORM OF [COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT

THIS [COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT, dated as of _____, 20__, is made by _____ ("Grantor"), in favor of BIOPHARMA CREDIT PLC (together with its successors and permitted assigns, the "Collateral Agent") on behalf of Lenders and the other Secured Parties (as defined in the Loan Agreement referred to below).

W I T N E S E T H:

WHEREAS, pursuant to the Loan Agreement, dated as of March 7, 2022 (as the same may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement"), by and among UROGEN PHARMA, INC., a Delaware corporation ("Borrower"), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "Parent" and a Credit Party), the other parties thereto from time to time, as additional Credit Parties, BIOPHARMA CREDIT PLC, as Collateral Agent, BPCR LIMITED PARTNERSHIP, (as a "Lender") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership acting by its general partner, BioPharma Credit Investments V GP LLC (as a "Lender"), each Lender has agreed to make extensions of credit to Borrower upon the terms and subject to the conditions set forth therein;

WHEREAS, Grantor [(other than Borrower)] has agreed, pursuant to a Guaranty and Security Agreement dated as of March 16, 2022 in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties (as such agreement may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"), to guarantee the Obligations (as defined in the Loan Agreement) of Borrower; and

WHEREAS, Grantor is party to the Guaranty and Security Agreement pursuant to which Grantor is required to execute and deliver this [Copyright] [Patent] [Trademark] Security Agreement;

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree, intending to be legally bound, as follows:

Section 1. Defined Terms. Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

Section 2. Grant of Security Interest in [Copyright] [Trademark] [Patent] Collateral. Grantor, as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Secured Obligations, hereby mortgages, pledges and hypothecates to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, and grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a Lien on and security interest in, all of its right, title and interest in, to and under the following Collateral of Grantor, in each case, solely to the extent constituting Collateral (and excluding any Excluded Property) (the "[Copyright] [Patent] [Trademark] Collateral"):

(a) [all of its Copyrights and all IP Licenses and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Copyright, including, without limitation, those referred to on Schedule 1 hereto;

(b) all renewals, reversions and extensions of the foregoing; and

(c) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

or

(a) [all of its Patents and all IP License and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Patent, including, without limitation, those referred to on Schedule 1 hereto;

(b) all reissues, reexaminations, continuations, continuations-in-part, divisionals, substitutes, renewals and any patent term extension or adjustment (including any supplementary protection certificate) of the foregoing, and any patent issued with respect to any of the foregoing, and any confirmation patent or registration patent or patent of addition based on any such patent; and

(c) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

or

(d) [all of its Trademarks and all IP Licenses and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Trademark, including, without limitation, those referred to on Schedule 1 hereto, but excluding any "intent-to-use" application for registration of a United States Trademark for which a "Statement of Use" pursuant to Section 1(d) of the Lanham Act, 15 U.S.C. § 1051 (or any successor provision) or an "Amendment to Allege Use" pursuant to Section 1(c) of the Lanham Act, 15 U.S.C. § 1051 (or any successor provision) has not been filed with and accepted by the Applicable IP Office (but only excluding such intent-to-use application until such statement of use or amendment to allege use (as applicable) is filed with and accepted by the Applicable IP Office);

(e) all renewals and extensions of the foregoing;

(f) all goodwill of the business connected with the use of, and symbolized by, each such Trademark; and

(g) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

Section 3. Guaranty and Security Agreement. The security interest granted pursuant to this [Copyright] [Patent] [Trademark] Security Agreement is granted in conjunction with the security interest granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties, pursuant to the Guaranty and Security Agreement and Grantor hereby acknowledges and agrees that the obligations, rights and remedies of Grantor and of the Collateral Agent on behalf of Lenders and the other Secured Parties with respect to the security interest in the [Copyright] [Patent] [Trademark] Collateral made and granted hereby are more fully set forth in the Guaranty and Security Agreement, the terms and provisions of which are incorporated by reference herein as if fully set forth herein.

Section 4. Grantor Remains Liable. Grantor hereby agrees that, anything herein to the contrary notwithstanding, Grantor shall assume full and complete responsibility for the prosecution, defense, enforcement or any other reasonably necessary actions in connection with their [Copyrights] [Patents] [Trademarks] and IP Licenses subject to a security interest hereunder.

Section 5. Counterparts. This [Copyright] [Patent] [Trademark] Security Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this [Copyright] [Patent] [Trademark] Security Agreement by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Section 6. Governing Law. THIS [COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HERETO SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION

OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN [COPYRIGHT] [PATENT] [TRADEMARK] COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT.

THE TERMS OF SECTION 10 OF THE LOAN AGREEMENT ARE INCORPORATED HEREIN BY REFERENCE, *MUTATIS MUTANDIS*, AS IF SET FORTH IN FULL HEREIN AND THE PARTIES HERETO AGREE TO SUCH TERMS AND TO BE BOUND BY SUCH TERMS.

Section 7. Termination. Upon the absolute, unconditional and irrevocable payment in full of the Secured Obligations in accordance with the provisions of the Loan Agreement and the expiration or termination of the Term Loan Commitments, the security interest in the [Copyright] [Patent] [Trademark] Collateral granted hereby shall automatically terminate, without delivery of any instrument or performance of any act by any party, and all rights to the [Copyright] [Patent] [Trademark] Collateral shall automatically revert to Grantors or any other Person entitled thereto. At such time, the Collateral Agent authorizes the filing by such Grantor of an appropriate termination hereof.

Section 8. Intercreditor Agreement. Notwithstanding anything herein to the contrary, the security interest granted pursuant to this [Copyright] [Patent] [Trademark] Security Agreement, the terms of this [Copyright] [Patent] [Trademark] Security Agreement and the exercise of any right or remedy hereunder are subject to the provisions of the Intercreditor Agreement, dated as of March 16, 2022, by and between the Collateral Agent, RTW Investments ICAV (for and on behalf of RTW Fund 2) and acknowledged and agreed to by Grantor and Borrower (as may be amended, restated, amended and restated, supplemented or otherwise modified from time to time).

IN WITNESS WHEREOF, Grantor has caused this [Copyright] [Patent] [Trademark] Security Agreement to be executed and delivered by its duly authorized officer as of the date first set forth above.

Very truly yours,

[GRANTOR]
as Grantor

By: _____
Name:
Title:

ACCEPTED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

SCHEDULE I
TO
[COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT

[Copyright] [Patent] [Trademark] Registrations

1. REGISTERED [COPYRIGHTS] [PATENTS] [TRADEMARKS]

[Include Registration Number and Date]

2. [COPYRIGHT] [PATENT] [TRADEMARK] APPLICATIONS

[Include Application Number and Date]

3. [IP LICENSES

[Include complete legal description of agreement (name of agreement, parties and date)]

ANNEX 4
TO
GUARANTY AND SECURITY AGREEMENT
FORM OF UNCERTIFICATED STOCK CONTROL AGREEMENT

This UNCERTIFICATED STOCK CONTROL AGREEMENT (this "**Agreement**"), dated as of _____ __, 20__, is made by and among [APPLICABLE GRANTOR], a [JURISDICTION OF ORGANIZATION] [ENTITY TYPE] (the "**Grantor**"), BIOPHARMA CREDIT PLC, a public limited company organized under the laws of England and Wales, as collateral agent on behalf of the Secured Parties (together with its successors and permitted assigns, the "**Collateral Agent**"), and [APPLICABLE INTEREST ISSUING COMPANY], a [JURISDICTION OF ORGANIZATION] [ENTITY TYPE] (the "**Issuer**"). All capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Security Agreement (as defined below) or the Loan Agreement (as defined below), as applicable.

WHEREAS, UROGEN PHARMA, INC., a Delaware corporation ("**Borrower**"), the Collateral Agent and the Lenders have entered into that certain Loan Agreement, dated as of March 7, 2022 (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**");

WHEREAS, the Grantor is the registered holder of [DESCRIBE PLEDGED UNCERTIFICATED STOCK] issued by the Issuer (the "**Pledged Stock**");

WHEREAS, pursuant to the Guaranty and Security Agreement, dated as of March 16, 2022, by and among the Grantor, the Collateral Agent and the other parties thereto (as amended, amended and restated, supplemented or otherwise modified from time to time, the "**Security Agreement**"), the Grantor has granted a continuing Lien on and security interest (the "**Security Interest**") in, all of its right, title and interest in, to and under the Pledged Stock (other than Excluded Equity Interests), whether now existing or hereafter arising or acquired; and

WHEREAS, it is a condition precedent to the making and maintaining of the Term Loans by Lenders under the Loan Agreement that the parties hereto execute and deliver this Agreement in order to perfect a first priority Security Interest in the Pledged Stock.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree, intending to be legally bound, as follows:

1. The Issuer confirms that:

(h) The Pledged Stock is Equity Interests that are not represented by certificates;

(i) The Issuer is the issuer of the Pledged Stock and the Grantor is registered on the books and records of the Issuer as the registered holder of the Pledged Stock; and

(j) The Security Interest in the Pledged Stock is registered on the books and records of the Issuer.

2. The Grantor hereby irrevocably agrees that, for so long as this Agreement remains in effect, the Collateral Agent, for the benefit of Lenders and the other Secured Parties, shall have exclusive control of the Pledged Stock. In furtherance of such agreement, the Grantor hereby irrevocably authorizes and directs the Issuer, and the Issuer hereby agrees:

(k) Subject to the provisions of Section 3 hereof, to comply with any and all written instructions delivered to the Issuer which directs that the transfer of any or all of the Pledged Stock to the Collateral Agent be registered on the books and records of the Issuer in the name of the Collateral Agent as the holder thereof, for the benefit of Lenders and the other Secured Parties, without further consent by the Grantor or any other Person; and

(l) Subject to the provisions of Section 3 hereof, not to comply with any instructions relating to any or all of the Pledged Stock originated by any Person other than the Collateral Agent, on behalf of Lenders and the other Secured Parties, or a court of competent jurisdiction. In the event of any conflict between any instruction originated by the Collateral Agent and any instruction originated by any other Person, the Issuer shall comply only with the instruction originated by the Collateral Agent.

3. In addition to, and not in lieu of, the obligation of the Issuer to honor instructions as agreed in Section 2 hereof, the Issuer and the Collateral Agent hereby agree as follows:

(m) Subject to the rights of the Grantor described herein, the Issuer agrees that, from and after the date hereof, the Pledged Stock shall be under the exclusive dominion and control of the Collateral Agent;

(n) So long as the Issuer has not received a written notice from the Collateral Agent that it is exercising exclusive control over the Pledged Stock (a "**Notice of Exclusive Control**"), the Issuer may comply with instructions of the Grantor concerning the Pledged Stock, which Notice of Exclusive Control shall only be given by the Collateral Agent following the occurrence and during the continuance of an Event of Default. After the Issuer receives a Notice of Exclusive Control from the Collateral Agent, the Issuer will not accept any instructions concerning the Pledged Stock from any Person other than the Collateral Agent, unless otherwise ordered by a court of competent jurisdiction; and

(o) Until the Issuer receives a Notice of Exclusive Control, the Grantor shall be entitled to direct the Issuer with respect to voting the Pledged Stock.

4. This Agreement shall not subject the Issuer to any obligation or liability except as expressly set forth herein and under any Requirements of Law. In particular, the Issuer need not investigate whether the Collateral Agent is entitled under the Security Agreement or otherwise to give an instruction or Notice of Exclusive Control.

5. The Issuer hereby represents, warrants and covenants with the Collateral Agent that:

(p) This Agreement has been duly authorized, executed and delivered by the Issuer and constitutes a legal, valid and binding obligation of the Issuer enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law);

(q) The Issuer has not entered into, and until termination of this Agreement will not enter into, any agreement with any other Person relating to the Pledged Stock pursuant to which it has agreed, or will agree, to comply with instructions provided by such Person. The Issuer has not entered into any other agreement with the Grantor purporting to limit or condition the obligation of the Issuer to comply with instructions as agreed in Section 3 hereof;

(r) Except for the claims and interests of the Collateral Agent, on behalf of Lenders and the other Secured Parties, and the Grantor in the Pledged Stock, the Issuer does not know of any claim to, or interest in, the Pledged Stock (except to the extent constituting Permitted Liens). If any Person asserts any Lien or adverse claim (including any writ, garnishment, judgment, attachment, execution or similar process) against the Pledged Stock (other than Permitted Liens), the Issuer will promptly notify the Collateral Agent and the Grantor thereof;

(s) There is no agreement (except this Agreement) between the Issuer and the Grantor or among the Issuer, the Grantor and any third Person with respect to the Pledged Stock [except for [IDENTIFY RELEVANT AGREEMENTS] (the "**Existing Agreements**")]. In the event of any conflict between this Agreement (or any portion hereof) and any other such agreement (including any Existing Agreement) with respect to the Pledged Stock, whether now existing or hereafter entered into, the terms of this Agreement shall prevail; and

(t) The granting by the Grantor of the Security Interest in the Pledged Stock to the Collateral Agent for the benefit of Lenders and the other Secured Parties does not violate the Operating Documents or any other agreement governing the Issuer or the Pledged Stock.

6. This Agreement shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective successors and assigns.

7. Each notice, request or other communication to a party hereto under this Agreement shall be in writing, will be sent to such party's address set forth under its name below or to such other address as such party may notify the other parties hereto and will be effective on receipt.

8. No amendment or modification of this Agreement or waiver of any right hereunder shall be binding on any party hereto unless it is in writing and is signed by all the parties hereto.

9. The rights and powers granted herein to the Collateral Agent (a) have been granted in order to perfect the Security Interest in the Pledged Stock, (b) are powers coupled with an interest and (c) will not be affected by any bankruptcy of the Grantor or any lapse in time. The obligations of the Issuer hereunder shall continue in effect until the Collateral Agent has notified the Issuer in writing that the Security Interest in the Pledged Stock has been terminated pursuant to the Security Agreement.

10. This Agreement shall be governed by and construed in accordance with the laws of the [ISSUER'S JURISDICTION OF ORGANIZATION], WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN [ISSUER'S JURISDICTION OF ORGANIZATION] SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN THE PLEDGED STOCK, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT].

11. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

12. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

[Signature Page Follows]IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

[GRANTOR]

By:

Name:

Title:

Address for Notices:

[ISSUER]

By:

Name:

Title:

Address for Notices:

BIOPHARMA CREDIT PLC,

a public limited company

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

Address for Notices:

BIOPHARMA CREDIT PLC
c/o Beaufort House
51 New North Road

Exeter EX4 4EP
United Kingdom
Attention: Company Secretary
Telephone: +44 01 392 477 500
Facsimile: +44 01 392 498 288

Email: biopharmacreditplc@linkgroup.co.uk

with copies (which shall not constitute notice) to:

Pharmakon Advisors LP

110 East 59th Street, #3300

New York, NY 10022

Attn: Pedro Gonzalez de Cosio

Phone: +1 (212) 883-2296

Fax: +1 (917) 210-4048

Email: Pharmakon@PharmakonAdvisors.com

and

Akin Gump Strauss Hauer & Feld LLP

One Bryant Park

New York, NY 10036-6745

Attn: Geoffrey E. Secol

Phone: (212) 872-8081

Fax: (212) 872-1002

Email: gsecol@akingump.com

EXHIBIT D

COMMITMENTS; NOTICE ADDRESSES

Lender	Commitments	Notice Address
BPCR Limited Partnership	Tranche A Commitment: $37,500,000.00 Tranche B Commitment: $12,500,000.00 Tranche C Commitment: $0.00	BPCR LIMITED PARTNERSHIP c/o Link Group, Company Matters Ltd. 6th Floor 65 Gresham Street London EC2V 7NQ United Kingdom

	Tranche D Commitment: $0.00	Attn: Company Secretary Tel: +44 01 392 477 500 Fax: +44 01 392 438 288 Email: biopharmacreditplc@linkgroup.co.uk with copies (which shall not constitute notice) to: PHARMAKON ADVISORS, LP 110 East 59th Street, #2800 New York, NY 10022 Attn: Pedro Gonzalez de Cosio Phone: +1 (212) 883-2296 Fax: +1 (917) 210-4048 Email: pharmakon@pharmakonadvisors.com and AKIN GUMP STRAUSS HAUER & FELD LLP One Bryant Park New York, NY 10036-6745 Attn: Geoffrey E. Secol Phone: (212) 872-8081 Fax: (212) 872-1002 Email: gsecol@akingump.com
BioPharma Credit Investments V (Master) LP	Tranche A Commitment: $37,500,000.00 Tranche B Commitment: $12,500,000.00 Tranche C Commitment: $25,000,000.00 Tranche D Commitment: $75,000,000.00	BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP c/o BioPharma Credit Investments V GP LLC c/o Walkers Corporate Limited 190 Elgin Avenue, George Town, Grand Cayman KY1-9008 Attn: Pedro Gonzalez de Cosio with copies (which shall not constitute notice) to: PHARMAKON ADVISORS, LP 110 East 59th Street, #2800 New York, NY 10022 Attn: Pedro Gonzalez de Cosio Phone: +1 (212) 883-2296 Fax: +1 (917) 210-4048 Email: pharmakon@pharmakonadvisors.com and AKIN GUMP STRAUSS HAUER & FELD LLP One Bryant Park New York, NY 10036-6745 Attn: Geoffrey E. Secol Phone: (212) 872-8081 Fax: (212) 872-1002 Email: gsecol@akingump.com

EXHIBIT E

COMPLIANCE CERTIFICATE

TO: BIOPHARMA CREDIT PLC

FROM: UROGEN PHARMA LTD.

The undersigned authorized officer of UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621, hereby certifies, solely in his/her capacity as a Responsible Officer of UroGen Pharma Ltd. and not in his/her personal capacity, that in accordance with the terms and conditions of the Amended and Restated Loan Agreement (the "**Loan Agreement**"; capitalized terms used, but not defined herein having the meanings given them in the Loan Agreement) dated as of March 13, 2024 by and among UROGEN PHARMA, INC. (as "**Borrower**"), UroGen Pharma Ltd. (as "**Parent**" and a Guarantor), the other Guarantors from time to time party thereto, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales with company number 10443190 (as the "**Collateral Agent**") and the Lenders:

(i) The Credit Parties are in complete compliance for the period ending _____ with all required covenants except as noted below;

(ii) No Default or Event of Default has occurred and is continuing, except as noted below;

(iii) Each Credit Party and each of its Subsidiaries has timely filed all U.S. federal income Tax returns and other material Tax returns and reports (or extensions thereof) of each Credit Party and each of its Subsidiaries required to be filed by any of them and such returns and reports are correct in all material respects, and has timely paid all material Taxes owed which are due and payable by such Credit Party or Subsidiary or upon their respective properties, assets, income, businesses and franchises, except as otherwise permitted pursuant to the terms of Section 4.10 or Section 5.3 of the Loan Agreement; and

(iv) No Liens have been levied or claims made against any Credit Party or any of its Subsidiaries relating to unpaid employee payroll or benefits of which (a) such Credit Party has not previously provided written notification to the Collateral Agent or (b) which do not constitute Permitted Liens.

Attached are the required documents, if any, supporting our certification(s). The undersigned Responsible Officer on behalf of Parent further certifies that the attached financial statements (which shall not be attached if such financial statements are deemed delivered by filing with the SEC on Form 10-Q or 10-K as applicable) fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of applicable the dates and for the applicable periods in accordance with Applicable Accounting Standards consistently applied.

Date: _____

[signature page follows]

UROGEN PHARMA LTD.,
as Parent

By_____

Name: _____

Title: _____

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Complies		
1)	Annual Financial Statements	90 days after year end	Yes	No	N/A
2)	Quarterly Financial Statements	45 days after quarter end	Yes	No	N/A
3)	Other Information after an Event of Default	5 Business Days after request	Yes	No	N/A
4)	Legal Action Notice	Promptly	Yes	No	N/A
5)	Notice of Default, etc.	Promptly (within 5 Business Days) after knowledge	Yes	No	N/A

Deposit and Securities Accounts ***(Please list all accounts and indicate each Excluded Account with an asterisk (*); attach separate sheet if additional space needed)***

	Bank	Account Number	New Account?		Acct Control Agmt in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No
5)			Yes	No	Yes	No
6)			Yes	No	Yes	No

Other Matters

Have there been any changes in management since the last Compliance Certificate? Yes No

Have there been any prohibited Transfers? Yes No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

_____

_____

_____

_____

LENDER USE ONLY

Compliance Status Yes

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-274423 and 333-268398) and Form S-8 (Nos. 333-275547, 333-266761, 333-263729, 333-258496, 333-243750, 333-232034, 333-227812, 333-222955, 333-221212, and 333-218992) of UroGen Pharma Ltd. of our report dated March 14, 2024 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
March 14, 2024

Exhibit 31.1

CERTIFICATIONS

I, Elizabeth Barrett, certify that:

1. I have reviewed this Annual Report on Form 10-K of UroGen Pharma Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2024

/s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Don Kim, certify that:

1. I have reviewed this Annual Report on Form 10-K of UroGen Pharma Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2024

/s/ Don Kim
Don Kim
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Elizabeth Barrett, Chief Executive Officer of UroGen Pharma Ltd. (the "Company"), and Don Kim, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 14, 2024

IN WITNESS WHEREOF, THE UNDERSIGNED HAVE SET THEIR HANDS HERETO AS OF THE 14TH DAY OF MARCH, 2024.

/s/ Elizabeth Barrett	/s/ Don Kim
Elizabeth Barrett	Don Kim
Chief Executive Officer	Chief Financial Officer

"This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of UroGen Pharma Ltd. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing."

UROGEN PHARMA LTD.

INCENTIVE COMPENSATION RECOUPMENT POLICY

1. INTRODUCTION

The Board of Directors (the "***Board***") and the Compensation Committee (the "***Compensation Committee***") of the Board of **UroGen Pharma Ltd.**, a company organized and existing under the laws of the State of Israel (the "***Company***"), have determined that it is in the best interests of the Company and its shareholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. DEFINITIONS

"Accounting Restatement" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"Accounting Restatement Date" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"Administrator" means the Compensation Committee or, in the absence of such committee, the Board.

"Code" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"Covered Officer" means each current and former Executive Officer.

"Exchange" means the Nasdaq Stock Market.

"Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended.

"Executive Officer" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"Financial Reporting Measures" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total shareholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"Incentive Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"Lookback Period" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"Recoverable Incentive Compensation" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regarding to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive

Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"SEC" means the U.S. Securities and Exchange Commission.

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards;

(ii) recoupment of the applicable Recoverable Incentive Compensation would violate home country law where that law was adopted prior to November 28, 2022; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the Exchange, that recoupment would result in such a violation, and shall provide such opinion to the Exchange in accordance with the Listing Standards;

(iii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("***SOX 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

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