UroGen Pharma Ltd.

2024 ANNUAL REPORT

UroGen® Pharma

Dear Shareholders,

It is with great enthusiasm and excitement that we share our annual update with you this year. We are embarking on a new era in our company as we strive for leadership in urothelial and specialty cancers. This past year has been monumental in advancing that goal as we hold true to our mission to bring innovative solutions to patients who deserve better.

We recently achieved a major milestone for UroGen with the FDA approval and launch of ZUSDURI™ (mitomycin) for intravesical solution (formerly UGN-102). Approved on June 12th, ZUSDURI is the first and only FDA-approved treatment for adults with recurrent low-grade, intermediate-risk non–muscle-invasive bladder cancer (LG-IR-NMIBC). Patients with this disease often face multiple surgeries under general anesthesia over many years. For the first time, they now have access to a non-surgical, intravesical therapy that may provide longer recurrence- and treatment-free intervals.

This approval positions ZUSDURI as a potential new standard of care and a cornerstone of our commercial business. We estimate the U.S. market opportunity exceeds $5 billion. This launch marks a pivotal step in UroGen's evolution from a rare disease-focused company to a multi-product organization serving a broader patient population. As our second FDA-approved product, ZUSDURI benefits from our existing commercial infrastructure and experience. We have expanded our sales force and strengthened customer support to help promote broad adoption and smooth integration into practice. We are encouraged by the interest we've seen among urologists, with our prior research indicating broad intent to adopt ZUSDURI in practice.

The approval and launch of ZUSDURI reflect years of dedicated work by the UroGen team, investigators, patients, and caregivers. We are deeply grateful for their partnership in advancing this innovative therapy, and we thank the FDA for its close collaboration.

Alongside ZUSDURI, our first product, JELMYTO, for low-grade upper tract urothelial carcinoma (LG-UTUC), continues to show growth across key metrics such as overall volume, patient enrollment forms, and new patient starts. Our commercial strategy leverages the impressive durability of response seen in long-term follow-up from the Olympus Phase 3 trial and real-world evidence. Our team remains focused on a high-touch approach with key accounts to ensure JELMYTO, which addresses a high unmet need for patients, remains an important part of our portfolio.

We have a robust development plan for our next-generation urothelial cancer investigational assets. UGN-103, for recurrent LG-IR-NMIBC and potentially other indications, combines our proprietary RTGel technology with medac GmbH's unique mitomycin formulation. The Phase 3 UTOPIA trial is fully enrolled with an NDA submission projected for 2026 and potential launch in 2027. In February, the FDA accepted our IND for UGN-104 for LG-UTUC, and we initiated the Phase 3 trial. We also expanded our pipeline with the acquisition of UGN-501 (formerly ICVB-1042), a unique oncolytic virus designed to selectively destroy cancer cells and trigger a robust immune response. UGN-501 has potential as a locally administered immunotherapy for high-grade bladder cancer and other specialty cancers, aligning with our vision to address critical gaps in care.

Our balance sheet remains strong, providing the necessary capital to fund the ZUSDURI launch while supporting the advancement of our pipeline and other strategic priorities. This is an exciting time for UroGen as we remain focused on creating long-term value for patients and you, our shareholders. We appreciate your confidence and your continued support.

Warm regards,

Liz Barrett
President and Chief Executive Officer

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, 2024

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 28, 2024 totaled approximately $675.1 million based on the closing price of 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 28, 2024.

As of March 3, 2025, there were 46,094,352 of the registrant's ordinary shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	**10-K Part**
Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 30, 2024 are incorporated by reference into Part III of this report.	III

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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 U.S. Generally Accepted Accounting Principles ("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” and “$” 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,” “continue,” “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 may 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.
- The data from our pivotal Phase 3 ENVISION trial and supporting ATLAS and OPTIMA II trials may be insufficient to support regulatory approval of UGN-102.
- 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 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 with Pharmakon Advisors, L.P. ("Pharmakon") 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 that receive regulatory approval 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 candidates, UGN-102 (mitomycin) for intravesical solution, UGN-103 (mitomycin) for intravesical solution and UGN-104 (mitomycin) for pyelocalyceal 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") in the case of *Jelmyto* and UGN-104 and low-grade intermediate risk non-muscle invasive bladder cancer ("low-grade intermediate risk NMIBC") in the case of UGN-102 and UGN-103. In addition, our immuno-uro-oncology pipeline includes UGN-301 (zalifrelimab), an anti-CTLA-4 antibody, which we are currently studying as both a 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 *Jelmyto,* UGN-102, UGN-103 and UGN-104. 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.

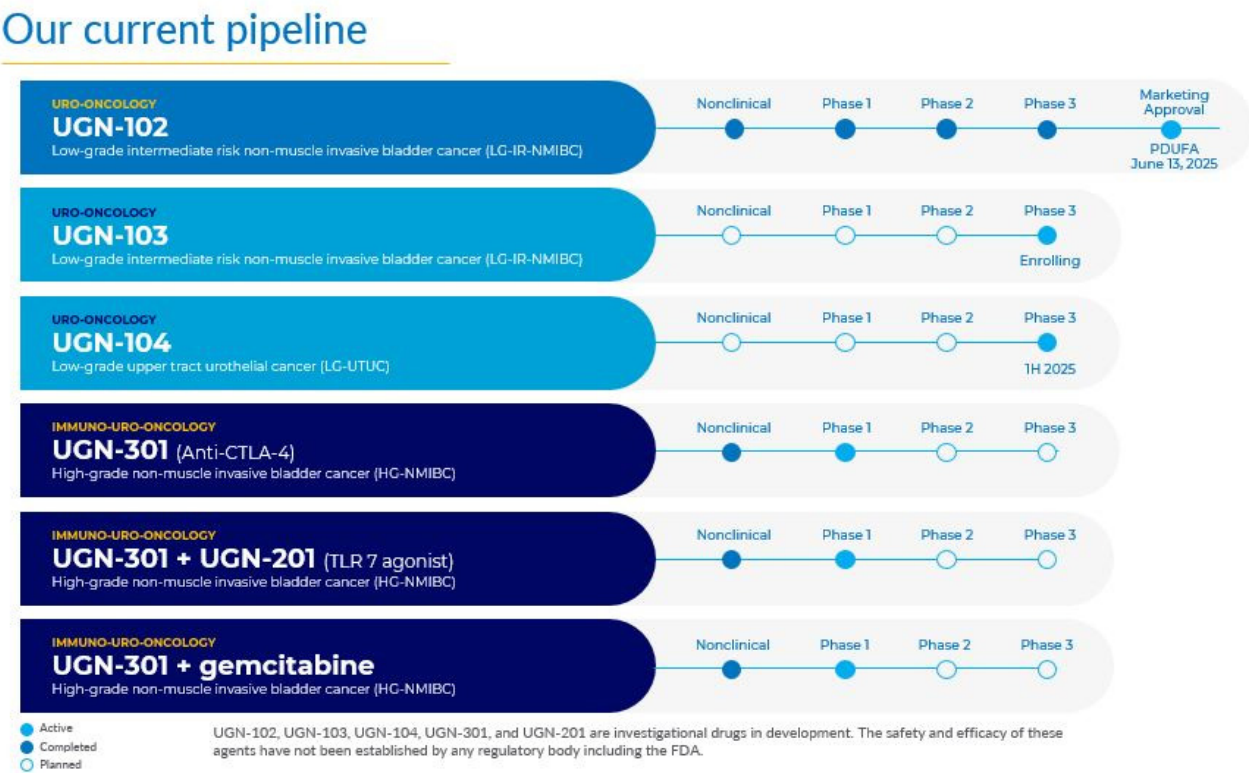
Mitomycin—Our Target Active Drug for the Treatment of Low-Grade UTUC and Low-Grade Intermediate Risk NMIBC

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. Increased dwell time, facilitated by our *RTGel* preparations *Jelmyto,* UGN-102, UGN-103 and UGN-104, is designed to increase cell killing in vitro when compared to aqueous solutions of mitomycin.

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 can impede the effectiveness of organ-sparing endoscopic tumor resection and instillation of adjuvant chemotherapy, 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). 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 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 November 2024, we published results from a long-term follow-up study with *Jelmyto* evaluating 20 of the 41 patients from the OLYMPUS trial who achieved a CR after primary chemoablation with *Jelmyto. T*he median duration of response in this subset of patients was 47.8 months. The study results are published online in the *Journal of Urology*.

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 eight regional business director positions, who are in turn supported by eight 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 a key account director who engages 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 100 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 Ambulatory Payment Classification ("APC"), 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 who 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. Moreover, we filed two new U.S. patent applications with the USPTO, that relate to compositions comprising UGN-102 and for the method of treating bladder cancer.

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: a 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 82,000 in the U.S. annually.

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

Recurrence is the primary threat for patients with low-grade NMIBC. Up to 70% of NMIBC patients experience at least one recurrence and low-grade intermediate risk NMIBC patients are even more likely to recur and face repeated TURBT procedures. 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

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 June 2024, we announced positive secondary endpoint duration of response (“DOR”) data from the Phase 3 ENVISION trial investigating UGN-102 for intravesical solution in patients with low-grade intermediate risk NMIBC. In the ENVISION trial, the 12-month DOR data by Kaplan-Meier estimate for patients who achieved a CR at three months after the first instillation of UGN-102 was 82.3% (95% CI, 75.9%, 87.1%). The ENVISION trial met its primary endpoint with patients having a 79.6% (73.9%, 84.5%) CR rate at three months after the first instillation of UGN-102. Among the patients in the ENVISION trial who achieved a CR at three months, 76.4% (69.8%, 82.3%) maintained a CR at 12 months. Among all 240 patients enrolled in the ENVISION trial, 60.8% (54.3%, 67.0%) were in CR at 12 months. In the ENVISION trial, DOR Kaplan-Meier estimates at 15 (n=43) and 18 (n=9) months were both 80.9% (95% CI, 73.9%, 86.2%) with a median follow-up time of 13.8 months after the 3-month CR. The ENVISION trial demonstrated a similar safety profile to that observed in the OPTIMA II and ATLAS trials, with treatment-emergent adverse events typically mild-to-moderate in severity. The ENVISION trial data was published online in The Journal of Urology in October 2024 and was included in the February 2025 print edition.

In March 2025, we announced updated 18-month DOR data from the Phase 3 ENVISION trial. The 18-month DOR by Kaplan-Meier estimate for patients who achieved a CR at three months after the first instillation of UGN-102 remained consistent with the 12-month DOR data: 80.6% (95% CI, 74.0%, 85.7%) at 18-months (n=101) compared to 82.5% (76.1%, 87.3%) at 12-months (n=146). Median follow-up time was 18.7 months after the 3-month CR.

We also completed 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 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. In August 2024, we completed the submission of the rolling NDA for UGN-102. In October 2024, the FDA accepted our NDA for UGN-102 (mitomycin) for intravesical solution and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 13, 2025. We anticipate, and are preparing for, an FDA advisory committee meeting. If approved, UGN-102 would become the first FDA-approved medicine for the treatment of low-grade intermediate-risk NMIBC.

UGN-103 (mitomycin) for intravesical solution and UGN-104 (mitomycin) for pyelocalyceal solution

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 80 mg mitomycin formulation with our *RTGel* technology, which we believe will provide advantages related to production, cost, supply and product convenience. Medac has intellectual property protection for its proprietary mitomycin formulation technology expected through June 2035. In April 2024, we announced that the FDA accepted our Investigational New Drug Application ("IND") for UGN-103 and we initiated our Phase 3 UTOPIA trial, a single-arm, multicenter study that will evaluate the efficacy and safety of UGN-103 in low-grade intermediate risk NMIBC. We plan to enroll 87 patients in the UTOPIA trial, with patients receiving 75 mg of mitomycin via intravesical instillation once a week for six weeks. Efficacy will be assessed by the CR rate at the three-month visit. Patients who have a CR at the three-month visit, defined as having no detectable disease in the bladder, will enter the follow-up period of the study. Patients will remain on study until disease recurrence, disease progression, death, or the last patient completes 12 months of follow-up (i.e., 15 months after the first instillation), whichever occurs first. In October 2024, we announced the first patient dosed in the UTOPIA trial. An NDA submission is projected for 2026, followed by a standard review period and potential approval and, if approved, the commercial launch in 2027. In February 2025, the FDA accepted our IND for UGN-104. We plan to initiate a Phase 3 trial of UGN-104 in low-grade UTUC in the first half of 2025.

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 surgical removal of the bladder, 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

Six 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; Adstiladrin® (nadofaragene firadenovec-vncg), which was approved by the FDA in 2022 for BCG unresponsive carcinoma in situ ("CIS") and Anktiva® (nogapendekin alfa inbakicept-pmln) in combination with BCG, which was approved by the FDA in 2024 for BCG unresponsive CIS. However, despite the approvals of these novel treatments, recurrence and progression rates remain high.

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. 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 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 are investigating these combinations to determine if they may 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 enrollment in all three of the current arms of the study are complete. Safety and dosing data from the first arm evaluating UGN-301 as monotherapy was presented in late 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.

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 45 granted patents worldwide and more than 45 pending patent applications filed in the US, Europe, Israel, Japan, Canada, China, Australia and Korea. In the United States, we currently have 18 granted unexpired 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, including, inter alia, compositions comprising a Botulinum Toxin,

UGN-201, UGN-301, the use of UGN-201 and UGN-301 and our other product candidates in development, including UGN-103 and UGN-104 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 2025 and 2041, and our patent applications, if issued, are set to expire between 2031 and 2043.

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.

In August 2024, we completed the submission of a rolling NDA for UGN-102. In October 2024, the FDA accepted our NDA for UGN-102 and assigned a PDUFA goal date of June 13, 2025. We believe that UGN-102 has the potential to be the first FDA-approved therapeutic option for the treatment of low-grade intermediate risk NMIBC patients.

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. In October 2024, we initiated a Phase 3 study 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 the first half of 2025 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, as well as UGN-103 and UGN-104, a proprietary *RTGel* technology, local compositions comprising different active ingredients, including, inter alia, compositions comprising a Botulinum Toxin, UGN-201, UGN-301, the use of UGN-201 and UGN-301, and our future product candidates that are under company research.

In total, our IP portfolio includes 45 granted patents worldwide and more than 45 pending patent applications filed in the US, Europe, Israel, Japan, Canada, China, Australia and Korea. In the United States, we currently have 18 granted unexpired 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, including, inter alia, compositions comprising a Botulinum Toxin, UGN-201, UGN-301, the use of UGN-201 and UGN-301 and our other product candidates in development, including UGN-103 and UGN-104 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 2025 and 2041, and our 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, Australia and Korea 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-CTLA4 (for example, zalifrelimab) for topical/intravesical administration as a monotherapy or a combo-therapy with immunomodulators or chemotherapy drugs.
- 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* ® and UroGen ® 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 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 ImPact Biotech with an IND granted in December 2020 that 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 Johnson & Johnson, CG Oncology, Aura Biosciences and LIPAC Oncology 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, and since its approval, only four other drugs have been approved for high-grade NMIBC: Valstar, approved by the FDA in 1998; Keytruda, approved by the FDA in 2020; Adstiladrin, approved by the FDA in 2022 for BCG unresponsive CIS; and Anktiva, approved by the FDA in 2024, in combination with BCG for BCG unresponsive CIS. Valstar is indicated for patients with CIS who 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. Additionally, in January 2025 Johnson & Johnson announced the submission of their NDA for TAR-200 for the treatment of patients with BCG unresponsive high-risk NMIBC with CIS.

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, Aura Biosciences, Inc., Biocancell Ltd., Bristol Myers Squibb, CG Oncology Inc., enGene Holdings, Ferring Pharmaceuticals, FKD Therapies Oy, GSK, ImmunityBio, ImPact Biotech, Johnson & Johnson, LIPAC Oncology, Merck Sharp & Dohme Corp, Pfizer, Prokarium, Protara Therapeutics, Roche, Samyang Biopharma, SURGE Therapeutics, Tyra Biosciences, 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. See Part I, Item 3. "Legal Proceedings" for additional discussion.

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 the 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 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, the American Rescue Plan Act of 2021 was signed 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, effective from October 1, 2023. A service is separately paid for 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 APC.

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 certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed 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 current administration will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2032 unless additional Congressional action is taken.

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, on November 15, 2021, the Infrastructure Investment and Jobs Act was signed into law. Effective 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 high expenditure single-source drugs that have been on the market for at least 7 years covered under Medicare (the "Medicare Drug Price Negotiation Program") and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, the an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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, particularly given the recent change in administration. The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation ("CMMI") to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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 *Jelmyto* or 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 *Jelmyto* and 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 of our product candidates that receives regulatory approval.

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 eight regional business director positions, who are in turn supported by eight 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 100 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, 2025, we had 235 employees worldwide, 195 in the United States and 40 in Israel, many of whom hold advanced degrees. 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 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 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 $126.9 million and $102.2 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $806.2 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 may 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, 2024, we had cash and cash equivalents and marketable securities of $241.7 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 TD Securities (USA) LLC (f/k/a Cowen and Company, LLC) (“TD 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. As of December 31, 2024, $27.3 million remains available for sale under the ATM Sales Agreement.

In March 2021, we announced a transaction (the “RTW 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. In return for the upfront cash payment, RTW is entitled to receive tiered future cash payments based on aggregate worldwide annual net product sales of *Jelmyto* and, subject to FDA approval, UGN-102, UGN-103 and UGN-104.

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 with funds managed by Pharmakon, 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 “Initial 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 was funded in September 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables.

We may 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. We may also 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 with Pharmakon could adversely affect our financial condition or restrict our future operations.

In March 2022, we entered into a loan agreement with Pharmakon pursuant to which the Lenders funded the Initial Term Loans to the 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. The third tranche of $25.0 million was funded in September 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables. There is no assurance that the additional term loan will become available.

The obligations of the Borrower under the loan agreement with Pharmakon 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 of 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. Other than the fourth tranche that may become available under the loan agreement with Pharmakon, 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 in us 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*. 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 of 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 the 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, other ongoing clinical studies and the ongoing uTRACT *Jelmyto* Registry to evaluate real world experience and outcomes of patients with low-grade UTUC treated with *Jelmyto* in the United States 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 and any future product candidates will be harmed.

Our sales force has only promoted *Jelmyto* since 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. We generally manage and deploy our sales force by geographic coverage across the United States. Open coverage due to turnover of personnel, and/or inability to identify and integrate additional personnel would have a negative impact on our ability to engage with physicians and other stakeholders. If we are unable to effectively train, deploy and retain 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,* any future product candidates, and their proper administration, our efforts to successfully commercialize *Jelmyto* and any future product candidates could be put in jeopardy, which would negatively impact our ability to generate product revenues.

There can be no assurance that our sales force 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, Aura Biosciences, Inc., Biocancell Ltd., Bristol Myers Squibb, CG Oncology Inc., enGene Holdings, Ferring Pharmaceuticals, FKD Therapies Oy, GSK, ImmunityBio, ImPact Biotech Ltd., Johnson & Johnson, LIPAC Oncology, Merck Sharp & Dohme Corp, Pfizer, Prokarium, Protara Therapeutics, Roche, Samyang Biopharma, SURGE Therapeutics, Tyra Biosciences, Viralytics Limited and Vyriad. We are aware that Ferring Pharmaceuticals is marketing Adstiladrin, approved by the FDA for the treatment of high-risk BCG-unresponsive NMIBC, and that in 2024 the FDA approved ImmunityBio's product ANKTIVA for the treatment of BCG-unresponsive NMIBC with CIS, with or without papillary tumors. 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, we received from Teva a Paragraph IV Certification Notice Letter in February 2024, 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. See Part I, Item 3. "Legal Proceedings" for additional discussion. If we are unable to maintain patent protection for *Jelmyto, Jelmyto* may be subject to immediate competition from FDA approved generic entrants after orphan drug exclusivity for *Jelmyto* 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 urothelial 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 the FDA accepted our NDA for UGN-102 in October 2024, there is no guarantee that the FDA will 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 approve NDAs for a variety of reasons. Additionally, the FDA or other comparable foreign regulatory authorities may also require a panel of experts, referred to as an advisory committee, to deliberate on the adequacy of the safety and efficacy data to support approval of UGN-102. We currently anticipate that the FDA will require an advisory committee for UGN-102. The opinion of the advisory committee, although not binding, may have a significant impact on our ability to obtain approval for UGN-102 based on the completed clinical trials, as the FDA or comparable foreign regulatory authorities often adheres to the advisory committee's recommendations. However, even if the advisory committee provides a positive recommendation, there is no guarantee that the FDA will follow the advisory committee's recommendations and there are numerous examples of the FDA departing from the recommendations of its advisory committee. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

The success of our product candidates is subject to significant risks and uncertainties, 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 decision to schedule an advisory committee meeting, and to conduct such meeting, in a timely manner to evaluate and make a recommendation regarding our NDA for UGN-102;
- the outcome of an advisory committee meeting remains uncertain and it is possible that the advisory committee will have an adverse or split recommendation with respect to our application to market UGN-102 or our other product candidates in the United States;
- if applicable, even if FDA's advisory committee recommends approval of 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 is not bound by the advisory committee's recommendation and there are a number of instances where the FDA has voted against the recommendations of advisory committees;
- the FDA's determination of safety and efficacy of our product candidates;
- the FDA's determination that the Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") regulatory pathway ("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 active ingredient, *RTGel* hydrogel, and finished product from third-party suppliers for product candidates, including UGN-102, UGN-103, UGN-104, UGN-201 and UGN-301, 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.

The data from our pivotal Phase 3 ENVISION trial and supporting ATLAS and OPTIMA II trials may be insufficient to support regulatory approval of UGN-102.

On July 27, 2023, we announced that UGN-102 met its primary endpoints in the Phase 3 ATLAS and ENVISION trials. Additionally, on June 13, 2024, we announced positive secondary endpoint DOR data from the Phase 3 ENVISION trial. The primary and secondary endpoints data from the ENVISION trial (and the other clinical trial data contained in NDA submission) may not be sufficient to satisfy the regulatory threshold for approval, or we may receive other data that negatively impacts the efficacy and safety profile of UGN-102.

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.

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 completed submission of our NDA for certain product candidates in our pipeline, and we may be delayed in obtaining or fail 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 after 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, as the clinical trials for UGN-102 progressed with incrementally larger study populations, 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 product 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.

We plan to devote a substantial portion of our resources to the continued clinical testing and potential approval and commercial launch 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 may need 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 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 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 supplier 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 the mitomycin contained in 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

manufacture our drug components or purchase required 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. 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* and planned future commercialization of UGN-102, if approved, 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, 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 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, 2025, we had 235 employees, of whom 40 are based in Israel and 195 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* and pre-commercialization efforts for UGN-102, 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 or market 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 as well as coverage to include the commercialization of *Jelmyto*. 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. 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 with whom we work, 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 of sensitive information related to our business; harm to our reputation; triggering our breach notification obligations; preventing 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 with whom we work, 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 with whom we work, 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 with whom we work. 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 with whom we work, 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 with whom we work 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. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

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 utilize third parties 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 certain third parties with whom we work), 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 with whom we work) 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 have required 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, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, regulators and investors, of certain security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Most jurisdictions have enacted laws requiring companies to notify individuals, regulatory authorities, and others of security incidents involving certain types of data. In addition, our agreements with collaborators may require us to notify them in the event of a security incident. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to 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 security 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 security 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 customers 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 could 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 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 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 2024 by a total of 1.2%. 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 affect 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 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, pandemics, 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 and 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 Jelmyto, 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 own, co-own or exclusively license 25 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, our proprietary *RTGel* technology, local compositions comprising different active ingredients, including, 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 2025 and 2041. In total, our IP portfolio includes 45 granted patents worldwide, and more than 45 pending patent applications filed in the U.S., Europe, Israel, Japan, Canada, China, Australia and Korea 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 and combination 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 application 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 any pending patent application 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 patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing laws 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. 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 *Jelmyto* or our product candidates, we may be open to competition from generic versions thereof. We received a Paragraph IV Certification Notice Letter from Teva in February 2024, 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. See Part I, Item 3. "Legal Proceedings" for additional discussion. 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 approved product or 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, we received a Paragraph IV Certification Notice Letter from Teva in February 2024, 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*. See Part I, Item 3. “Legal Proceedings” for additional discussion.

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 initiate 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. The AIA's procedures include inter partes review and post grant review. These procedures bring 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 or 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 or 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. Under the Israeli Patents Law, 5727-1967 (the "Patent Law"), inventions conceived by an employee during the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent an agreement between the employee and employer giving the employee service invention rights. The Patents Law also provides that if there is no agreement between an employer and an employee determining whether the employee is entitled to receive remuneration for service inventions and on what terms, the Israeli Compensation and Royalties Committee (the "Committee"), a body constituted under the Patents Law, has the authority to determine whether the employee is entitled to remuneration for his or her inventions and the scope of such remuneration. Case law clarifies that the right to receive consideration for "service inventions" can be waived by the employee. The Committee will examine, on a case-by-case basis, the general contractual framework between the parties, using interpretation rules of general Israeli contract law. Further, the Committee has not yet determined one specific formula for calculating this remuneration, but rather uses the criteria specified in the Patents Law. Although we enter into agreements with our Israeli employees pursuant to which such individuals assign to us all rights to any inventions created during and as a result of their employment with us and waive their right to remuneration for service inventions, we may nonetheless face claims by employees demanding remuneration beyond their regular salary and benefits. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and/or former employees, or be forced to litigate such claims, which could negatively affect our business.

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, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA") was signed into law. The ACA 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 and amendments to certain aspects of the For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed 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 current administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2032 unless additional Congressional action is taken. Further, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, previously set at 100% of a drug's AMP, for single source and innovator multiple source drugs, effective 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, on November 15, 2021, the Infrastructure Investment and Jobs Act was signed into law. On January 1, 2023, manufacturers began to be required to pay quarterly refunds to the Centers for Medicare & Medicaid Services ("CMS")for discarded amounts of certain single-dose container and single-use package drugs payable under part B of the Medicare program. Refunds are generally 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 the U.S. Department of Health and Human Services ("HHS") to negotiate the price of certain high expenditure, single-source drugs that have been on the market for at least 7 years covered under Medicare (the "Medicare Drug Price Negotiation Program") and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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. Further, the current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the CMMI to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper Bright"), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for Jelmyto or our future product candidates, if approved, which could have a material adverse effect on our business, financial condition and results of operations.

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 to 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 and the third parties with whom we work 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") 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 and allows private litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws are being considered at the federal, state, and local levels and we expect more states to pass similar laws in the future. Furthermore, we are 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 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 or have already adopted similarly stringent 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 CROs, 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. Regulators in the United States, such as the Department of Justice, are also increasingly scrutinizing certain personal data transfers and have proposed and may enact certain data localization requirements, for example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

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, whitepapers, and other statements such as statements related to security or compliance with certain certifications or self-regulatory principles, regarding concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, 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 require 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 with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work 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 or restrictions 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; and 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 and any product candidates that receive regulatory approval 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, 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 APC.

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 began to 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, 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 success of our ongoing commercialization 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;
- the sale or proposed sale, by us or 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 TD Cowen, acting as sales agent or principal, in any manner deemed to be an "at-the market offering." As of December 31, 2024, $27.3 million remains available for sale under the ATM Sales Agreement. The shares will be offered and sold, if any, 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, or a subsequent shelf registration statement.

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, 2024. 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 above a fixed profit margin of large multinational companies to market jurisdictions based, broadly, on customer location (referred to as the Pillar One rules) as well as the introduction of a global minimum tax (referred to as the Pillar Two rules). Many countries have enacted, or are in the process of enacting, core elements of the Pillar Two rules. Based on our current understanding of the minimum revenue thresholds, we currently expect to be outside the scope of both the Pillar One and Pillar Two rules, but could fall within their scope in the future, which could increase our tax obligations and compliance costs.

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. 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, may decide to 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. In response, Israel's security cabinet declared war against Hamas. Since the commencement of these events, there have been continued hostilities along Israel's northern border with Lebanon (with Hezbollah) and on other fronts from various extremist groups in region, such as the Houthis in Yemen and various rebel militia groups in Syria and Iraq. In addition, Iran launched direct attacks on Israel. Although a ceasefire was agreed to between Israel and Hezbollah in Lebanon in November 2024, and a ceasefire was agreed to between Israel and Hamas in January 2025, it is possible that the conflict between Israel and Hezbollah in Lebanon, the conflict between Israel and Hamas in Gaza, the Houthi attacks, and other ongoing conflicts will escalate into a greater regional conflict, and that other countries and non-state organizations will join or escalate their involvement in such hostilities.

The scope, intensity and duration of Israel-Hamas war are difficult to predict, as are the economic implications on our business and operations and on Israel's economy in general. For example, these events may be intertwined with wider macroeconomic factors relating to a deterioration of Israel's economic standing that may involve, for instance, a downgrade in Israel's credit rating and outlook by rating agencies. Any of these implications on Israel's security, business, economic or financial conditions may have an adverse effect on our ability to effectively conduct our business, our results of operations and our ability to raise additional funds.

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 certain 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, 2025, 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 for periods ranging from several days to several weeks per year (and in some cases more) until they reach the age of 40 (and in some cases, older) and, in the event of a military conflict, may be called to active duty for extended periods of time. For example, following October 7, 2023, the Israeli Defense Forces 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.

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 granting tax relief to 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 considered to be beneficial by some of our shareholders and may limit the price that investors may be willing to pay in the future for our ordinary shares.

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

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 U.S. federal securities laws, may not be collectible in the United States. Moreover, Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or this director. Additionally, it may also be difficult 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.

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 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, 2025, we had 235 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 us or 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 a proxy contest or matters arising from a 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 war, other hostilities 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 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 recently finalized rules designed to enhance and standardize climate-related disclosures. These climate disclosure rules have been challenged in court and the SEC has issued an order staying their implementation pending the outcome of judicial review. These new climate-related disclosures, if required, may significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to impact our reputation negatively and/or that harm our share price.

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 Vice President of Information Technology 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 reports and 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, our Executive Vice President of Talent, Advocacy & Communications, Vice President of IT, and Associate Director of IT Operations. Our Vice President 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 Executive Vice President of Talent, Advocacy & Communications and Vice President 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

We lease 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

On April 2, 2024, UroGen Pharma Ltd. filed a lawsuit in the U.S. District Court for the District of Delaware against Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd., alleging infringement of U.S. Patent Numbers 9,040,074 and 9,950,069 and seeking a permanent injunction preventing market entry of a generic product from Teva prior to the expiry of such patents. The Company stipulated to the dismissal of Teva Pharmaceutical Industries, Ltd. without prejudice and the action continues against the other two Teva entities. Both patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for *Jelmyto*. The lawsuit follows an Abbreviated New Drug Application filed by Teva Pharmaceuticals, Inc., which seeks authorization from the FDA to manufacture, use or sell a generic version of mitomycin for pyelocalyceal solution, 40 mg/vial in the United States before the expiry of the two patents referenced above. By order dated February 27, 2025, the court approved the parties' joint stipulation to remove the Markman hearing and any related claim-construction proceedings from the court's calendar. This matter is scheduled for a bench trial in October 2026.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Other than as set forth above, we are not currently a party to any material legal proceedings. 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 3, 2025, there were 10 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 candidates, UGN-102 (mitomycin) for intravesical solution, UGN-103 (mitomycin) for intravesical solution and UGN-104 (mitomycin) for pyelocalyceal 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") in the case of *Jelmyto* and UGN-104 and low-grade intermediate risk non-muscle invasive bladder cancer ("low-grade intermediate risk NMIBC")in the case of UGN-102 and UGN-103. In addition, our immuno-uro-oncology pipeline includes UGN-301 (zalifrelimab), an anti-CTLA-4 antibody, which we are currently studying as both monotherapy and combination therapy.

If approved, UGN-102 would become the first U.S. Food and Drug Administration ("FDA") approved medicine for low-grade intermediate risk NMIBC. We estimate that the annual treatable population of low-grade intermediate risk NMIBC in the United States is approximately 82,000, of which approximately 23,000 are estimated to be newly diagnosed and 59,000 are estimated to be recurrent patients. We estimate that the total addressable market opportunity for UGN-102 in low-grade intermediate risk NMIBC is potentially over $5.0 billion, assuming an expected pricing range of $16,000 to $19,000 per dose.

UGN-102, if approved, may be an alternative to the current standard of care for low-grade intermediate risk NMIBC, trans-urethral resection of bladder tumor ("TURBT"). We estimate that approximately 68% of low-grade intermediate risk NMIBC patients have two or more recurrences, with approximately 23% of recurrent patients having five or more recurrences. Repeated TURBT procedures to treat these recurrences can impact patients' physical health and quality of life. We estimate that around 35% of patients will experience an adverse event within 90 days of undergoing a TURBT, and patients who have had two to four procedures have an estimated 14% greater risk of death than patients who have only had one procedure.

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 *Jelmyto,* UGN-102, UGN-103 and UGN-104. 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 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).

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 to 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 radical nephroureterectomy ("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:

- Complete response ("CR") rate (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 November 2024, we published results from a long-term follow-up study with *Jelmyto* evaluating 20 of the 41 patients from the OLYMPUS trial who achieved a CR after primary chemoablation with *Jelmyto. T*he median duration of response in this subset of patients was 47.8 months. The study results are published online in the *Journal of Urology*.

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 eight regional business director positions, who are in turn supported by eight 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 a key account director who engages 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 100 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. The Centers for Medicare & Medicaid Services has granted *Jelmyto* a New Technology 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 who 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 each of the first three fiscal years beginning after the initiation of our commercial launch of *Jelmyto* in June 2020, we experienced a moderate decline in revenue during the third quarter from the preceding quarter. We believe this result was primarily attributable to the nature of low-grade disease, which does not require immediate treatment and therefore we believe there could be an impact in the summer months. However, we did not observe this trend in 2024 and therefore cannot 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 without knowledge of the data. 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. ATLAS continued until the last ongoing patient completed the month 15 visit. On July 27, 2023, we announced topline data from our Phase 3 trials, ATLAS and ENVISION. In the ATLAS trial, UGN-102 with or without TURBT met its primary endpoint of disease-free survival, reducing risk of recurrence, progression, or death by 55% compared to TURBT alone. 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 79.6% rate of CR at three-months following the initial instillation. In both trials, the safety profile of UGN-102 was acceptable, and comparable to that observed in previous clinical trials of UGN-102.

In June 2024, we announced positive secondary endpoint duration of response (“DOR”) data from the Phase 3 ENVISION trial investigating UGN-102 for intravesical solution in patients with low-grade intermediate risk NMIBC. In the ENVISION trial, the 12-month DOR data by Kaplan-Meier estimate for patients who achieved a CR at three months after the first instillation of UGN-102 was 82.3% (95% CI, 75.9%, 87.1%). The ENVISION trial met its primary endpoint with patients having a 79.6% (73.9%, 84.5%) CR rate at three months after the first instillation of UGN-102. Among the patients in the ENVISION trial who achieved a CR at three months, 76.4% (69.8%, 82.3%) maintained a CR at 12 months. Among all 240 patients enrolled in the ENVISION trial, 60.8% (54.3%, 67.0%) were in CR at 12 months. In the ENVISION trial, DOR Kaplan-Meier estimates at 15 (n=43) and 18 (n=9) months were both 80.9% (95% CI, 73.9%, 86.2%) with a median follow-up time of 13.8 months after the 3-month CR. The ENVISION trial demonstrated a similar safety profile to that observed in the OPTIMA II and ATLAS trials, with treatment-emergent adverse events typically mild-to-moderate in severity. The ENVISION trial data was published online in The Journal of Urology in October 2024 and was included in the February 2025 print edition.

In March 2025, we announced updated 18-month DOR data from the Phase 3 ENVISION trial. The 18-month DOR by Kaplan-Meier estimate for patients who achieved a CR at three months after the first instillation of UGN-102 remained consistent with the 12-month DOR data: 80.6% (95% CI, 74.0%, 85.7%) at 18-months (n=101) compared to 82.5% (76.1%, 87.3%) at 12-months (n=146). Median follow-up time was 18.7 months after the 3-month CR.

We also completed 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 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. In August 2024, we completed the submission of the rolling NDA for UGN-102. In October 2024, the FDA accepted our NDA for UGN-102 (mitomycin) for intravesical solution and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 13, 2025. We anticipate, and are preparing for, an FDA advisory committee meeting. If approved, UGN-102 would become the first FDA-approved medicine for the treatment of low-grade intermediate-risk NMIBC.

UGN-103 (mitomycin) for intravesical solution and UGN-104 (mitomycin) for pyelocalyceal solution

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 80 mg mitomycin formulation with our *RTGel* technology, which we believe will provide advantages related to production, cost, supply and product convenience. In April 2024, we announced that the FDA accepted our Investigational New Drug Application (“IND”) for UGN-103 and we initiated our Phase 3 UTOPIA trial, a single-arm, multicenter study that will evaluate the efficacy and safety of UGN-103 in low-grade intermediate risk NMIBC. We plan to enroll 87 patients in the UTOPIA trial, with patients receiving 75 mg of mitomycin via intravesical instillation once a week for six weeks. Efficacy will be assessed by the CR rate at the three-month visit. Patients who have a CR at the three-month visit, defined as having no detectable disease in the bladder, will enter the follow-up period of the study. Patients will remain on study until disease recurrence, disease progression, death, or the last patient completes 12 months of follow-up (i.e., 15 months after the first instillation), whichever occurs first. In October 2024, we announced the first patient dosed in the UTOPIA trial. An NDA submission is projected for 2026, followed by a standard review period and potential approval and, if approved, the commercial launch in 2027. In February 2025, the FDA accepted our IND for UGN-104. We plan to initiate a Phase 3 trial of UGN-104 in low-grade UTUC in the first half of 2025.

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 surgical removal of the bladder, 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 toll like receptor 7 ("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. We are investigating these combinations to determine if they may 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 enrollment in the current arms of the study are complete. Safety and dosing data from the first arm evaluating UGN-301 as monotherapy was presented in late 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.

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, 2024 and December 31, 2023, we recognized $90.4 million and $82.7 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 expenses.

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 contract research organizations, 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 programs, 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)	**2024**	**2023**
Personnel, facility and equipment, and other overhead costs	$ 16,054	$ 16,245
Clinical and other development costs	41,091	29,369
Total	$ 57,145	$ 45,614

See Note 20 to our consolidated financial statements appearing elsewhere in this Annual Report for additional disaggregation of significant research and development expenses. 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 expenses will depend on their clinical success. Research and development expenses 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 expenses 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 expenses 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, UGN-103, UGN-104 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. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through revenues from commercial sales of *Jelmyto* and a combination of equity or debt financings and collaboration arrangements.

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.

Selling and Marketing Expenses

To date, selling and marketing expenses consist primarily of commercial personnel costs (including share-based compensation) along with commercialization activities related to *Jelmyto* and pre-commercialization activities related to UGN-102.

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 transaction with RTW Investments (the "RTW Transaction") (see Note 9 to our consolidated financial statements appearing elsewhere in this Annual Report).

Interest Expense

Interest expense is primarily comprised of interest related to our long-term debt with Pharmakon Advisors, L.P. ("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 $533.9 million as of December 31, 2024. 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, 2024 and 2023

The following table sets forth our results of operations for the years ended December 31, 2024 and 2023.

	Year Ended December 31,		
	2024	2023	Change
		(in thousands)	
Revenue	$ 90,398	$ 82,713	$ 7,685
Cost of revenue	8,881	9,361	(480)
Gross profit	81,517	73,352	8,165
Operating expenses:			
Research and development	57,145	45,614	11,531
Selling and marketing	75,232	54,703	20,529
General and administrative	45,922	38,571	7,351
Total operating expenses	178,299	138,888	39,411
Operating loss	(96,782)	(65,536)	(31,246)
Financing on prepaid forward obligation	(23,411)	(21,552)	(1,859)
Interest expense on long-term debt	(12,521)	(14,715)	2,194
Interest and other income, net	8,672	3,479	5,193
Loss before income taxes	(124,042)	(98,324)	(25,718)
Income tax expense	(2,832)	(3,920)	1,088
Net loss	$ (126,874)	$ (102,244)	$ (24,630)

Revenue

Revenues were $90.4 million and $82.7 million for the years ended December 31, 2024 and 2023, respectively. The increase of $7.7 million was primarily driven by increased underlying demand sales of *Jelmyto,* partially offset by a decrease in CREATES Act sales, which totaled $3.0 million in 2024, compared to $4.4 million of CREATES Act sales in 2023.

Cost of Revenue

Cost of revenue was $8.9 million and $9.4 million for the years ended December 31, 2024 and 2023, respectively. The decrease of $0.5 million is primarily attributable to certain nonrecurring payments made in connection with our supply arrangement in the prior year, lower shipping and warehousing costs and a decrease in the *Jelmyto* unit cost.

Research and Development Expenses

Research and development expenses were $57.1 million and $45.6 million for the years ended December 31, 2024 and 2023, respectively. The increase in research and development expenses of $11.5 million is primarily attributable to higher manufacturing costs, which are recognized as research and development expenses prior to our product candidates receiving FDA approval, regulatory expenses in connection with UGN-102, and costs associated with the Phase 3 UTOPIA trial for UGN-103, partially offset by lower UGN-102 clinical trial costs and costs related to the research into ingredient scale-up and production efficiency for *Jelmyto*.

Selling and Marketing Expenses

Selling and marketing expenses were $75.2 million and $54.7 million for the years ended December 31, 2024 and 2023, respectively. The increase in selling and marketing expenses of $20.5 million is primarily attributable to UGN-102 commercial preparation activities as well as an increase in overall commercial operation costs including compensation, advisory, meetings, conferences, trainings and software costs.

General and Administrative Expenses

General and administrative expenses were $45.9 million and $38.6 million for the years ended December 31, 2024 and 2023, respectively. The increase in general and administrative expenses of $7.3 million is primarily attributable to higher compensation expenses, costs for announcements and communications related to UGN-102, third-party advisory services, and ongoing managed services.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation was $23.4 million and $21.6 million for the years ended December 31, 2024 and 2023, 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. The increase in financing on prepaid forward obligation of $1.8 million was driven primarily by changes in underlying assumptions for remeasuring the effective rate.

Interest Expense on Long-term Debt

Interest expense was $12.5 million and $14.7 million for the years ended December 31, 2024 and 2023, respectively. The decrease of $2.2 million was primarily attributed to the decrease in the margin interest rate and the related impact to amortization of the discount on the Pharmakon loan as a result of the amended and restated loan agreement in March 2024.

Interest and Other Income, Net

Interest and other income, net was $8.7 million and $3.5 million for the years ended December 31, 2024 and 2023, respectively. The increase of $5.2 million in interest and other income, net was primarily due to higher cash and investment balances.

Liquidity and Capital Resources

As of December 31, 2024, we had $241.7 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, 2024, we funded our operations primarily through public equity offerings, private placements of equity securities and our funding arrangements with RTW and Pharmakon.

ATM Sales Agreement

In December 2019, we entered into the ATM Sales Agreement with TD Securities (USA) LLC (f/k/a Cowen and Company, LLC) (“TD 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.

In the first quarter of 2024, we sold 3,400,468 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $56.1 million. The net proceeds to us after deducting sales commissions to TD Cowen were approximately $54.7 million. The remaining capacity under the ATM Sales Agreement was approximately $27.3 million as of December 31, 2024. The shares will be offered and sold, if any, 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, or a subsequent shelf registration statement.

Prepaid Forward Agreement

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.

Pharmakon Loan Agreement

On March 7, 2022, we entered into a loan agreement with Pharmakon (the "Loan Agreement") 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 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 accrued interest using a benchmark rate of 3-month SOFR plus 8.25% plus an additional adjustment of 0.26161%.

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 was funded in September 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables.

Securities Purchase Agreement

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.

Underwritten Public Offering

On June 17, 2024, we entered into an underwriting agreement (the "Underwriting Agreement") with TD Securities (USA) LLC and Guggenheim Securities, LLC, as representatives of the several underwriters named therein (collectively, the "Underwriters"), relating to the issuance and sale in a public offering of 5,000,000 ordinary shares of the Company for $17.50 per share and pre-funded warrants to purchase 1,142,857 ordinary shares of the Company for $17.499 per pre-funded warrant. The offering closed on June 20, 2024. The gross proceeds from this closing of the offering were $107.5 million, before deducting underwriting discounts and commissions and offering expenses of $7.3 million. Each pre-funded warrant has an exercise price of $0.001 per ordinary share, subject to customary adjustments, is exercisable at any time 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. In addition, the Underwriters were granted an option exercisable for 30 days, to purchase up to 921,428 additional shares at the public offering price, less the underwriting discounts and commissions. On July 18, 2024, we completed the closing of the sale of 921,428 additional shares in the offering following the exercise in full of the

Underwriters' option to purchase additional shares, which resulted in additional gross proceeds of $16.1 million before deducting underwriting discounts and commissions and offering expenses of $1.0 million.

We have incurred losses since our inception and negative cash flows from our operations, and as of December 31, 2024 we had an accumulated deficit of $806.2 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 expenses, 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 the advancement of UGN-102 through regulatory approval, our ability to raise additional capital to fund our operations, and produce cash inflows from Jelmyto product sales. Based on our cash, cash equivalents and marketable securities as of December 31, 2024, together with management's cash flow projections, we believe we have sufficient cash and cash equivalents to fund our operations beyond one year from the issuance of our consolidated financial statements appearing elsewhere in this Annual Report. If we are unable to obtain approval for UGN-102 and generate sufficient cash inflows from the sale and distribution of UGN-102, we may need to raise additional capital in the future or reduce operating expenditures. There can be no assurances that we will be able to secure such additional financing on terms that are satisfactory to us, in an amount sufficient to meet our needs, or at all. In the event we are not successful in obtaining sufficient funding, this could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.

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,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (96,766)	$ (76,376)
Investing activities	(20,613)	(953)
Financing activities	194,619	116,931
Net change in cash and cash equivalents	$ 77,240	$ 39,602

Operating Activities

Net cash used in operating activities was $96.8 million during the year ended December 31, 2024, compared to $76.4 million used in operating activities during the year ended December 31, 2023. The $20.4 million increase was attributable primarily to higher net loss driven by increased operating expenses such as regulatory and commercial preparation costs related to UGN-102, as well as timing of certain payments and accruals.

Investing Activities

Net cash used in investing activities was $20.6 million during the year ended December 31, 2024, compared to net cash used in investing activities of $1.0 million during the year ended December 31, 2023. The increase of $19.6 million is attributable primarily to additional investment in marketable securities in 2024 as compared to 2023.

Financing Activities

Net cash provided by financing activities was $194.6 million during the year ended December 31, 2024, compared to net cash provided by financing activities of $116.9 million during the year ended December 31, 2023. The increase of $77.7 million is attributable primarily to proceeds from the issuance of ordinary shares under the ATM Sales Agreement, the underwritten public offering and the issuance of debt related to the third tranche of the Pharmakon loan as compared to proceeds from the Private Placement 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-301, UGN-103 and UGN-104;
- nonclinical studies and clinical trials for any of our other product candidates;
- the costs related to obtaining regulatory approval UGN-102, UGN-301, UGN-103, UGN-104 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, if approved, 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-103, UGN-104, UGN-301, *RTGel* reverse thermal hydrogel technology and any other product candidates; and
- the repayment of outstanding debt.

Accordingly, we may need to obtain additional funding in connection with our continuing operations. There can be no assurance that we will be able to secure such additional financing on terms that are satisfactory to us, in an amount sufficient to meet our needs, or at all. In the event we are not successful in obtaining sufficient funding, we may be forced to delay, limit, reduce or terminate 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 in us 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 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.

In July 2024, we entered into a new master lease agreement for vehicles, primarily for use by employees in sales, field services, and roles that require regular travel. Under the terms of the master lease agreement, we will lease various vehicles from time to time with an initial lease term of 48 months commencing on the delivery date of the vehicle with an option to continue month-to-month for an unlimited period of time.

The total obligation for future minimum lease payments under our operating and finance leases are $0.8 million and $3.0 million, respectively, as of December 31, 2024. 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 was funded in September 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables.

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 possible upon FDA approval of an NDA for UGN-102 by June 30, 2025. All outstanding loans with Pharmakon can be prepaid in whole at our discretion, at any time, subject to prepayment premiums and make-whole amounts.

The obligations of UroGen Pharma, Inc., as the borrower under the loan agreement (the "Borrower") are guaranteed on a full and unconditional basis by UroGen Pharma Ltd. and the other guarantor parties thereto and are secured by substantially all of the respective Credit Parties’ tangible and intangible assets and property, including intellectual property, subject to certain exceptions.

On June 26, 2024, we entered into a separation agreement with Jeff Bova, our former Chief Commercial Officer, which sets forth the terms of Mr. Bova's termination of employment, effective as of September 30, 2024. The arrangement includes cash severance, a pro rata portion of the target annual bonus for calendar year 2024, and partial acceleration of share-based compensation. We recognized $1.1 million of expenses during the year ended December 31, 2024 in relation to this arrangement. On October 7, 2024, we entered into a separation and consulting agreement with Don Kim, pursuant to which Mr. Kim resigned from his positions as our Chief Financial Officer, principal financial officer and principal accounting officer, effective October 8, 2024. The arrangement includes cash severance, target annual bonus for calendar year 2024, a post-separation consulting arrangement, and partial acceleration of share-based compensation. We recognized $0.8 million of expenses during the year ended December 31, 2024 in relation to this arrangement.

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

Net revenue from product sales is recognized at the transaction price when the specialty distributors obtain control of our products, which occurs at a point in time, typically upon delivery of the product to the treating physician. All product sales of *Jelmyto* are recognized through our arrangements with two customers as defined by ASC 606, both of which are third-party national specialty distributors. Payment terms with these customers are 60 days and 90 days. 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 launch of *Jelmyto* and the development of UGN-102 in return for tiered, future cash payments based on net sales of *Jelmyto* and, subject to FDA approval, UGN-102*,* UGN-103 and UGN-104. 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, 2024, we had approximately $241.7 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, 2024, 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, 2024.

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 2024 by a total of 1.2%. 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, 2024 and 2023, 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, 2024 and 2023, 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.

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.

Emphasis of Matter

As discussed in Note 2 to the consolidated financial statements, if the Company is unable to obtain approval for UGN-102 and generate sufficient cash inflows from the sale and distribution of UGN-102, the Company may need to raise additional capital in the future or reduce operating expenditures. Management's evaluation of the events and conditions and management's plans to mitigate these matters are also described in Note 2.

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 transaction price when the specialty distributors obtain control of the Company's products, which occurs at a point in time, typically upon delivery of the product to the treating physician. All product sales of Jelmyto are recognized through the Company's arrangements with two customers as defined by ASC 606, both of which are third-party national specialty distributors. Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customers, 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 $90.4 million for the year ended December 31, 2024, 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 customers, (iv) confirming a sample of outstanding customer invoice balances as of December 31, 2024, 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 10, 2025

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,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 171,987	$ 95,002
Marketable securities	64,698	41,966
Restricted cash	1,076	821
Accounts receivable, net	20,302	15,443
Inventories	9,227	5,673
Prepaid expenses and other current assets	8,845	10,281
Total current assets	276,135	169,186
Non-current assets:		
Property and equipment, net	655	689
Restricted deposit	176	225
Right-of-use assets	3,134	1,671
Marketable securities	5,022	4,502
Other non-current assets	589	2,038
Total Assets	$ 285,711	$ 178,311
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 27,431	$ 16,538
Employee related accrued expenses	10,570	10,814
Other current liabilities	7,948	3,860
Total current liabilities:	45,949	31,212
Non-current liabilities:		
Prepaid forward obligation	121,387	109,722
Long-term debt	121,734	98,551
Long-term lease liabilities	1,653	844
Uncertain tax positions liability	3,791	3,194
Total Liabilities	294,514	243,523
Commitments and Contingencies (Note 19)		
Shareholders' Deficit:		
Ordinary shares, NIS 0.01 par value; 100,000,000 shares authorized at December 31, 2024 and 2023; 42,231,746 and 32,490,119 shares issued and outstanding as of December 31, 2024 and 2023, respectively	115	89
Additional paid-in capital	797,248	614,035
Accumulated deficit	(806,222)	(679,348)
Accumulated other comprehensive income	56	12
Total Shareholders' Deficit	(8,803)	(65,212)
Total Liabilities and Shareholders' Deficit	$ 285,711	$ 178,311

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,	
	2024	**2023**
Revenue	$ 90,398	$ 82,713
Cost of revenue	8,881	9,361
Gross profit	81,517	73,352
Operating expenses:		
Research and development expenses	57,145	45,614
Selling, general and administrative expenses	121,154	93,274
Operating loss	(96,782)	(65,536)
Financing on prepaid forward obligation	(23,411)	(21,552)
Interest expense on long-term debt	(12,521)	(14,715)
Interest and other income, net	8,672	3,479
Loss before income taxes	(124,042)	(98,324)
Income tax expense	(2,832)	(3,920)
Net Loss	$ (126,874)	$ (102,244)
Statements of Comprehensive Loss		
Net loss	$ (126,874)	$ (102,244)
Other comprehensive income (loss)		
Unrealized gain on investments	44	119
Comprehensive Loss	$ (126,830)	$ (102,125)
Net loss per ordinary share - basic and diluted	$ (2.96)	$ (3.55)
Weighted average number of shares outstanding used in computation of basic and diluted loss per ordinary share	42,876,737	28,834,303

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, 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)
Changes during 2024						
Exercise of options into ordinary shares	419,731	1	320			321
Share-based compensation			13,108			13,108
Issuance of pre-funded warrants, net of issuance costs			18,641			18,641
Issuance of ordinary shares, net of issuance costs	9,321,896	25	151,144			151,169
Other comprehensive income					44	44
Net loss				(126,874)		(126,874)
Balance as of December 31, 2024	42,231,746	$ 115	$ 797,248	$ (806,222)	$ 56	$ (8,803)

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,	
	2024	**2023**
Cash Flows From Operating Activities		
Net loss	$ (126,874)	$ (102,244)
Adjustment to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	329	802
Accrued financing on prepaid forward obligation	15,077	11,504
Accretion on marketable securities	(2,891)	(1,034)
Share-based compensation	13,108	9,343
Amortization (accretion) of discount on long-term debt	(1,305)	1,014
Amortization of right-of-use assets	857	903
Changes in operating assets and liabilities:		
Inventory	(3,554)	(1,348)
Accounts receivable, net	(4,859)	(2,739)
Prepaid expenses and other current assets	1,436	820
Other non-current assets	1,449	702
Accounts payable and accrued expenses	10,893	4,155
Employee related accrued expenses	(244)	2,557
Other current liabilities	200	—
Lease liabilities	(1,034)	(987)
Restricted deposit	49	—
Uncertain tax positions	597	176
Net cash used in operating activities	(96,766)	(76,376)
Cash Flows From Investing Activities		
Purchases of marketable securities	(128,023)	(49,832)
Maturities of marketable securities	107,705	49,073
Purchases of property and equipment	(295)	(194)
Net cash used in investing activities	(20,613)	(953)
Cash Flows From Financing Activities		
Proceeds from exercise of options into ordinary shares	321	873
Proceeds from issuance of long-term debt, net of issuance costs	24,488	—
Proceeds from pre-funded warrant issuance, net of issuance costs	18,641	48,700
Proceeds from ordinary shares issuance, net of issuance costs	151,169	67,358
Net cash provided by financing activities	194,619	116,931
Increase in Cash and Cash Equivalents	77,240	39,602
Cash, Cash Equivalents and Restricted Cash at Beginning of Year	95,823	56,221
Cash, Cash Equivalents and Restricted Cash at End of Year	$ 173,063	$ 95,823
Supplemental Disclosures of Non-Cash Activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 2,321	$ 122

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, advancing UGN-102 through regulatory approval, 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. *Jelmyto* consists of mitomycin, an established chemotherapy, and sterile hydrogel, using the Company's 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.

In August 2024, the Company completed the submission of the rolling NDA for UGN-102. In October 2024, the FDA accepted the Company's NDA for UGN-102 (mitomycin) for intravesical solution and assigned a Prescription Drug User Fee Act ("PDUFA") goal date of June 13, 2025.

NOTE 2 – BASIS OF PRESENTATION

The Company has experienced net losses since its inception and has an accumulated deficit of $806.2 million and $679.3 million as of December 31, 2024 and 2023, 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 12 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 the advancement of UGN-102 through regulatory approval, its ability to raise additional capital to fund its operations, and produce cash inflows from Jelmyto product sales.

Based on the Company's cash, cash equivalents and marketable securities as of December 31, 2024, together with management's cash flow projections, the Company believes that it has sufficient cash and cash equivalents to fund its operations beyond one year from the issuance of these consolidated financial statements. If the Company is unable to obtain approval for UGN-102 and generate sufficient cash inflows from the sale and distribution of UGN-102, the Company may need to raise additional capital in the future or reduce operating expenditures. There can be no assurances that the Company will be able to secure such additional financing on terms that are satisfactory to the Company, in an amount sufficient to meet the Company's needs, or at all. In the event the Company is not successful in obtaining sufficient funding, this could force the Company to delay, limit, reduce or terminate the Company's product development, commercialization efforts or other operations.

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. Generally Accepted Accounting Principles 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 $241.7 million as of December 31, 2024. 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 accounts receivables are composed of net sales of *Jelmyto* arising from the Company's arrangements with two third-party national specialty distributors. 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 arrangements with customers 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. Costs related to inventories that are not expected to be manufactured and sold within the next 12 months are classified as long-term assets and presented within Other non-current assets on the consolidated balance sheets.

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 launch of *Jelmyto* and the development of UGN-102 in return for tiered, future cash payments based on net sales of *Jelmyto* and, subject to FDA approval, UGN-102, UGN-103 and UGN-104. 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 and finance leases, primarily for office space, office equipment and vehicles.

The Company accounts for leases in accordance with ASC Topic 842, "Leases." The Company determines if an arrangement is a lease at inception. The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease. Right-of-use ("ROU") assets and lease liabilities are recognized based on the present value of lease payments over the lease term as of the commencement date. Certain adjustments to the ROU asset may be required for items such as initial direct costs paid or incentives received. Operating and finance lease ROU assets are presented as right-of-use assets on the consolidated balance sheets. The current portion of 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.

Lease expense for operating leases is recognized on a straight-line basis over the lease term. For finance leases, the expense consists of interest on the lease liability and amortization of the right-of-use asset. 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 selling, general and administrative expenses in the consolidated statements of operations. The Company has elected the practical expedient to not separate between lease and non-lease components.

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 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

Net revenue from product sales is recognized at the transaction price when the specialty distributors obtain control of the Company's products, which occurs at a point in time, typically upon delivery of the product to the treating physician. All product sales of *Jelmyto* are recognized through the Company's arrangements with two customers as defined by ASC 606, both of which are third-party national specialty distributors. Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customers, 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's outstanding pre-funded warrants 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 applicable issuance date using a relative fair value allocation method. The Company valued the pre-funded warrants at the applicable issuance date, concluding that their sales price approximated their fair value, and allocated the net sales proceeds from the applicable equity transaction proportionately to the ordinary shares and pre-funded warrants.

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 require 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."

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,	
	2024	2023
Basic and diluted:		
Loss attributable to equity holders of the Company	$ (126,874)	$ (102,244)
Weighted-average number of ordinary shares	42,876,737	28,834,303
Loss per ordinary share	$ (2.96)	$ (3.55)

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 has adopted the new guidance, which applies to all public entities, including those with a single reportable segment. The amendments primarily enhance segment expense 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.

In November 2024, the FASB issued Accounting Standards Update No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) ("ASU 2024-03"), which provides guidance to improve the disclosures about a public business entity's expenses. Public entities must adopt the new guidance for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is currently evaluating the potential impact of the adoption of ASU 2024-03 on the Company's financial disclosures.

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, 2024 and 2023 (in thousands):

	December 31, 2024	December 31, 2023
Accounts payable	$ 10,931	$ 6,514
Accrued sales reserves	5,151	4,391
Accrued clinical expenses	2,027	1,246
Accrued research and development expenses	2,173	1,049
Accrued selling, general and administrative expenses	6,000	2,752
Accrued other expenses	1,149	586
Total accounts payable and accrued expenses	$ 27,431	$ 16,538

Interest and Other Income, Net

Interest and other income, net consisted of the following for the year ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Interest income	$ 8,901	$ 2,641
Other income (loss), net	(229)	838
Total interest and other income, net	$ 8,672	$ 3,479

NOTE 5 – INVENTORIES

Inventories consisted of the following as of December 31, 2024 and December 31, 2023 (in thousands):

	December 31, 2024	December 31, 2023
Raw materials [(1)]	$ 4,924	$ 4,464
Finished goods	4,522	2,877
Total inventories	$ 9,446	$ 7,341

[(1)] $0.2 million and $1.7 million of raw materials are included within other non-current assets on the consolidated balance sheets at December 31, 2024 and December 31, 2023, respectively. These raw materials are not expected to be manufactured and sold within the next 12 months. Changes in non-current inventories 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, 2024 are as follows (in thousands):

		Fair Value Measurements Using	
	Balance as of December 31, 2024	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash equivalents			
Money market funds	$ 41,008	$ 41,008	$ —
Marketable securities			
U.S. government	$ 26,053	$ 26,053	$ —
Corporate bonds	14,980	—	14,980
Commercial paper	26,622	—	26,622
Certificates of deposit	2,065	—	2,065
Total marketable securities	$ 69,720	$ 26,053	$ 43,667
Total assets at fair value	$ 110,728	$ 67,061	$ 43,667

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

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, 2024 and 2023. 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, 2024 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Assets:				
Cash equivalents				
Money market funds	$ 41,008	$ —	$ —	$ 41,008
Marketable securities				
U.S. government	$ 26,019	$ 34	$ —	$ 26,053
Corporate bonds	14,966	15	(1)	14,980
Commercial paper	26,608	15	(1)	26,622
Certificates of deposit	2,071	—	(6)	2,065
Total marketable securities	$ 69,664	$ 64	$ (8)	$ 69,720
Total assets at fair value	$ 110,672	$ 64	$ (8)	$ 110,728

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

The Company classifies its investments as available-for-sale, and they consist entirely of debt securities. As of December 31, 2024, the amortized cost of investments included an immaterial amount of accrued interest. As of December 31, 2024, 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, 2024, the aggregate fair value of investments held by the Company in an unrealized loss position was $14.4 million which consisted of 12 securities. The unrealized loss was primarily driven by fluctuations in 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, 2024, 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, 2024 mature at various dates through November 2026. The fair values of investments by contractual maturity consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Maturities within one year	$ 105,706	$ 51,670
Maturities after one year through three years	5,022	4,502
Total investments	$ 110,728	$ 56,172

NOTE 8 – PROPERTY AND EQUIPMENT

Property and equipment, consists of the following as of December 31, 2024 and 2023 (in thousands):

	December 31,	
	2024	2023
Laboratory equipment	$ 473	$ 464
Computer equipment and software	2,542	2,293
Furniture	612	612
Leasehold improvements	626	617
Manufacturing equipment	683	655
	4,936	4,641
Less: accumulated depreciation and amortization	(4,281)	(3,952)
Property and equipment, net	$ 655	$ 689

Depreciation and amortization expense was $0.3 million and $0.8 million for the years ended December 31, 2024 and 2023, respectively.

NOTE 9 – PREPAID FORWARD OBLIGATION

In March 2021, the Company entered into a prepaid forward agreement with RTW. Under the terms of the RTW Transaction, the Company received $75.0 million ($72.4 million net of transaction costs) to support the 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* and, subject to FDA approval, UGN-102, UGN-103 and UGN-104, 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. Pursuant to the agreement, the initial cash payment rate of 9.5% on *Jelmyto* aggregate worldwide annual net sales of up to $200 million was increased to 13.0% and remained at that rate during the year ended December 31, 2024 because certain revenue thresholds were not met.

In addition, subject to FDA approval of UGN-102 and UGN-103, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of UGN-102 and UGN-103 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 June 30, 2025, 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 of December 31, 2024, the cumulative amounts paid and payable by the Company were $34.8 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,* UGN-102, UGN-103 and UGN-104, 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, 2024 and 2023 (in thousands):

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
Financing on prepaid forward obligation		23,411
Amounts paid and payable [(1)]		(11,746)
Carrying value of prepaid forward obligation as of December 31, 2024	$	121,387

[(1)] $6.5 million and $3.0 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, 2024 and December 31, 2023, respectively.

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.

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 accrued interest using a benchmark rate of 3-month SOFR plus 8.25% plus an additional adjustment of 0.26161%.

On March 13, 2024, the Company 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 was funded in September 2024. The fourth tranche of $75.0 million will become available at the Company's option no later than August 29, 2025, subject to (i) receiving FDA approval of a new drug application (“NDA”) for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables. Under the amended and restated loan agreement, 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 possible upon FDA approval of an NDA for UGN-102 by June 30, 2025. All outstanding loans with Pharmakon can be prepaid in whole at the Company's discretion, at any time, subject to prepayment premiums and make-whole amounts. The Company is not required to maintain any financial covenants.

The Company incurred financing expenses of $4.2 million related to the first and second tranches funded in 2022, and $0.5 million related to the third tranche funded in 2024, 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:

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
Third tranche of Pharmakon loan	25,000
Capitalized costs and discounts	(512)
Interest expense	12,521
Amounts paid	(13,826)
Carrying value of Pharmakon loan as of December 31, 2024	$ 121,734

NOTE 11 – LEASES

Operating Leases

The Company had the following office and laboratory facility leases during the period covered by this report:

- 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 $0.2 million as of December 31, 2024.

- 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. In November 2019, UPI entered into a sublease for this office space, with a lease commencement date of January 1, 2020, which continued until 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 Company accounted for the sublease as an 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 $0.6 million as of December 31, 2024.

Finance Leases

- In July 2024, UPI entered into a new master lease agreement for vehicles, primarily for use by employees in sales, field services, and roles that require regular travel. Under the terms of the master lease agreement, the Company will lease various vehicles from time to time with an initial lease term of 48 months commencing on the delivery date of the vehicle with an option to continue month-to-month for an unlimited period of time. Lease payments are fixed, with payments due monthly in advance, and include charges for depreciation, maintenance, and other related services. At the end of each lease term, the Company is required to make a terminal rental adjustment based on the difference between the vehicle's contractual book value and its estimated wholesale value, which may result in additional payments or refunds. The Company may also be required to pay additional rent if the vehicle exceeds certain mileage limits or shows abnormal wear and tear during the lease term. The Company's remaining contractual obligation under this lease is approximately $3.0 million as of December 31, 2024.

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 active leases expire at various dates from 2025 through 2028, with varying renewal and termination options.

The components of lease cost for the year ended December 31, 2024 and 2023 were as follows (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2023
Finance lease cost:		
Amortization of right-of-use assets	$ 36	$ —
Interest on lease liabilities	20	—
Operating lease cost	900	934
Sublease income	(42)	(224)
Variable lease cost	70	73
	$ 984	$ 783

The amounts recognized as of December 31, 2024 and 2023 were as follows (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2023
Finance lease right-of-use assets	$ 2,285	$ 1,671
Operating lease right-of-use assets	849	—
Finance long-term lease liabilities	1,595	844
Operating long-term lease liabilities	58	—
Other current liabilities related to finance leases	745	—
Other current liabilities related to operating leases	785	819

As of December 31, 2024, no impairment losses have been recognized.

Supplemental information related to leases for the periods reported is as follows (in thousands, except for lease terms and discount rate amounts):

	Year Ended December 31, 2024	Year Ended December 31, 2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 933	$ 1,169
Right-of-use assets obtained in exchange for new finance lease liabilities	$ 2,321	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 122
Weighted-average remaining lease term of finance leases (in years)	3.94	—
Weighted-average remaining lease term of operating leases (in years)	1.02	1.92
Weighted-average discount rate of finance leases	13.82%	—
Weighted-average discount rate of operating leases	10.24%	10.21%

As of December 31, 2024, maturities of lease liabilities were as follows (in thousands):

	Finance Leases
Years ending December 31,	
2025	$ 998
2026	657
2027	657
2028	642
Total future minimum lease payments	$ 2,954
Less: Interest	(614)
Present value of lease liabilities	$ 2,340

	Operating Leases
Years ending December 31,	
2025	$ 824
2026	58
Total future minimum lease payments	$ 882
Less: Interest	(39)
Present value of lease liabilities	$ 843

NOTE 12 – REVENUE FROM PRODUCT SALES

Net product sales consist of the following for the year ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2023
Jelmyto	$ 90,398	$ 82,713

All product sales of *Jelmyto* are recognized through the Company's arrangements with two customers as defined by ASC 606, both of which are third-party national specialty distributors. The Company's largest customer comprises over 90% of product sales throughout the full year 2024, and approximately 80% of accounts receivables at December 31, 2024. Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customers, 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 estimates these elements of variable consideration based on the contractual or statutory terms governing the arrangements and the Company's historical experience, and constrains the net revenue recognized for product sales to the value that is not probable to be reversed when the uncertainty associated with the variable consideration is subsequently resolved. Reserves for chargebacks and returns are net settled and recognized as contra accounts receivable while the 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, 2024 and 2023, in thousands:

	Reserves related to government sponsored programs	Medicare refunds for discarded drug reserve	Other reserves	Total accrued sales reserves
Balance as of December 31, 2022	$ 590	$ —	$ 847	$ 1,437
Changes during 2023				
Accruals	11,110	3,451	8,807	23,368
Utilizations	(10,638)	—	(8,196)	(18,834)
Balance as of December 31, 2023	$ 1,062	$ 3,451	$ 1,458	$ 5,971
Changes during 2024				
Accruals	13,870	3,920	11,273	29,063
Utilizations	(13,822)	—	(10,785)	(24,607)
Changes to prior period estimates	(223)	358	—	135
Balance as of December 31, 2024	$ 887	$ 7,729	$ 1,946	$ 10,562

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 non-muscle invasive bladder cancer.

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.

NOTE 15 – SHAREHOLDERS' EQUITY

The Company had 100.0 million ordinary shares authorized for issuance as of December 31, 2024 and 2023. The Company had 42.2 million and 32.5 million ordinary shares issued and outstanding as of December 31, 2024 and 2023, 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 the Company's inception, the Board has not declared any dividends.

ATM Sales Agreement

In December 2019, the Company entered into a sales agreement (the "ATM Sales Agreement") with TD Securities (USA) LLC (f/k/a Cowen and Company, LLC) ("TD Cowen") pursuant to which the Company may from time to time offer and sell the Company's ordinary shares having an aggregate offering price of up to $100.0 million.

During the first quarter of 2024, the Company sold 3,400,468 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $56.1 million. The net proceeds to the Company after deducting sales commissions to TD Cowen were approximately $54.7 million. The remaining capacity under the ATM Sales Agreement was approximately $27.3 million as of December 31, 2024. The shares will be offered and sold, if any, pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC on November 15, 2022, which was declared effective on November 29, 2022, or a subsequent shelf registration statement.

Securities Purchase Agreement

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 to the extent that 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 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. On January 24, 2025, the Company issued 3,206,271 ordinary shares through a conversion of 3,206,271 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 at the time, purchased 1,572,327 of the Shares in the Private Placement, for an aggregate purchase price of $15.0 million. Dr. Cohen was the Chair and Chief Investment Officer of Monograph at the time of purchase.

Underwritten Public Offering

On June 17, 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with TD Securities (USA) LLC and Guggenheim Securities, LLC, as representatives of the several underwriters named therein (collectively, the "Underwriters"), relating to the issuance and sale in a public offering of 5,000,000 ordinary shares of the Company for $17.50 per share and pre-funded warrants to purchase 1,142,857 ordinary shares of the Company for $17.499 per pre-funded warrant. The offering closed on June 20, 2024. The gross proceeds to the Company from the closing of the offering were $107.5 million, before deducting underwriting discounts and commissions and offering expenses of $7.3 million. Each pre-funded warrant has an exercise price of $0.001 per ordinary share, subject to customary adjustments, is exercisable at any time 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. In addition, the Underwriters were granted an option exercisable for 30 days, to purchase up to 921,428 additional shares at the public offering price, less the underwriting discounts and commissions. On July 18, 2024, the Company completed the closing of the sale of 921,428 additional shares in the offering following the exercise in full of the Underwriters' option to purchase additional shares, which resulted in additional gross proceeds to the Company of $16.1 million before deducting underwriting discounts and commissions and offering expenses paid by the Company of $1.0 million.

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 RSUs, upon commencement of employment. Also, eligible employees may receive an annual grant of options, RSUs and/or PSUs. 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 Company also grants PSUs to certain employees. The PSU's currently outstanding vest based on either the earlier of obtaining regulatory approval for the Company's lead product candidate UGN-102 or the occurrence of a change in control, or for certain other awards, the achievement of the first commercial sale of UGN-102 in the United States following UGN-102's receipt of regulatory approval. In June 2024, the Company amended certain RSU and PSU awards granted to the chief executive officer to defer vesting until the end of 2025. The Company accounted for the modification as a Type I probable-to-probable modification under ASC 718. As the modification did not result in any incremental fair value at the modification date, the Company continues to recognize the original grant-date fair value ratably over the original service period or expected performance period.

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 shares 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 shares 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 shares to a total share reserve of 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 shares to a total share reserve of 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 shares to a total share reserve of 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 shares to a total share reserve of 5,200,167 shares. On August 6, 2024, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 800,000 shares to a total of 6,000,167 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 an increase to the number of shares authorized for issuance under the Inducement Plan of 300,000 shares. In June 2024, the Board approved an increase to the number of shares authorized for issuance under the Inducement Plan of 600,000 shares to a total of 1,800,000 shares.

As of December 31, 2024, 4,119,671 ordinary shares are subject to outstanding awards under the Company's share-based compensation plans and 1,654,692 ordinary shares remain available for future awards.

Options granted:

Set forth below are grants made by the Company as of December 31, 2024. The majority of options vest over three years and expire on the tenth anniversary of the date of grant. During 2024, the Company granted 238,614 options with exercise prices ranging from $13.11 to $15.16 per share.

The weighted average fair value of options granted during 2024 and 2023 was $2.5 million and $4.3 million, respectively.

The total unrecognized compensation cost of options as of December 31, 2024 was $3.1 million, which is expected to be recognized over a weighted average period of 1.75 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:

	2024	2023
Value of ordinary shares	$13.11-15.16	$8.84-17.94
Dividend yield	0%	0%
Expected volatility	81.00%-89.12%	67.21%-81.00%
Risk-free interest rate	3.61%-4.42%	3.47%-4.42%
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 Plans for the years ended December 31, 2024 and 2023, and related information:

	Number of options	Weighted average exercise price per share	Weighted average remaining contractual life	Aggregate intrinsic value
Outstanding as of December 31, 2023	2,685,796	$ 25.35	7.37	$ 5,131
Granted	238,614	13.80		
Forfeited	(277,901)	24.05		
Exercised	(34,666)	9.25		
Outstanding as of December 31, 2024	2,611,843	$ 24.65	5.80	$ 1,092
Vested and expected to vest, December 31, 2024	2,611,843	$ 24.65	5.80	$ 1,092
Exercisable, December 31, 2024	2,051,867	$ 28.24	5.04	$ 743

The intrinsic value of stock options exercised was $0.2 million and $0.7 million for the years ended December 31, 2024 and 2023, respectively.

The following table summarizes information about RSU activity as of December 31, 2024:

	Outstanding Restricted Stock Units
Outstanding as of December 31, 2023	1,098,684
Granted	964,369
Vested and released	(385,065)
Forfeited	(170,160)
Outstanding as of December 31, 2024	1,507,828

The fair value of RSUs granted during 2024 and 2023 was $14.5 million and $10.4 million, respectively. The total unrecognized compensation cost of RSUs as of December 31, 2024 is $12.1 million with a weighted average recognition period of 2.00 years.

The following table illustrates the effect of share-based compensation on the Statements of Operations:

	Year ended December 31,	
	2024	2023
Research and development expenses	$ 2,235	$ 1,905
Selling, general and administrative expenses	10,873	7,439
Total share-based compensation expense	$ 13,108	$ 9,344

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 2023 and thereafter is 23%.

For financial reporting purposes, the expense for current income taxes consists of the following (in thousands):

	2024	2023
Current taxes:		
U.S. Federal	$ 2,206	$ 2,937
U.S. State	626	983
Total current taxes	$ 2,832	$ 3,920

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,	
	2024	2023
In respect of:		
Net operating loss carryforward	$ 122,944	$ 103,566
Research and development expenses	26,231	22,451
Stock-based compensation	12,441	11,953
Accrued expenses	2,371	2,310
Interest expense	2,630	1,345
In-process research and development	815	1,102
Lease Liabilities	683	283
Issuance costs	221	—
Other	988	877
Total deferred tax assets	169,324	143,887
Less—valuation allowance	(168,555)	(143,566)
Deferred tax assets, net of valuation allowance	769	321
Right-of-use asset	(725)	(276)
Depreciation of fixed assets	(44)	(45)
Total deferred tax liabilities	(769)	(321)
Net deferred tax assets	$ —	$ —

The change in valuation allowance for the years ended December 31, 2024 and 2023 were as follows (in thousands):

	2024	2023
Balance at the beginning of the year	$ (143,566)	$ (129,601)
Changes during the year	(24,989)	(13,965)
Balance at the end of the year	$ (168,555)	$ (143,566)

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,	
	2024	2023
Pretax loss	$ (124,042)	$ (98,324)
Statutory rate	23%	23%
Income tax expense/(benefit) at statutory rate	(28,530)	(22,615)
Additional tax (tax saving) in respect of:		
Non-deductible expenses	6,929	5,704
R&D and orphan drug credits	(510)	(1,197)
Different tax rate of foreign subsidiaries	(669)	(689)
Uncertain tax positions	597	176
Change in valuation allowance[(1)]	24,989	22,898
Other	26	(358)
Income tax expense	$ 2,832	$ 3,920

[(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 2023.

Pretax loss for December 31, 2024 and 2023 includes pretax loss from foreign (United States) jurisdictions of $11.0 million and $17.9 million, respectively.

The Internal Revenue Code of 1986, as amended (the "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, 2024 and 2023, the Company had approximately $533.9 million and $452.0 million of carryforward tax losses, prior to tax effecting, respectively, available to reduce future taxable income without limitation of use. The Company's carryforward tax losses relate to losses generated in Israel and can be carried forward indefinitely.

Uncertain tax positions

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	2024	2023
Unrecognized tax benefits at the beginning of the year	$ 1,974	$ 1,974
Gross increases — tax positions in current period	—	—
Gross increases — tax positions in prior period	—	—
Unrecognized tax benefits at the end of the year	$ 1,974	$ 1,974

The liability for uncertain tax positions of $3.8 million as of December 31, 2024 is related to transfer pricing between affiliated entities. The uncertain tax positions liability on the consolidated balance sheets includes $1.8 million and $1.2 million of accrued interest and penalties related to unrecognized tax benefits at December 31, 2024 and December 31, 2023, respectively. The Company recognizes interest accrued and penalties related to uncertain tax positions as a component of income tax expense. If recognized, balances of uncertain tax positions as of December 31, 2024 would result in incremental net operating loss carryforwards, which would be expected to require a full valuation allowance based on present circumstances, therefore, the uncertain tax positions will not impact the effective tax rate.

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 recognizes its gross uncertain tax positions as a long-term liabilities. 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. Approximately $1.4 million of the liability for uncertain tax positions relate to tax years for which the statute of limitations will expire within the next 12 months. Based upon the information currently available, the Company does not reasonably expect any other changes in its existing uncertain tax positions in the next 12 months.

The Company has received final tax assessments up to and including its 2017 tax year in Israel and 2020 in the US.

NOTE 18 – RELATED PARTIES

There were no related party transactions for the year ended December 31, 2024. See Note 15 for discussion regarding an affiliated investor in the private placement transaction for the year ended December 31, 2023. See Note 21 for discussion related to a subsequent event in February 2025 which involved a related party.

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, 2024 and 2023. The Company does not anticipate recognizing any significant losses relating to these arrangements.

On February 25, 2024, the Company received from Teva, a Paragraph IV Certification Notice Letter dated February 20, 2024, providing notification that Teva 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. On April 2, 2024, the Company filed a lawsuit in the U.S. District Court for the District of Delaware against Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd., alleging infringement of U.S. Patent Numbers 9,040,074 and 9,950,069 and seeking a permanent injunction preventing U.S. market entry of Teva's generic product prior to the expiry of such patents. The Company stipulated to the dismissal of Teva Pharmaceutical Industries, Ltd. without prejudice and the action continues against the other two Teva entities. If the Company is unsuccessful in securing the requested court relief, *Jelmyto* may be subject to immediate competition from an FDA approved generic product after regulatory exclusivity for *Jelmyto* expires in April 2027.

Separation Agreements

On June 26, 2024, the Company entered into a separation agreement with Jeff Bova, the Company's former Chief Commercial Officer, which sets forth the terms of Mr. Bova's termination of employment with the Company, effective as of September 30, 2024. The arrangement includes cash severance, a pro rata portion of the target annual bonus for calendar year 2024, and partial acceleration of share-based compensation. The Company recognized $1.1 million within selling, general and administrative expenses during the year ended December 31, 2024 in relation to this arrangement.

On October 7, 2024, the Company entered into a separation and consulting agreement with Don Kim, pursuant to which Mr. Kim resigned from his positions as the Company's Chief Financial Officer, principal financial officer and principal accounting officer, effective October 8, 2024. The arrangement includes cash severance, target annual bonus for calendar year 2024, a post-separation consulting arrangement, and partial acceleration of share-based compensation. The Company recognized $0.8 million within selling, general and administrative expenses during the year ended December 31, 2024 in relation to this arrangement.

Leases

See Note 11 for further discussion regarding lease commitments.

NOTE 20 – SEGMENT REPORTING

The Company is engaged in the development and commercialization of innovative solutions for the treatment of urothelial and specialty cancers. The Company has a single operating segment and reportable segment focused on these business activities, and its operations are managed on a consolidated basis. The primary revenue source for the segment comes from sales of the Company's approved product, Jelmyto, primarily conducted in the United States.

The Company's Chief Operating Decision Maker ("CODM") is the Chief Executive Officer ("CEO"). The CODM assesses performance and allocates resources based on net income or loss, which is the primary measure of performance, as reported in the Consolidated Statements of Operations and Comprehensive Loss. Additionally, net income or loss is used to monitor performance relative to budgeted targets and to evaluate financial performance in relation to the Company's strategic goals. For additional information, refer to the Consolidated Statements of Operations and Comprehensive Loss for detailed measures of segment revenues, expenses, and profit or loss.

Information about significant segment expenses regularly provided to the CODM is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development expenses		
R&D project materials & services	$ 38,556	$ 26,928
Employee compensation	14,882	14,796
Rent, office, utilities & technology	2,972	3,569
Other expenses	735	321
Total research and development expenses	$ 57,145	$ 45,614
Selling, general and administrative expenses		
Employee compensation	$ 59,709	$ 52,605
Commercial & medical affairs services	27,205	14,210
Professional services	14,031	11,650
Travel, meetings & conferences	12,962	8,796
Rent, office, utilities & technology	3,283	2,790
Other expenses [(1)]	3,964	3,223
Total selling, general and administrative expenses	$ 121,154	$ 93,274

[(1)] Other expenses primarily consist of insurance, sponsorship, grants, other fees and taxes.

NOTE 21 – SUBSEQUENT EVENTS

On January 24, 2025, the Company issued 3,206,271 ordinary shares through a conversion of 3,206,271 pre-funded warrants for the purchase of ordinary shares of the Company. See Note 15 for further discussion related to shareholders' equity.

On February 14, 2025 (the "Closing Date"), the Company entered into an Asset Purchase Agreement (the "Agreement") with IconOVir Bio, Inc. ("IconOVir"), pursuant to which the Company purchased and acquired certain assets of IconOVir (the "Transferred Assets"), including the product candidate ICVB-1042 and certain contracts, intellectual property rights, regulatory applications, submissions and registrations, and data and other rights related thereto, and assumed certain liabilities and obligations of IconOVir arising under certain contracts of IconOVir acquired by the Company.

As consideration for the Transferred Assets and subject to the terms and conditions of the Agreement, on the Closing Date the Company (i) issued 374,843 ordinary shares of the Company (the "Company Shares") to IconOVir, which represents a purchase price of $4.0 million divided by the volume-weighted average closing price of the Company Shares on The Nasdaq Stock Market over the 30 consecutive trading days ending on (and including) the trading day immediately prior to the Closing Date, (ii) agreed to pay IconOVir a one-time payment of $15.0 million in cash upon the achievement of a cumulative aggregate worldwide net sales milestone for all products, including combination products, that incorporate or comprise ICVB-1042 ("ICVB Products"), (iii) agreed to pay IconOVir a low, single-digit percentage royalty, on an ICVB Product-by-ICVB Product basis, on the annual, worldwide net sales of such ICVB Product during the royalty term, subject to certain reductions as set forth in the Agreement, and (iv) agreed to assume certain immaterial liabilities arising under certain acquired contracts ((i), (ii), (iii), and (iv) collectively, the "Purchase Price").

The Company also granted IconOVir certain piggyback registration rights with respect to the Company Shares issued to IconOVir, subject to customary exceptions and cutback rights.

Entities affiliated with Arie Belldegrun, M.D., the Chair of the Board of Directors of the Company, hold certain promissory notes of IconOVir that may entitle such entities to receive, in the aggregate, approximately 28.3% of the Purchase Price paid to IconOVir pursuant to the Agreement.

NOTE 22 - SELECTED UNAUDITED QUARTERLY FINANCIAL DATA

Certain unaudited selected quarterly financial results for the quarters within 2024 and 2023 are presented as follows:

	2024						
	For the Three Months Ended March 31	For the Three Months Ended June 30	For the Six Months Ended June 30	For the Three Months Ended September 30	For the Nine Months Ended September 30	For the Three Months December 31	For the Year Ended December 31
Revenue	$ 18,781	$ 21,848	$ 40,629	$ 25,204	$ 65,833	$ 24,565	$ 90,398
Gross profit	$ 17,053	$ 19,619	$ 36,672	$ 22,751	$ 59,423	$ 22,094	$ 81,517
Net loss	$ (32,286)	$ (33,403)	$ (65,689)	$ (23,673)	$ (89,362)	$ (37,512)	$ (126,874)
Weighted-average number of ordinary shares [(1)]	37,059,186	40,501,315	38,785,924	46,779,637	41,476,892	47,030,820	42,876,737
Basic and diluted loss per ordinary share [(1)].....	$ (0.87)	$ (0.82)	$ (1.69)	$ (0.51)	$ (2.15)	$ (0.80)	$ (2.96)

[(1)] The loss per share, both basic and diluted, for the first, second, and third quarters of 2024 was revised to record an immaterial correction to the amounts originally reported in the March 31, 2024 Form 10-Q filed on May 13, 2024, June 30, 2024 Form 10-Q filed on August 13, 2024, and September 30, 2024 Form 10-Q filed on November 6, 2024, by incorporating the 3,679,400 shares of pre-funded warrants outstanding as of each respective reporting period, which were not included in the previous calculations and are now reflected in the weighted average shares outstanding.

	2023						
	For the Three Months Ended March 31	For the Three Months Ended June 30	For the Six Months Ended June 30	For the Three Months Ended September 30	For the Nine Months Ended September 30	For the Three Months December 31	For the Year Ended December 31
Revenue	$ 17,192	$ 21,139	$ 38,331	$ 20,852	$ 59,183	$ 23,530	$ 82,713
Gross profit	$ 14,927	$ 18,696	$ 33,623	$ 18,485	$ 52,108	$ 21,244	$ 73,352
Net loss	$ (30,213)	$ (24,136)	$ (54,349)	$ (21,879)	$ (76,228)	$ (26,016)	$ (102,244)
Weighted-average number of ordinary shares	23,279,951	23,462,016	23,371,878	32,298,182	26,358,719	36,153,634	28,834,303
Basic and diluted loss per ordinary share	$ (1.30)	$ (1.03)	$ (2.33)	$ (0.68)	$ (2.89)	$ (0.72)	$ (3.55)

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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), as of December 31, 2024. 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, 2024, 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, 2024.

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 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

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 our definitive proxy statement for our 2025 annual meeting of shareholders, or an amendment to this Annual Report on Form 10-K, to be filed with the SEC by April 30, 2025 (the "Proxy Statement/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 *www.urogen.com* under the Governance section of our Investors page. To the extent requirement by applicable SEC rules, we intend to 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 Proxy Statement/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 Proxy Statement/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 Proxy Statement/Form 10-K Amendment.

Item 14. Principal Accountant Fees and Services

The information required by this item will be set forth in the Proxy Statement/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.
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).
4.4	Form of June 2024 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 June 18, 2024).
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 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 8, 2024).
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 Performance Stock Award Grant Notice and Performance Stock Award Agreement under the UroGen Pharma Ltd. Israeli Sub-Plan to 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2024).
10.6	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).
10.7	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).

10.8	Amendment to Form of Restricted Stock Unit Grant Notice under the UroGen Pharma Ltd. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024)
10.9	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).
10.10	Amendment to Form of Performance-Based Restricted Stock Unit Grant Notice under the UroGen Pharma Ltd. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2024).
10.11*	UroGen Pharma Ltd. 2019 Inducement 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 August 13, 2024).
10.12	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).
10.13	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).
10.14	Amendment to Form of Restricted Stock Unit Grant Notice under the UroGen Pharma Ltd. 2019 Inducement Plan (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.15*	UroGen Pharma Ltd. 2024 Non-Employee Director and Officer Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 8, 2024).
10.16*	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).
10.17*	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).
10.18*	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).
10.19*	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).
10.20*	Amended Restricted Stock Unit Grant Notice by and between the Registrant and Elizabeth Barrett, dated as of December 20, 2023 (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.21*	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).

10.22* 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).

10.23* 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).

10.24* 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).

10.25* 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).

10.26* Employment Agreement between the Company and Chris Degnan, dated October 7, 2024 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 9, 2024).

10.27* Separation Agreement between the Company and Don Kim, dated October 7, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 9, 2024).

10.28† 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).

10.29 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).

10.30 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).

10.31†** 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).

10.32†** 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).

10.33†** 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).

10.34†** Amendment 2 to Manufacturing & Supply Agreement, dated as of December 28, 2023 by and between UroGen Pharma Ltd. and Cenexi-Laboratoires Thissen s.a. (incorporated by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).

10.35†**	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. (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.36	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 (incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.37†**	Pre-Paid Forward Contract by and among the Registrant and RTW Investments ICAV for and on behalf of RTW Fund 2, dated as of March 18, 2021, as amended April 30, 2021 and August 14, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 6, 2024).
19.1	UroGen Pharma Ltd. Insider Trading Policy.
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 (incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
101	The following financial information from the Annual Report on Form 10-K of UroGen Pharma Ltd. for the year ended December 31, 2024, 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 10, 2025

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 Chris Degnan, 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 10, 2025
/s/ Chris Degnan Chris Degnan	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 10, 2025
/s/ Arie Belldegrun Arie Belldegrun, M.D.	Chair	March 10, 2025
/s/ Cynthia Butitta Cynthia Butitta	Director	March 10, 2025
/s/ Leana S. Wen Leana S. Wen, M.D., M.Sc.	Director	March 10, 2025
/s/ Stuart Holden Stuart Holden, M.D.	Director	March 10, 2025
/s/ James Robinson Jr. James Robinson Jr.	Director	March 10, 2025
/s/ Dan Wildman Dan Wildman	Director	March 10, 2025

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

(Amendment No. 1)

(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, 2024

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 28, 2024 totaled approximately $675.1 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 28, 2024.

As of April 23, 2025, there were 46,107,451 of the registrant's ordinary shares outstanding.

Auditor Firm ID: 238 **Auditor Name:** PricewaterhouseCoopers LLP **Auditor Location:** Florham Park, New Jersey

EXPLANATORY NOTE

UroGen Pharma Ltd. (the "Company," "our," "us" or "we") is filing this Amendment No. 1 on Form 10-K/A (this "Amendment No. 1") to our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (the "Form 10-K"), which was filed with the U.S. Securities and Exchange Commission (the "SEC") on March 10, 2025, to provide the information required by Part III of Form 10-K. This Amendment No. 1 amends and restates in their entirety Items 10, 11, 12, 13 and 14 of Part III of the Form 10-K.

In addition, as required by Section 302 of the Sarbanes-Oxley Act of 2002 and Rule 12b-15 of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, updated certifications of the Company's principal executive officer and principal financial officer are included as Exhibits 31.3 and 31.4 hereto. Because no financial statements have been included in this Amendment No. 1 and this Amendment No. 1 does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, paragraphs 3, 4, and 5 of the certifications have been omitted. We are also not including the certifications under Section 906 of the Sarbanes-Oxley Act of 2002 as no financial statements are being filed with this Amendment No. 1. This Amendment No. 1 also amends Item 15 of Part IV to add the foregoing certifications.

No other changes have been made to the Form 10-K other than those described above. This Amendment No. 1 does not reflect subsequent events occurring after the original filing date of the Form 10-K or modify or update in any way the financial statements, consents or any other items or disclosures made in the Form 10-K in any way other than as required to reflect the amendments discussed above. Accordingly, this Amendment No. 1 should be read in conjunction with the Form 10-K and the Company's other filings with the SEC subsequent to the filing of the Form 10-K.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information Concerning Our Directors

Our Board currently consists of seven directors. The brief biographies below include information, as of the date of this Amendment No. 1, regarding the specific and particular experience, qualifications, attributes or skills of each director that qualify such director to serve on our Board.

Name	Age	Position Held With the Company
Arie Belldegrun, M.D., FACS	75	Chair of the Board
Elizabeth Barrett	62	President, Chief Executive Officer and Director
Cynthia M. Butitta	70	Director
Stuart Holden, M.D.	82	Director
James A. Robinson, Jr	55	Director
Leana Wen, M.D., M.SC.	42	Director
Daniel G. Wildman	68	Director

Arie Belldegrun, M.D., FACS has served as our Chair of the Board since December 2012. Dr. Belldegrun is a co-founder of Allogene Therapeutics, a public biopharmaceutical company, and has served as Executive Chairman of its board of directors since November 2017. From March 2014 until October 2017 Dr. Belldegrun served as the President and Chief Executive Officer of Kite Pharma, Inc. and as a member of its board of directors from June 2009 until October 2017. He was also a Director of Gingko Bioworks (from September 2021 to November 2024). Dr. Belldegrun currently serves as Chairman of Bellco Capital LLC (since 2004); Chairman and Partner of Two River (since June 2009); Co-chairman of Breakthrough Properties LLC and Breakthrough Services, L.L.C. (since April 2019); Chairman of Kronos Bio (since November 2017); Co-chairman of Symbiotic Capital (since June 2023); and Director of ByHeart, Inc. (since October 2019). Dr. Belldegrun is also Senior Managing Director of Vida Ventures, LLC (since November 2017). Dr. Belldegrun is a Research Professor, holds the Roy and Carol Doumani Chair in Urologic Oncology, and is Founder and Director of the UCLA Institute of Urologic Oncology at the David Geffen School of Medicine at UCLA. Prior to joining UCLA, Dr. Belldegrun was at the National Cancer Institute/NIH as a research fellow in surgical oncology and immunotherapy under Dr. Steven A. Rosenberg. He completed his M.D. at the Hebrew University Hadassah Medical School in Jerusalem, his post-graduate studies in Immunology at the Weizmann Institute of Science, and his residency in urologic surgery at Harvard Medical School. He has authored several books on oncology and more than 500 scientific and medical papers related to urological cancers, immunotherapy, gene therapy and cancer vaccines. He is certified by the American Board of Urology and the American Association of Genitourinary Surgeons. Our Board believes Dr. Belldegrun's business and medical knowledge and experience qualify him to serve on our Board.

Elizabeth Barrett has served as our President and Chief Executive Officer and as a director since January 2019. Prior to joining UroGen, Ms. Barrett served as the Chief Executive Officer of Novartis Oncology and a member of the Novartis Executive Committee since February 2018. Prior to Novartis, Ms. Barrett served at Pfizer Inc. in various leadership capacities, most recently as the Global President of Oncology and, before that, as President of Global Innovative Pharma for Europe, President of the Specialty Care Business Unit for North America, and Regional President of United States Oncology. Prior to Pfizer, Ms. Barrett was Vice President and General Manager of the Oncology Business Unit at Cephalon Inc. Ms. Barrett received an M.B.A. degree in Business Administration-Marketing from Saint Joseph's University and a B.S. from the University of Louisiana. Ms. Barrett also currently serves on the boards of directors of Sage Therapeutics, Inc. (since 2019) and Allogene Therapeutics, Inc. (since 2021). Our Board believes Ms. Barrett's service as our Chief Executive Officer and her leadership of both large organizations and growing businesses qualify her to serve on our Board.

Cynthia M. Butitta has served as our director since October 2017. Ms. Butitta served as Chief Financial Officer of Kite Pharma, Inc. from January 2014 to May 2016 and as Chief Operating Officer from March 2014 to September 2017. From May 2011 to December 2012, she was Senior Vice President and Chief Financial Officer at NextWave Pharmaceuticals Inc., a specialty pharmaceutical company. Prior to that, Ms. Butitta served as Chief Operating Officer of Telik, Inc., a biopharmaceutical company, from March 2001 to December 2010 and as its Chief Financial Officer from August 1998 to December 2010. Ms. Butitta also served as Principal Accounting Officer of Telik, Inc. until December 2010. She has served as a Director of Autolus, Ltd., a biotechnology company, since March 2018; a board member of Olema Oncology since August 2020 and Century Therapeutics, Inc. since February 2021. Ms. Butitta received her B.S. degree with honors in Business and Accounting from Edgewood College in Madison, Wisconsin and her M.B.A. degree in Finance from the University of Wisconsin-Madison. Our Board believes Ms. Butitta's financial knowledge and experience qualify her to serve on our Board.

Stuart Holden, M.D. has served as our director since December 2015. Dr. Holden has been the Chair of ProQuest Investments' Scientific Advisory Board since it was founded in 1998. Since May 2014, Dr. Holden has served as a member of the UCLA faculty as a Health Sciences Clinical Professor of Urology, Spielberg Family Chair in Urologic Oncology, in the Department of Urology at the UCLA David Geffen School of Medicine and Associate Director of the UCLA Institute of Urologic Oncology. Dr. Holden has worked in the field of prostate cancer for more than 36 years. Dr. Holden also serves as Medical Director of the Prostate Cancer Foundation since the foundation's inception in 1993. Dr. Holden was the director of the Louis Warschaw Prostate Cancer Center at Cedars-Sinai Medical Center and the first holder of the Warschaw, Robertson, Law Families Chair in Prostate Cancer. Dr. Holden has served as a member of the board of directors of Telormedix SA from 2008 to 2017 and served as a member of the board of directors of Acurian, Inc. from 1999 through 2014. Dr. Holden also served on the Board of the American College of Medical Informatics from 1999 through 2006 and is currently on the board of Clarus Therapeutics, Inc. In addition, he was a founding partner at Tower Urology in Los Angeles. Dr. Holden received a B.S. degree from the University of Wisconsin-Madison and completed his medical degree and received his surgical training at Weill Cornell Medical College and the New York Hospital-Cornell University Medical College. He completed his urology residency at Emory University School of Medicine and fellowships in urology and developmental genetics at Memorial Sloan-Kettering Cancer Center. He also was awarded a clinical fellowship from the American Cancer Society. Our Board believes Dr. Holden's medical knowledge and experience qualify him to serve on our Board.

James A. Robinson, Jr. has served as our director since July 2023. Mr. Robinson currently serves as the President, Chief Executive Officer and member of the board directors of A2 Biotherapeutics, Inc. Prior to this role, he served as the Chief Executive Officer of Urovant Sciences, Inc. from March 2020 through June 2023 and has served as a member of Urovant's board of directors from March 2019 through June 2023. Prior to Urovant Sciences, Mr. Robinson held the position of President and Chief Operating Officer at Paragon Biosciences where he oversaw Paragon's operations from April 2019 to March 2020. Previously, Mr. Robinson served as the President and Chief Operating Officer of Alkermes, where he was responsible for global commercial, new product planning, corporate planning, manufacturing, quality, human resources and business development functions. Prior to Alkermes, Mr. Robinson spent over twelve years at Astellas U.S., most recently as President, Americas Operations, where his responsibilities included all aspects of operations for North and South America. Prior to that, he was President of Astellas Pharma US, where he was responsible for leading the U.S. commercial organization. Prior to Astellas, Mr. Robinson spent thirteen years at Schering-Plough Pharmaceuticals, where his last role was Vice President, Hepatitis Sales and Managed Care. Mr. Robinson currently serves as an advisor to BridgeBio Pharma, Inc. and on the board of directors of Eledon Pharmaceuticals, Inc., a public biotechnology company, and Petauri Health, a private healthcare service company. Previously, Mr. Robinson served on the board of directors of Neos Therapeutics, Inc. prior to its acquisition by Aytu Biopharma, Inc. as well as the board of directors of Applied Genetic Technologies Corporation until its acquisition by Syncona LTD in November 2022. He also previously served on the board of directors of the Pharmaceutical Research and Manufacturers of America ("PhRMA") and served as Chairman of PhRMA's State Committee. He is a founding member of MATTER. Mr. Robinson received a Bachelor of Science degree from DePaul University. Our Board believes Mr. Robinson's broad business leadership experience, including his experience as an executive of commercial organizations, qualifies him to serve on our Board.

Leana S. Wen, M.D., M.Sc. has served as our director since August 2022. Dr. Wen is an emergency physician and has served as a faculty member at the George Washington University since September 2019. She has been a contributing columnist for The Washington Post since June 2020, writing on health policy and public health, and a health and medical expert for CNN since August 2020. From January 2015 to October 2018, she was the health commissioner for the city of Baltimore, where she led the nation's oldest continuously operating health department to combat the opioid epidemic and improve maternal and child health. From 2013 to 2015, Dr. Wen served as director of patient-centered care research in the department of emergency medicine at George Washington University, and authored a critically-acclaimed book on patient advocacy. She is currently on the board of the Bipartisan Policy Center and the Baltimore Community Foundation, and chairs the advisory board of the Behavioral Health Group. She has also been a global health fellow at the World Health Organization, a consultant with the China Medical Board, and a nonresident senior fellow at the Brookings Institution. Dr. Wen also served as the President of Planned Parenthood from 2018 through 2019. She has been a member of more than ten nonprofit boards, including serving as the chair of Behavioral Health System Baltimore. Dr. Wen has also served on the board of directors of Glaukos Corporation since March 2021 and also serves on its audit committee. Dr. Wen's work has been recognized by numerous professional organizations, including as one of Modern Healthcare's Top 50 Physician-Executives and a member of the Council on Foreign Relationships. In 2019, she was named one of TIME magazine's 100 Most Influential People and in 2022 as one of Modern Healthcare's 100 Most Influential People in Healthcare. She holds a B.S. from California State University, Los Angeles, an M.D. from Washington University School of Medicine and two M.Sc.s from the University of Oxford, where she was a Rhodes Scholar. She completed her residency training at Brigham & Women's Hospital and Massachusetts General Hospital, where she was a clinical fellow at Harvard Medical School. Our Board believes Dr. Wen's experience as a practicing physician, combined with her extensive experience working in governmental sectors, with innovative health companies, and serving on a public company board and audit committee and on nonprofit boards and foundations qualify her to serve on our Board.

Daniel G. Wildman has served as our director since November 2022. Mr. Wildman is Chairman of the Board of Progenerative Medical, Inc., a pre-commercial company translating clinically proven reduced pressure technology into medical treatments for orthopedic surgeries. He also serves on the board of directors for Nyxoah S.A., Progenerative Medical, Inc. and PanTher Therapeutics, Inc. At Johnson & Johnson, Mr. Wildman led the Digital Surgery Strategy initiative where he was tasked with developing an integrated strategy for robotic surgery for the company. This strategy directly led to the 2019 acquisition of Auris Health, Inc. Prior to Digital Surgery, Mr. Wildman led Depuy Synthes Spine. In this role, he had overall responsibility for the second-largest spine surgery business in the world ($1.8B). He served in this capacity from August of 2015 to September of 2017, and during this period developed and implemented an integrated turn-around plan for the company. Previously, Mr. Wildman served as Worldwide President of Ethicon Biosurgery, a division of Ethicon, Inc. From 2003-2015 he led this global business dedicated to delivering innovative and life-saving solutions to surgeons via development and commercialization of biomaterial, biologic and combination products that changed the standard of care for intraoperative hemostasis. In this role, Mr. Wildman transitioned the company from Advanced Wound Care to Biosurgery through a combination of acquisitions, divestitures, and internal capability development, all focused on development and commercialization of meaningful innovations. The Biosurgery business at Ethicon continues to be one of the fastest growing companies in Johnson & Johnson's portfolio. Prior to Johnson & Johnson, Mr. Wildman spent 10 years with Boston Scientific Corporation in a variety of sales, marketing, operations and strategic planning roles of increasing responsibility. Mr. Wildman is an accomplished global leader. Throughout his career, he has earned a solid reputation for his strategic vision, motivational leadership, innovative technologies, ability to execute and his commitment to people development. Mr. Wildman received a Bachelor of Arts degree in Economics from St. Lawrence University in New York. Our Board believes Mr. Wildman's business and executive experience qualify him to serve on our Board.

Information Concerning Our Executive Officers

The following table sets forth information concerning our executive officers, including their ages.

Name of Executive Officer	Age	Position(s)
Elizabeth Barrett	62	Chief Executive Officer and Director
Chris Degnan	45	Chief Financial Officer
Mark P. Schoenberg, M.D.	67	Chief Medical Officer
Jason Smith	53	General Counsel and Chief Compliance Officer

The biography of Ms. Barrett is set forth under the heading "Information Concerning Our Directors" above.

Chris Degnan has served as our Chief Financial Officer since October 2024. Prior to joining UroGen, Mr. Degnan served as the Chief Financial Officer of Galera Therapeutics, Inc., a public, late-stage biopharmaceutical company focused on oncology, from October 2019 to August 2024. Prior to Galera, Mr. Degnan served as the Chief Financial Officer of Verrica Pharmaceuticals Inc., a public, biotechnology company focused on medical dermatology, from March 2018 to October 2019. Prior to Verrica, Mr. Degnan held roles of increasing responsibility at Endo International plc, a generics and specialty branded pharmaceutical company, beginning in November 2014. At Endo, Mr. Degnan most recently served as the Vice President of Finance, Corporate FP&A and International Pharmaceuticals Segment Chief Financial Officer from December 2016 to March 2018. Prior to that, he served as the Vice President of Finance, Chief Financial Officer for Endo's U.S. Branded Pharmaceuticals segment from March 2016 to December 2016, and as the Senior Finance Director, U.S. Branded Pharmaceuticals from November 2014 to March 2016. Prior to joining Endo, Mr. Degnan held roles of increasing responsibility at AstraZeneca plc, a global biopharmaceutical company, beginning in 2004. At AstraZeneca, Mr. Degnan most recently served as Senior Finance Director, U.S. Commercial Finance from July 2013 to November 2014. Mr. Degnan is a Certified Public Accountant in the State of Pennsylvania (voluntary inactive status) and holds a B.B.A. degree in Accountancy from the University of Notre Dame.

Mark P. Schoenberg, M.D. has served as our Chief Medical Officer since December 2017 and, prior to that, served as our Medical Director since February 2016. Dr. Schoenberg has over 20 years of experience in clinical practice and research focused on the care of patients with all forms of bladder cancer. Since April 2014, Dr. Schoenberg has been University Professor and Chair of the Urology Department at The Montefiore Medical Center for The Albert Einstein College of Medicine of Yeshiva University. Prior to joining Montefiore, from 2005 to 2014, Dr. Schoenberg served as Director of Urologic Oncology and Bernard L. Schwartz Distinguished Professor of Urologic Oncology at Johns Hopkins Hospital. Dr. Schoenberg is also the past chair of the Medical Advisory Board of the Bladder Cancer Advocacy Network, the author of The Guide to Living with Bladder Cancer, co-editor of The Textbook of Bladder Cancer, a contributor to Campbell's Urology and a past Senior Editor of the journal Seminars in Urologic Oncology. Dr. Schoenberg received his M.D. (Alpha Omega Alpha) from the University of Texas Health Sciences Center and completed his residency in General Surgery and Urology at the Hospital of The University of Pennsylvania, where he served as chief resident and urology instructor, before completing basic research and clinical urologic oncology fellowships at Johns Hopkins under the auspices of The American

Cancer Society. Dr. Schoenberg is a fellow of the American College of Surgeons, as well as a member of the American Association of Cancer Research, the Society of Urologic Oncology and the American Urological Association.

Jason Smith has served as our General Counsel, Chief Compliance Officer and Corporate Secretary since August 2020. Mr. Smith is responsible for leading our legal, intellectual property, and corporate compliance functions. Mr. Smith joined us from Pfizer Inc., where he served as Chief Counsel, Oncology from August 2016 to August 2020. Prior to Pfizer, Mr. Smith worked in the legal department at Wyeth in a variety of roles including as antitrust counsel, Global Product Counsel and Chief Counsel, U.S. Pharmaceuticals, leading a team of lawyers supporting the prescription pharmaceuticals businesses. Before joining Wyeth, Mr. Smith was an associate at Howrey, Simon, Arnold & White in Washington, DC, in the antitrust and commercial litigation groups. Mr. Smith received his bachelor's degree in Economics, cum laude from Binghamton University and his juris doctor degree, with high honors, from George Washington University.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company's directors and executive officers, and persons who own more than ten percent of a registered class of the Company's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of ordinary shares and other equity securities of the Company. Officers, directors and greater than ten percent shareholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file.

During the year ended December 31, 2024, Mr. Kim, Dr. Schoenberg, and Mr. Smith each filed a Form 4 on September 12, 2024 for transactions that occurred September 9, 2024.

Conduct and Ethics

We have adopted a Corporate Code of Ethics and Conduct (the "Code of Conduct") applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.urogen.com. Our Audit Committee is responsible for monitoring the implementation of the Code of Conduct and must approve any material changes to or waivers of the Code of Conduct regarding our directors or executive officers, and disclosures made in the Company's annual report in such regard. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of the applicable stock exchange concerning any amendments to, or waivers from, any provision of the Code of Conduct.

Audit Committee

Our Board of Directors has a standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Our Audit Committee consists of Ms. Butitta, Dr. Holden and Dr. Wen. Ms. Butitta serves as Chair of the Audit Committee. All members of our Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our Board has determined that Ms. Butitta is an "audit committee financial expert" as such term is defined in the applicable SEC rules and has the requisite financial experience as defined by the Nasdaq listing standards. Each of the members of our Audit Committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act and satisfies the independent director requirements under the Nasdaq listing standards.

Insider Trading Policy; Hedging and Pledging Policy

We have adopted an insider trading policy ("Insider Trading Policy") governing the purchase, sale, and/or other dispositions of the Company's securities by directors, officers, and other employees of the Company that is designed to promote compliance with insider trading laws, rules and regulations, as well as procedures designed to further the foregoing purposes. A copy of our Insider Trading Policy is filed as an exhibit to the Form 10-K for our fiscal year ended December 31, 2024. In addition, it is the Company's intent to comply with applicable laws and regulations relating to insider trading.

Our Insider Trading Policy also prohibits our directors, officers and employees, and generally any entities or family members of such individuals whose trading activities are controlled or influenced by any such persons, from engaging in short sales, transactions in put or call options, hedging transactions, margin accounts or other inherently speculative transactions with respect to our equity securities, which protects against short-term decision making.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION

We are a "smaller reporting company" under Item 10 of Regulation S-K promulgated under the Exchange Act and the following compensation disclosure is intended to comply with the requirements applicable to smaller reporting companies. Although the rules allow us to provide less detail about our executive compensation program than companies that are not smaller reporting companies, our Compensation Committee is committed to providing the information necessary to help shareholders understand its executive compensation-related decisions. Accordingly, this section includes supplemental narratives that describe our 2024 compensation program for our named executive officers.

Overview

Our fundamental objective is to advance patient care while creating consistent long-term value for our shareholders. To accomplish this objective, we have established an overall compensation program intended to attract and retain highly qualified executives, incentivize achievement of our key performance goals in order to align our executives' interests with those of our shareholders and link pay to company performance. We take a holistic approach to assessing Company performance, and identify corporate objectives that align with our short- and long-term strategic priorities, and build towards creation of long-term, sustainable shareholder value.

Our 2024 corporate performance highlights include the following:

- Our UGN-102 Pivotal ENVISION trial demonstrated a 12-month duration of response of 82.3% (95% CI, 75.9%, 87.1%), by Kaplan-Meier estimate, for patients who achieved a complete response at three months after the first instillation of UGN-102.

- Our new drug application (NDA) for UGN-102 was accepted in October 2024 and is under review by the FDA, with a Prescription Drug User Fee Act (PDUFA) target action date set for June 13, 2025.

- We secured an exclusive license from medac GmbH to develop a next-generation novel mitomycin-based formulation for urothelial cancers.

- We received a new U.S. patent that covers the use of our UGN-103 and UGN-104 development programs in the treatment of low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC) and low-grade upper tract urothelial cancer (LG-UTUC), respectively. The U.S. patent has an expiration date in December 2041. UGN-103 and UGN-104 combine our proprietary *RTGel* technology with medac GmbH's licensed proprietary lyophilized mitomycin formulation.

- We entered into multiple strategic research collaborations to explore the potential of our proprietary *RTGel* technology to enhance clinical effectiveness of multiple immunotherapies in support of long-term growth strategy.

- We restructured our loan agreement with Pharmakon Advisors providing UroGen with additional funding of up to $100 million.

- We completed an underwritten public offering of ordinary shares for aggregate gross proceeds of $123.6 million, before deducting underwriting discounts and commissions and offering expenses.

- JELMYTO® achieved net product revenue of $90.4 million in 2024, compared with $82.7 million in 2023, driven by underlying demand revenue growth of 12% for 2024.

The following discussion describes our executive compensation process and policies. It provides qualitative information on the factors relevant to these decisions and the manner in which compensation is awarded to our named executive officers for the fiscal year ended December 31, 2024, which consisted of our principal executive officer, our current principal financial officer, our general counsel and chief compliance officer, and our former principal financial officer. These named executive officers were as follows:

Name	Position(s)
Elizabeth Barrett	President and Chief Executive Officer
Chris Degnan	Chief Financial Officer
Jason Smith	General Counsel and Chief Compliance Officer
Don Kim	Former Chief Financial Officer

Objectives, Philosophy and Elements of Executive Compensation

Our compensation program aims to achieve the following main objectives:

- attract, retain and reward highly qualified executives;
- provide incentives that motivate executives to achieve our key performance goals that create shareholder value;
- align our executives' interests with those of our shareholders; and
- link pay to company performance.

The Company's executive compensation program is overseen by the Compensation Committee with the advice and support of an independent third-party compensation consultant. The following are key characteristics of the Company's executive compensation program:

- **A substantial portion of executive pay is tied to performance**. We structure a significant portion of our named executive officers' compensation to be variable. Annual cash performance bonuses and long-term equity compensation are dependent on achievement of corporate performance objectives and determined by the Compensation Committee.

- **Our executive bonuses are dependent on the Company and the officer achieving annually determined objectives**. As a smaller reporting company with significant development-stage activities, we take a holistic approach to evaluating the Company's performance. We measure performance against challenging objectives established at the beginning of each performance cycle. We establish a broad set of measurable performance objectives that align with our long-term strategic priorities and build towards lasting long-term value. Our annual performance-based bonus opportunities for all our named executive officers are determined by the Compensation Committee, and ultimately the Board, based upon the Company's and the officer's achievement of objectives determined on an annual basis by the Company.

- **We emphasize long-term equity incentives**. Equity awards are an integral part of our executive compensation program and comprise the primary "at-risk" portion of our named executive officer compensation package. During 2024, we granted our executive officers options to purchase our ordinary shares, restricted stock units and performance stock units. These awards strongly align our executive officers' interests with those of our shareholders by providing a continuing financial incentive to maximize value for our shareholders and by encouraging our executive officers to remain in our long-term employ. Options and restricted stock units granted to our named executive officers in 2024 vest in equal annual installments over three years from the vesting commencement date. Performance stock units granted to our executive officers in 2024 will vest upon the first sale of our product candidate UGN-102, directly tying a substantial component of our executive officers' total compensation to performance against one of the primary drivers of long-term value.

- **Our Compensation Committee has retained Compensia as an independent third-party compensation consultant for guidance in making compensation decisions**. The compensation consultant advises the Compensation Committee on market practices, including identifying a peer group of companies and their compensation practices, so that our Compensation Committee can regularly assess the Company's individual and total compensation programs against these peer companies, the general marketplace and other industry data points.

- **We do not provide our executive officers with any excise tax gross ups**.

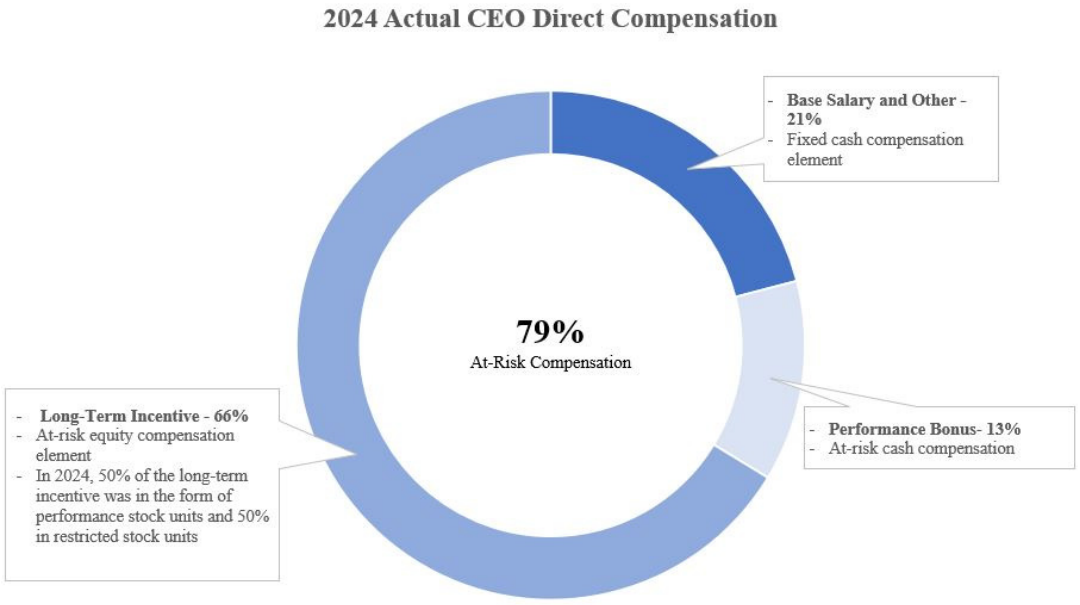
- **We have not repriced options**.

- **We do not provide executive fringe benefits or perquisites to our executives**.

Our executive compensation program generally consists of, and is intended to strike a balance among, the following three principal components: base salary, annual performance-based bonuses and long-term incentive compensation. We provided signing bonuses to our executive officers when they joined the Company. We also provide our executive officers with benefits available to all our employees, including participation in employee benefit plans. The following chart summarizes the three main elements of compensation, their objectives and key features.

Element of Compensation	**Objectives**	**Key Features**
Base Salary **(fixed cash)**	Provides financial stability and security through a fixed amount of cash for performing job responsibilities.	Generally reviewed annually and determined based on a number of factors, including in part, market data provided by our independent compensation consultant.
Performance Bonus **(at-risk cash)**	Motivates and rewards for attaining key annual Company and executive officer performance objectives.	Target bonus amounts are generally reviewed annually and determined based upon positions that have similar impact on the organization and competitive bonus opportunities in our market. Bonus opportunities are dependent upon achievement of specific corporate performance objectives consistent with our strategic plan and individual performance objectives that relate to the officer's role and expected contribution toward reaching our corporate goals, determined by the Board and communicated at the beginning of the year. Actual bonus amounts earned are determined at the end of the year, taking into account corporate and individual performance objectives.
Long-Term Incentive **(at-risk equity)**	Motivates and rewards for long-term Company performance; aligns executives' interests with shareholder interests and changes in shareholder value. Attracts highly qualified executives and encourages their continued employment over the long-term.	Equity opportunities are generally reviewed annually and may be granted during the first half of the year or as appropriate during the year for new hires, promotions, or other special circumstances, such as to encourage retention, or as a reward for significant achievement. Individual awards are determined based on a number of factors, including current corporate and individual performance and market data provided by our independent compensation consultant.

We focus on providing a competitive compensation package to our executive officers which provides short- and long-term incentives for the achievement of measurable Company and executive officer objectives. We believe that this approach provides an appropriate blend of short-term and long-term incentives to maximize shareholder value. We generally do not have any formal policies for allocating compensation among salary, performance bonus awards and equity grants, short-term and long-term compensation or among cash and non-cash compensation, although total annual cash bonus compensation to any individual is capped at 150% of such individual's salary pursuant to our Officers Compensation Policy. Our Compensation Committee uses its judgment to establish a total compensation program for each named executive officer that is a mix of current, short-term and long-term incentive compensation, and cash and non-cash compensation, that it believes is appropriate to achieve the goals of our executive compensation program and our corporate objectives. In 2024 our Actual CEO compensation was as follows:



To ensure the alignment of our executive officer incentives with shareholder interests, we have historically structured a significant portion of the named executive officers' total target compensation with performance-based bonus opportunities and long-term incentive equity awards. Additionally, in 2024, half of the value of our CEO's long-term incentive equity awards were in the form of performance stock units which vest upon the first sale of our lead product candidate UGN-102, directly tying a substantial component of our CEO's total compensation to performance against one of the primary drivers of long-term value creation. Our CEO's total direct compensation for 2024 was positioned at approximately the 20th percentile of our compensation peer group. Our non-CEO executives' total direct compensation for 2024 was positioned at approximately the 15th percentile of our compensation peer group (see section titled "Use of Competitive Market Compensation Data" below for more detail on the selection of our compensation peer group).

2024 Say-on-Pay Results

At our 2024 annual meeting of shareholders, we held a shareholder advisory vote on executive compensation, commonly referred to as a "say-on-pay" vote, which resulted in over 87% of the total votes cast being in favor of the advisory proposal, representing a significant increase over the prior year's approval percentage.

We continue to assess and enhance our approach to executive compensation by seeking feedback from shareholders and reviewing the analyses of the Institutional Shareholder Services and Glass Lewis published reports. Our approach to aligning pay and performance focuses on maintaining a significant portion of executive's annual total compensation based on evaluation of individual executives' performance against our corporate objectives. We take a holistic approach to assessing Company performance, undertake a robust goal-setting process to determine corporate objectives that align with our short- and long-term strategic priorities, and build towards creation of shareholder value.

We continually endeavor to align our executives' interests with those of our shareholders, and link pay to company performance. We have identified receipt of U.S. regulatory approval for our lead product candidate UGN-102 as critical short and long-term strategic objectives. In 2024 and 2025, we have included performance stock units as part of our officers' long-term incentive compensation, with vesting of these performance stock units upon the first commercial sale of UGN-102 and upon achievement of a net product sales target for UGN-102, respectively, directly tying a substantial component of our officers' total compensation to the primary drivers of long-term value.

Our next "say-on-pay" vote will be held at our 2025 annual meeting of shareholders.

Our Compensation Governance Structure

Role of our Compensation Committee, Management and the Board

The Compensation Committee is appointed by the Board and has responsibilities related to the compensation of the Company's directors, officers, and employees and the development and administration of the Company's compensation plans. For details on the Compensation Committee's oversight of the executive compensation program, see the section above titled "Compensation Committee". Our Compensation Committee consists solely of independent members of the Board.

The Compensation Committee reviews all compensation paid to our executive officers, including our named executive officers. The Chief Executive Officer evaluates and provides to the Compensation Committee performance assessments and compensation recommendations. While the Chief Executive Officer discusses her recommendations with the Compensation Committee, she does not participate in the deliberations concerning her own compensation. More specifically, the Compensation Committee discusses and makes final recommendations to the Board with respect to executive compensation matters without the Chief Executive Officer present during discussions of the Chief Executive Officer's compensation. From time to time, various other members of management and other employees as well as outside advisors or consultants may be invited by the Compensation Committee to make presentations, provide financial or other background information or advice or otherwise participate in the Compensation Committee meetings.

The Compensation Committee meets periodically throughout the year to manage and evaluate our executive compensation program, and generally determines the principal components of compensation (base salary, performance bonus and equity awards) for our executive officers on an annual basis; however, decisions may occur at other times for new hires, promotions or other special circumstances as our Compensation Committee determines appropriate. The Compensation Committee does not delegate authority to approve executive officer compensation. The Compensation Committee does not maintain a formal policy regarding the timing of equity awards to our executive officers. The Compensation Committee will continue to monitor and evaluate our executive compensation program in light of our shareholders' views, before making any adjustments, and continue to consider the outcome of our say-on-pay votes and our shareholders' views when making future compensation decisions for our named executive officers.

Role of Compensation Consultant

The Compensation Committee has the sole authority to retain compensation consultants to assist in its evaluation of executive compensation, including the authority to approve the consultant's reasonable fees and other retention terms. The Compensation Committee has retained Compensia, Inc. ("Compensia"), a management consulting firm that provides executive compensation and advisory services to compensation committees of life sciences companies, as its compensation consultant. A representative of Compensia attends meetings of the Compensation Committee at the invitation of the Committee. In addition, Compensia supported the selection of companies included in our compensation peer group, provided competitive market assessments of the compensation of our executive officers and non-employee director compensation programs, and provided support on other matters as requested by the Compensation Committee.

The Compensation Committee has analyzed whether the work of Compensia as compensation consultant raises any conflict of interest, taking into account relevant factors in accordance with SEC guidelines. Based on its analysis, our Compensation Committee determined that the work of Compensia and the individual compensation advisors employed by Compensia does not create any conflict of interest pursuant to the SEC rules and Nasdaq listing standards.

Use of Competitive Market Compensation Data

The Compensation Committee believes that it is important when making its compensation decisions to be informed as to the current practices of comparable public companies with which we compete for top talent.

Working with Compensia, the Compensation Committee approved a group of companies that were identified as peers based on alignment with our Company's industry, stage of drug development, headcount, and market capitalization. The peer group that was identified and used in research that informed executive compensation for 2024 included the following companies: 2seventy bio, Arcus Biosciences, Day One Biopharmaceuticals, Deciphera Pharmaceuticals, Eagle Pharmaceuticals, Erasca, IDEAYA Biosciences, Inhibrx, iTeos Therapeutics, Karyopharm Therapeutics, Kura Oncology, RAPT Therapeutics, Rigel Pharmaceuticals, Syndax Pharmaceuticals, Tango Therapeutics, Verastem, Xencor and Y-mAbs Therapeutics.

Compensia completed a benchmarking assessment of our historical executive compensation at the end of 2023 to inform the Compensation Committee's determinations regarding executive compensation for 2024 using data compiled from the aforementioned peer group. Identification of peers included consideration of comparable market capitalization, revenues, investigational and/or in-line portfolio, number of employees as well as stage and maturity of the peer company. Compensia prepared and the Compensation Committee reviewed, a range of market data reference points with respect to base salary, performance bonuses, target total cash compensation (base salary and the annual target performance bonus), equity compensation, and total direct compensation (target total cash compensation and equity compensation) with respect to each of the named executive officers.

Additionally, Compensia performed benchmarking analysis of actual 2024 executive compensation awarded as compared to the following peers: Acrivon Therapeutics, Arcus Biosciences, Arvinas, Aura Biosciences, C4 Therapeutics, Day One Biopharmaceuticals, Erasca, IDEAYA Biosciences, iTeos Therapeutics, Kura Oncology, Olema Pharmaceuticals, Rigel Pharmaceuticals, Sutro Biopharma, Syndax Pharmaceuticals, Tango Therapeutics, Tyra Biosciences, Xencor and Y-mAbs Therapeutics. Changes in the peer group were driven by consideration of comparable market capitalization, as well the acquisition of several companies in the prior peer group. This benchmarking analysis found that overall target total direct compensation awarded in 2024 was at approximately the 15th percentile for our executive officers excluding the CEO and the 20th percentile for the CEO. This analysis of 2024 compensation and other research performed by Compensia is then used to inform the Compensation Committee's determinations regarding executive compensation for 2025.

Factors Used in Determining Executive Compensation

Our Compensation Committee sets the compensation of our executive officers at levels they determine to be competitive and appropriate for each named executive officer, using their professional experience and judgment. Pay decisions are not made by use of a formulaic approach or benchmark; the Compensation Committee believes that executive pay decisions require consideration of a multitude of relevant factors which may vary from year to year. In making executive compensation decisions, the Compensation Committee generally takes into consideration the factors listed below.

- Company performance and existing business needs
- Each named executive officer's individual performance, scope of job function and the critical skill set of the named executive officer to the Company's future performance
- The need to attract new talent to our executive team and retain existing talent in a highly competitive industry
- A range of market data reference points, as described above under "Use of Competitive Market Compensation Data"
- Recommendations from consultants on compensation policy determinations for the executive officer group

2024 Executive Compensation Summary

Base Salary

The base salaries of our executive officers are designed to compensate them for day-to-day services rendered during the fiscal year. Appropriate base salaries are used to recognize the experience, skills, knowledge and responsibilities required of each executive officer and to allow us to attract and retain individuals capable of leading us to achieve our business goals in competitive market conditions.

The base salaries of our executive officers are reviewed at least annually by our Compensation Committee and adjustments are made to reflect Company and individual performance, as well as competitive market practices. Our Compensation Committee also takes into account subjective performance criteria, such as an executive officer's ability to lead, organize and motivate others, develop the skills necessary to mature with us, set realistic goals to be achieved in his or her respective area, and recognize and pursue new business opportunities that enhance our growth and success. Our Compensation Committee does not apply specific formulas to determine increases, but instead makes an evaluation of each executive officer's contribution to our long-term success. Annual adjustments to base salaries are effective as of March 1 of each year, with mid-year adjustments to base salaries made under special circumstances, such as promotions or increased responsibilities, or to align certain base salaries with those of individuals in comparable positions at the companies in our compensation peer group.

The 2024 base salaries for our named executive officers were as follows:

Executive	Base Salary	Percentage Increase in Base Salary from December 2023
Elizabeth Barrett	$831,342	4.00%
Chris Degnan	$500,000	*
Jason Smith	$478,067	4.00%
Don Kim	$435,120	12.00%

* Mr. Degnan commenced employment with us in October 2024.

Annual Performance Bonus

Our named executive officers are eligible to receive performance-based cash bonuses, which are designed to provide appropriate incentives to our executive officers to achieve defined annual corporate goals and to reward them for individual performance towards these goals. The annual performance-based bonus that each named executive officer is eligible to receive is generally based on the extent to which we achieve the corporate objectives that the Board establishes each year. At the end of the year, the Board and Compensation Committee review the Company's performance and approve the extent to which we achieved each of these corporate goals. Generally, the Board and Compensation Committee will assess each named executive officer's individual contributions towards reaching our annual corporate goals and objectives but does not typically establish specific individual goals for our named executive officers.

The table below sets forth the targets for our named executive officers for 2024, as provided for in their respective employment agreements. The target percentage is paid as a percentage of such executive officer's base salary. For example, if 100% of the Company's performance goals are achieved, this would yield our Chief Executive Officer, Elizabeth Barrett, a cash incentive award of 75% of her base salary.

Executive Officer	Target Percentage of Base Salary
Elizabeth Barrett	75%
Chris Degnan	50%
Jason Smith	50%
Don Kim	50%

In late 2023, the Compensation Committee finalized the corporate goals for the 2024 performance year as described below. Our objective corporate goals were designed to be challenging to achieve and are directly aligned with our specific strategic goals, including advancing our development programs, our research function, our clinical activities, commercialization activities and certain corporate and financial goals, which we believe will create value for shareholders. The maximum possible corporate achievement for 2024 was 150% of our 2024 corporate goals (up to 100% for the core goals and 50% for the stretch goals), regardless of whether the maximum weighting of 60% for the stretch goals were achieved. In December 2024, the Compensation Committee and the Board evaluated the accomplishments and performance of the Company against such corporate goals, including progress towards the goal in making their recommendations for the ultimate funding levels, and the Board made the following determinations regarding corporate performance achieved against the pre-established performance goals.

Corporate Goal – Core	**Weighting**	**Corporate Achievement**
FDA acceptance of UGN-102 application by Oct 31st 2024	65%	Achieved
Achieve $100 million in revenue	35%	Not Achieved

Corporate Goal – Stretch	**Weighting**	**Corporate Achievement**
Exceed $100 million revenue target by 10%, 20%, 30%	5%, 10%, 15% (max 15%)	Not Achieved
Accelerated FDA acceptance of UGN-102 by 30, 60, 90 days ahead of Oct 31st, 2024	10%, 15% 25% (max 25%)	Not Achieved
Execute a Strategic Partnership/Business Development Deal (1)	20%	Achieved

(1) Entered into multiple strategic research collaborations to explore the potential of our proprietary *RTGel* technology to enhance clinical effectiveness of multiple immunotherapies in support of long-term growth strategy.

In January 2025, the Board reviewed and approved corporate cash incentives as set forth in the table below. The Compensation Committee or Board may, in its sole discretion, eliminate any individual cash incentive or reduce or increase the amount of compensation payable with respect to any individual cash incentive.

	2024 Target Annual Cash Incentive		**2024 Actual Annual Cash Incentive Paid**	
Named Executive Officer	**% of Base Salary**	**$**	**% of Target Annual Cash Incentive**	**$**
Elizabeth Barrett	75%	$ 623,507	85%	$ 529,981
Chris Degnan	50%	$ 250,000	92%	$ 53,125 (1)
Jason Smith	50%	$ 239,034	85%	$ 203,179
Don Kim (2)	50%	$ 217,560	—	—

(1) The actual annual cash incentive paid to Mr. Degnan has been prorated for the period from the date of hire, October 8, 2024, to year-end, December 31, 2024.

(2) Mr. Kim resigned from his positions as the Company's Chief Financial Officer, Principal Financial Officer, and Principal Accounting Officer, effective October 8, 2024. As a result, his annual cash incentive is included under "All Other Compensation" in the Summary Compensation Table, as part of his separation agreement.

Equity Awards

In 2024, the Compensation Committee approved the following grants of options to purchase our ordinary shares, restricted stock units and performance stock units to our named executive officers.

Executive	Share Option Grant (# shares)	Restricted Stock units (# shares)	Performance Stock units (# shares)
Elizabeth Barrett	-	87,615	87,615
Chris Degnan [(1)]	74,142	13,450	-
Jason Smith	-	16,500	16,500
Don Kim	-	12,000	12,000

(1) Grants to Mr. Degnan reflect new hire grants. Since Mr. Degnan commenced employment with us in October 2024, he did not receive a performance stock unit.

All options and restricted stock units granted to our named executive officers above vest in equal annual installments over three years from the vesting commencement date, subject to the continued service of the named executive officer through each vesting date. Performance stock units vest based on the first commercial sale of our lead product candidate UGN-102, subject to the continued service of the named executive officer through the vesting date. The annual equity grants to our named executive officers are evaluated and approved by the Compensation Committee in the context of each named executive officer's total compensation and take into account the market data provided by compensation consultants in addition to the individual officer's responsibilities and performance. New hire equity grants to our named executive officers are evaluated and approved by the Compensation Committee and the Board based on competitive market data provided by compensation consultants as well as such officer's experience and expected contributions. The Compensation Committee also takes into account the recommendations of the Chief Executive Officer with respect to appropriate grants and any particular individual circumstances, other than with respect her own grants.

Other Features of Our Executive Compensation Program

Agreements with Our Named Executive Officers

We have entered into written employment agreements with each of our executive officers. Each of these employment agreements provides for "at will" employment and set forth the initial compensation arrangements for the executive officer, including an initial base salary, an annual cash opportunity, and an equity award recommendation. These agreements and the proprietary information and invention assignment agreements each executive officer executes upon commencing employment at the Company also set forth the rights and responsibilities of each party and include, among other rights and responsibilities, the prohibition on the executive officer from engaging directly or indirectly in competition with us, soliciting any of our employees, or disclosing our confidential information.

Below are descriptions of our employment agreements with our named executive officers. For a discussion of the severance payments and other benefits to be provided in connection with an involuntary termination of employment, including in connection with a change in control of the Company under the arrangements with our executive officers, please see "Severance and Change in Control Benefits" below.

Elizabeth Barrett. On January 3, 2019, we entered into an employment agreement with Ms. Barrett, which was amended in January 2021 to provide certain change in control benefits, as described in more detail below under "Severance and Change in Control Benefits". Pursuant to her employment agreement, Ms. Barrett (i) received a signing bonus of $300,000 (subject to full repayment if she resigned without good reason, or the Company terminated her employment for cause, before January 3, 2020); (ii) received an initial annual base salary of $700,000; (iii) was eligible to receive an annual discretionary bonus for 2019 of up to 100% of her base salary, with 50% guaranteed; and (iv) is eligible to receive annual discretionary bonuses for years following 2020, with an annual target bonus of 50% of her base salary. In December 2023, the Board approved an increase in the annual bonus target from 50% to 75% to be effective starting with the 2024 performance year.

Pursuant to her employment agreement, Ms. Barrett was also initially granted a restricted stock unit covering 317,065 of our ordinary shares and an option to purchase 277,432 ordinary shares. Under the terms of an omnibus amendment of Ms. Barrett's prior equity award agreements, executed in January 2021, the remainder of the unvested shares underlying both of these equity awards vested in full in January 2022, in lieu of the prior monthly vesting.

Chris Degnan. On October 7, 2024, we entered into an employment agreement with Mr. Degnan. Pursuant to the terms of the agreement, Mr. Degnan receives an annual base salary of $500,000 and is eligible for a target annual cash bonus equal to 50% of his base salary (pro-rated in the case of a partial year). Mr. Degnan was granted an initial new hire option to purchase 74,142 ordinary shares and 13,450 restricted stock units.

Jason Smith. On August 12, 2020, we entered into an employment agreement with Mr. Smith, which was amended in January 2021 to provide certain change in control benefits, as described in more detail below under "Severance and Change in Control Benefits". Pursuant to the terms of the agreement, Mr. Smith (i) received a signing bonus of $100,000 (which was subject to full repayment if his employment with the Company had terminated for any reason before August 31, 2021), (ii) received an initial annual base salary of $425,000 and (iii) was eligible for a target annual cash bonus equal to 50% of his base salary. Mr. Smith was granted an initial new hire option to purchase 60,000 ordinary shares and 25,000 restricted stock units.

Don Kim. On March 20, 2022, we entered into an employment agreement with Mr. Kim. Pursuant to the terms of the agreement, Mr. Kim (i) received an initial annual base salary of $370,000 and (ii) is eligible for a target annual cash bonus equal to 50% of his base salary. Mr. Kim was granted an initial option to purchase 20,000 ordinary shares. On October 8, 2024, Mr. Kim resigned as the Company's Chief Financial Officer.

On October 7, 2024, we entered into a separation and consulting agreement with Mr. Kim, pursuant to which Mr. Kim resigned from his positions as the Company's Chief Financial Officer, effective October 8, 2024, and agreed to provide consulting services to us on a part-time basis through April 28, 2025 in exchange for a cash payment of $36,260. The consulting agreement was subsequently extended to September 30, 2025. Mr. Kim's outstanding equity awards as of October 8, 2024 remain eligible for continued vesting through September 30, 2025. In addition, pursuant to the separation agreement, we have paid or will pay Mr. Kim: (i) the equivalent of nine months of his base salary in effect as of October 8, 2024, paid as salary continuation over nine months, (ii) a lump sum payment equal to $217,590, which was equal to Mr. Kim's target performance bonus for 2024, and (iii) reimbursement for COBRA premiums for up to nine months following October 8, 2024.

Severance and Change in Control Benefits

Our employment agreements with Ms. Barrett, Mr. Degnan, Mr. Smith, and Mr. Kim (prior to his resignation) provide that they are eligible for severance benefits upon certain involuntary terminations of employment, including in connection with a change in control, as described below.

Pursuant to their respective employment agreements (or amended employment agreements in the case of Ms. Barrett and Mr. Smith), if the named executive officer is terminated by the Company without cause, by the named executive officer for good reason, or due to the named executive officer's death or disability, then the named executive officer will be entitled to the following severance benefits: (i) continuing base salary payments for 6 months (or 12 months in the case of Ms. Barrett); (ii) a prorated target annual bonus for the year of termination (to the extent earned based on Company performance and with any individual performance component deemed achieved); (iii) any unpaid annual bonus earned with respect to the year preceding termination; (iv) the accelerated vesting of restricted shares and options held by the named executive officer at the time of such termination (in the case of Ms. Barrett, the portion of the award otherwise scheduled to vest within the 12 month period following termination; and in the case of Mr. Degnan, Mr. Smith and Mr. Kim, vesting will be accelerated by $1/12^{th}$, such that 8.33% of the total restricted shares and options subject to the awards will be deemed immediately vested and exercisable); and (v) COBRA payment reimbursement for up to 6 months for Mr. Degnan, Mr. Smith and Mr. Kim, and 12 months in the case of Ms. Barrett following such termination.

If there is a change in control and the named executive officer is terminated without cause or resigns for good reason, in either case within three months prior to, or 24 months following the effective date of the change in control, all four named executive officers will be entitled to 100% vesting and exercisability of all of his or her Company equity awards or other equity interests that are outstanding and unvested as of the termination or resignation date as well as the following severance benefits, in lieu of the corresponding severance benefits described above: (i) a lump sum payment equal to the sum of (1) 12 months (18 months in the case of Ms. Barrett) of his or her then-current annual base salary and (2) 100% of his or her current target annual bonus; and (ii) the amount of any COBRA premium payments made by the named executive officer during the 12 months (or 18 months in the case of Ms. Barrett) following such termination.

Payment of the severance benefits described in the preceding paragraphs is subject to the named executive officer signing and not revoking a separation agreement and release of claims in a form satisfactory to us.

Other Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We provided a 401(k) plan to all of our U.S. employees, including our named executive officers. We do not generally provide perquisites or personal benefits to our named executive officers. We do, however, pay the premiums for term life insurance and disability insurance for all of our employees, including our named executive officers.

Tax and Accounting Implications

Under Financial Accounting Standard Board ASC Topic 718 ("ASC Topic 718"), we are required to estimate and record an expense for each award of equity compensation over the vesting period of the award. We record share-based compensation expense on an ongoing basis according to ASC Topic 718.

Under Section 162(m) of the Code, compensation paid to each of our "covered employees" that exceeds $1 million per taxable year is generally non-deductible. Although the Compensation Committee will continue to consider tax implications as one factor in determining executive compensation, it also looks at other factors in making its decisions and retains the flexibility to provide compensation for our named executive officers in a manner consistent with the goals of our executive compensation program and our best interests, and the best interests of our shareholders, which may include providing for compensation that is not deductible by us due to the deduction limit under Section 162(m) of the Code.

Clawbacks

As a public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal 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, certain covered officers, including the Chief Executive Officer and Chief Financial Officer, may be legally required to reimburse our Company for any cash bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of section 304 of the Sarbanes-Oxley Act of 2002. Additionally, we have adopted an incentive compensation recoupment policy to comply with Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder and Nasdaq Listing Rule 5608.

Risk Analysis of Our Compensation Policies and Practices

The Compensation Committee has reviewed the Company's compensation policies and practices, in consultation with Compensia and outside Company counsel, to assess whether they encourage employees to take inappropriate risks. After reviewing and assessing the Company's compensation philosophy, terms and practices, including the mix of fixed and variable, short and long-term incentives and overall pay, incentive plan structures, and the checks and balances built into, and oversight of, each plan and practice, the Compensation Committee determined that any risks arising from our compensation policies and practices for our employees are not reasonably likely to have a material adverse effect on our Company as a whole. The Compensation Committee believes that the mix and design of the elements of executive compensation do not encourage management to assume excessive risks; the mix of short-term compensation (in the form of salary and annual bonus, if any, which is based on a variety of performance factors), and long-term compensation (in the form of options to purchase our ordinary shares and restricted stock units) prevents undue focus on short-term results and helps align the interests of the Company's executive officers with the interests of our shareholders.

2024 Summary Compensation Table

The following table sets forth all of the compensation awarded to, earned by or paid to our named executive officers during the years indicated.

Name and Principal Position	Year	Salary ($)	Bonus ($) [1]	Stock Awards ($) [2]	Option Awards ($) [3]	Non-Equity Incentive Plan Compensation ($) [4]	All Other Compensation ($) [5]	Total ($)
Elizabeth Barrett.....	2024	826,013	—	2,751,111	—	529,981	42,753	4,149,858
Chief Executive Officer	2023	794,243	19,984	2,464,250	836,533	479,620	44,959	4,639,589
Chris Degnan [6]	2024	115,530	—	176,330	695,294	53,125	13,510	1,053,789
Chief Financial Officer	2023	—	—	—	—	—	—	—
Jason Smith	2024	475,003	—	518,100	—	203,179	79,182	1,275,464
General Counsel and Chief Compliance Officer	2023	456,733	47,984	376,300	267,691	275,808	83,663	1,508,179
Don Kim [7].....	2024	363,694	—	376,800	—	—	623,728	1,364,222
Former Chief Financial Officer	2023	—	—	—	—	—	—	—

(1) Represents discretionary bonuses paid to the named executive officer for the applicable year. Discretionary bonuses earned in 2023 were approved by the Board based on assessment of overall achievements in the business and individual performance, including the accomplishments noted in our 2023 corporate performance highlights, above.

(2) Represents the aggregate grant-date fair value of the restricted stock units and, except for Mr. Degnan, performance stock units awarded to the named executive officer for the applicable year, calculated in accordance with ASC Topic 718 and does not take into account estimated forfeitures, which value is based on the closing market price of our ordinary shares on the date of grant. The grant date fair value of the restricted stock units is based on the closing market price of the Company's ordinary shares on the date of the grant. The grant date fair value and the maximum potential value of the performance stock units are the same and are based on the closing market price of our ordinary shares on the date of grant.

(3) Represents the aggregate grant-date fair value of the stock options awarded to the named executive officer for the applicable year, calculated in accordance with ASC Topic 718, and does not take into account estimated forfeitures related to service-based conditions. The assumptions used in the calculation of these amounts are included in Note 16 of the Form 10-K for the year ended December 31, 2024, filed with the SEC on March 10, 2025.

(4) For more information, see "Annual Performance Bonus" above.

(5) The amounts reported in this column represent the value of Company-paid life insurance, Company contributions to 401(k) plans, other Company paid health, dental, disability and insurance premiums, and/or amounts paid or accrued under a plan or arrangement in connection with a termination, severance, or change of control (in the case of Mr. Kim).

(6) Mr. Degnan commenced employment with us in October 2024.

(7) Mr. Kim resigned from his positions as the Company's Chief Financial Officer, Principal Financial Officer, and Principal Accounting Officer, effective October 8, 2024. As a result, Mr. Kim's "All Other Compensation" included amounts paid or accrued under a plan or arrangement in connection with his termination of $585,182, which included his severance, annual cash incentive, a post-separation consulting arrangement, and COBRA payment reimbursement. Mr. Kim was not a named executive officer in 2023.

2024 Outstanding Equity Awards at Fiscal Year End Table

The following table shows for the fiscal year ended December 31, 2024, certain information regarding outstanding equity awards at fiscal year-end for our named executive officers.

Name	Grant Date	Option Awards: Number of Securities Underlying Unexercised Options (#) Exercisable[1]	Option Awards: Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)[2]	Option Expiration Date	Stock Awards: Number of Shares of Stock that have not Vested (#)	Stock Awards: Market Value of Shares of Stock that have not Vested ($)[3]	Equity Incentive Plan Awards: Number of Unearned Shares, units or other rights that have not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that have not Vested ($)[4]
Elizabeth Barrett....	1/3/2019	277,432	—	47.57	1/3/2029	—	—		
	1/31/2020	45,000	—	29.41	1/31/2030	—	—		
	1/31/2021					13,334	142,007		
	1/31/2021	150,000	—	22.07	1/31/2031	—	—		
	1/31/2022	100,000	50,000	7.72	1/31/2032	—	532,500		
	1/31/2023					75,000	798,750		
	1/31/2023	41,666	83,334	10.39	1/31/2033	—	887,507		
	9/7/2023							100,000	1,065,000
	1/31/2024					87,615	933,100		
	1/31/2024							87,615	933,100
Chris Degnan.....	10/8/2024 [5]					13,450	143,243		
	10/8/2024 [5]	—	74,142	13.11	10/8/2034	—	789,612		
Jason Smith	10/1/2020 [5]	60,000	—	19.66	10/1/2030	—	—		
	1/31/2021	8,000	—	22.07	1/31/2031	—	—		
	6/5/2021	15,000	—	17.98	6/5/2031	—	—		
	1/31/2022					2,500	26,625		
	1/31/2022	20,000	10,000	7.72	1/31/2032	—	106,500		
	1/31/2023					13,334	142,007		
	1/31/2023	13,333	26,667	10.39	1/31/2033	—	284,004		
	9/7/2023					6,667	71,004		
	1/31/2024					16,500	175,725		
	1/31/2024							16,500	175,725
Don Kim.....	12/1/2021	10,000	—	11.92	12/1/2031	—	—		
	1/31/2022					3,334	35,507		
	3/25/2022	13,333	6,667	8.61	3/25/2032	—	71,004		
	1/31/2023					6,667	71,004		
	1/31/2023	12,666	25,334	10.39	1/31/2033	—	269,807		
	9/7/2023					5,000	53,250		
	1/31/2024					12,000	127,800		
	1/31/2024							12,000	127,800

(1) Options granted to Ms. Barrett, Mr. Degnan, Mr. Smith, and Mr. Kim vest in equal annual installments over three years from the vesting commencement date.

(2) Options to purchase our ordinary shares were granted with a per share exercise price equal to the fair market value of one ordinary share on the date of grant, as determined in good faith by our Board.

(3) RSU and option grants with amounts that have not yet vested vest in equal annual installments over three years from the grant date. Market value is based on the Company's share price as of December 31, 2024.

(4) Represents performance stock units which vest upon the earlier of the receipt of U.S. regulatory approval for our lead product candidate UGN-102 in the three years following the grant or the occurrence of a change in control, or for certain other awards, the achievement of the first commercial sale of UGN-102 in the United States following UGN-102's receipt of regulatory approval. Market value is based on the Company's share price as of December 31, 2024.

(5) Awards granted to Mr. Smith and Mr. Degnan in 2020 and 2024, respectively, were granted as inducement awards under equity compensation plans not approved by security holders. All other equity awards were granted under our 2017 Plan.

Compensation Committee Interlocks and Insider Participation

None of our directors who serve as a member of our Compensation Committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our Board or Compensation Committee.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

From time to time, the Company grants stock options to its employees, including the named executive officers. Historically, the Company has generally granted new-hire option awards to our executive officers on or shortly following the executive's employment start date. For other new hires, new-hire option awards are generally granted in the first week of the month following the new hire's employment start date. Promotion option grants are generally granted in the month following the promotion date. The Company's typical practice is to grant annual employee equity awards on January 31st of each year, which includes stock options for certain employees, including the named executive officers. These grants are recommended by the Compensation Committee at a regularly scheduled meeting in December of the preceding year. Our non-employee directors receive automatic grants of initial and annual stock option awards, at the time of a director's initial appointment or election to the Board and at the time of each annual meeting of the Company's shareholders, respectively, pursuant to the Non-Employee Director Compensation Policy, as further described under the heading, "Director Compensation—Non-Employee Director Compensation Policy," below. The Company does not otherwise maintain any written policies on the timing of awards of stock options, stock appreciation rights, or similar instruments with option-like features. Because we have a practice of generally granting new-hire, promotion and annual refresh options at specified times, as described above, the Board and the Compensation Committee generally do not take material non-public information ("MNPI") into account when determining the timing or terms of awards, and they do not seek to time the award of stock options in relation to the Company's public disclosure of MNPI. The Company has not timed the release of MNPI for the purpose of affecting the value of executive compensation.

The following table is provided pursuant to Item 402(x) of Regulation S-K:

Name	Grant Date	Number of Securities Underlying the Award	Exercise Price of the Award ($/Share)	Grant Date Fair Value of the Award	Percentage Change in the Closing Market Price of the Securities Underlying the Award Between the Trading Day Immediately Prior to the Disclosure of Material Nonpublic Information and the Trading Day Beginning Immediately Following Disclosure of Material Nonpublic Information
Chris Degnan[(1)]	10/8/2024	74,142	13.11	$695,294	(9.3%)

(1) On October 9, 2024, the Company filed a Current Report on Form 8-K reporting the departure of its former Chief Financial Officer and the appointment of Mr. Degnan as the Company's new Chief Financial Officer.

DIRECTOR COMPENSATION

Non-Employee Director Compensation

The following table sets forth in summary form information concerning the compensation that we paid or was earned or awarded during the year ended December 31, 2024 to each of our non-employee directors:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) [1]	Total ($)
Arie Belldegrun, M.D., FACS [2]	200,000	131,911	331,911
Cynthia M. Butitta [3]	62,011	131,911	193,922
Stuart Holden, M.D. [4]	54,511	131,911	186,422
Leana Wen, M.D., M.SC. [5]	64,510	131,911	196,421
Daniel G. Wildman (Wildman Ventures LLC) [6]	62,391	131,911	194,302
James A. Robinson, Jr. [7]	52,011	131,911	183,922
Fred E. Cohen, M.D., D.Phil [8]	39,076	131,911	170,987

(1) The amounts reported in this column do not reflect the amounts that may actually be received by our non-employee directors. Instead, these amounts reflect the aggregate grant date fair value of options to purchase our ordinary shares granted to our non-employee directors during the fiscal year ended December 31, 2024, as computed in accordance with ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 16 in the Form 10-K for the year ended December 31, 2024, filed with the SEC on March 10, 2025. As required by SEC rules, the amounts reported exclude the impact of estimated forfeitures related to service-based vesting conditions. Our non-employee directors who have received shares will only realize compensation with regard to these options to the extent the market price of our ordinary shares is greater than the exercise price of such options.

(2) Aggregate number of option awards outstanding held by Dr. Belldegrun at December 31, 2024 was 82,500.

(3) Aggregate number of option awards outstanding held by Ms. Butitta at December 31, 2024 was 112,500.

(4) Aggregate number of option awards outstanding held by Dr. Holden at December 31, 2024 was 72,500.

(5) Aggregate number of option awards outstanding held by Dr. Wen at December 31, 2024 was 27,500.

(6) Aggregate number of option awards outstanding beneficially owned by Mr. Wildman at December 31, 2024 was 25,833.

(7) Aggregate number of option awards outstanding held by Mr. Robinson at December 31, 2024 was 20,833.

(8) Dr. Cohen resigned from our Board effective on September 12, 2024. Dr. Cohen did not hold any outstanding options at December 31, 2024.

The cash fees paid to or earned by our directors in 2024, as reflected in the table above, were paid pursuant to our director compensation policy. In August 2024, our shareholders approved an increase of the annual cash compensation for non-employee directors from $40,000 to $45,000 for their service on the Board, except for our Chair, Dr. Belldegrun, who received $195,000 for his service as Chair of our Board. Members of the Compensation Committee, Nominating and Corporate Governance Committee, and the Compliance Committee, received an additional $5,000 per year, or $15,000 in the case of the committee Chair. Members of the Audit Committee received an additional $7,500 per year, or $20,000 in the case of the committee Chair.

Non-Employee Director Compensation Policy

Our Board adopted a Director Compensation Policy pursuant to which each of our directors who is not an employee of our company, which is currently all directors other than Ms. Barrett, is eligible to receive compensation for service on our Board and committees of our Board. Under the Director Compensation Policy, each non-employee member of our Board is entitled to receive a cash retainer in the following amounts for service in each specified role:

Annual Board Service Retainer:

- Chair of the Board: $195,000
- All other eligible directors: $45,000 (which amount was increased from $40,000 upon shareholder approval in August 2024)

Annual Committee Member Service Retainer (in addition to Board Service Retainer):

- Member of the Audit Committee: $7,500
- Member of the Compensation Committee: $5,000
- Member of the Nominating and Corporate Governance Committee: $5,000
- Member of the Compliance Committee: $5,000

Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):

- Chair of the Audit Committee: $20,000
- Chair of the Compensation Committee: $15,000
- Chair of the Nominating and Corporate Governance Committee: $15,000
- Chair of the Compliance Committee: $15,000

Each non-employee director is also entitled to receive an initial option grant to purchase 20,000 of our ordinary shares, and an annual option grant to purchase 10,000 of our ordinary shares on the date of each annual shareholders meeting of the Company, contingent upon their continued service as a non-employee member of the Board. If a director joins the Board between annual meetings, the annual grant awarded at his/her first annual meeting will be pro-rated based on the duration of service leading up to the meeting date: (i) for service between 0 (zero) and 90 (ninety) days – no grant; (ii) for service between 91 (ninety-one) and 180 (one hundred eighty) days – 5,000 (five thousand) options; and (iii) for service of at least 181 (one hundred eighty-one) days – 10,000 (ten thousand) options. The exercise price per share of each stock option granted under the non-employee director compensation policy will be equal to 100% of the fair market value of the underlying ordinary share on the date of grant. The initial option grants vest in equal quarterly installments over a period of three years. The annual option grants vest in equal quarterly installments over a period of one year.

Additionally, a grant in excess of the 20,000 ordinary share initial option grant may be applied as an inducement for eligible or prospective non-employee directors.

Our non-employee directors also received reimbursement of their actual out-of-pocket costs and expenses incurred in connection with attending Board meetings.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes our compensation plans under which our equity securities are authorized for issuance at December 31, 2024:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights[3]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	2,323,729	$25.82	1,223,963
Equity compensation plans not approved by security holders[1]	288,114[2]	$10.69	430,729
Total	2,611,843	$24.15	1,654,692

1. In May 2019, we adopted the UroGen Pharma Ltd. 2019 Inducement Plan (the "Inducement Plan") without the approval of our security holders. Under the Inducement Plan, the Company is authorized to issue up to 900,000 ordinary shares pursuant to awards issued under the Inducement Plan. In December 2021, the Board approved a 300,000 increase in the share reserve of the Inducement plan. In June 2024, the Board approved a 600,000 increase in the share reserve of the Inducement plan. Our Inducement Plan provides for the grant of nonstatutory stock options, restricted stock unit awards, and other awards. The only persons eligible to receive awards under our Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) or 5635(c)(3) 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 addition, awards granted under our Inducement Plan must be approved by either a majority of the Company's "independent directors" (as such term is defined in Nasdaq Marketplace Rule 5605(a)(2)) or the Compensation Committee, provided such committee comprises solely independent directors. The terms of our Inducement Plan are otherwise substantially similar to our Amended 2017 Plan (including with respect to the treatment of awards upon corporate transactions involving us or certain changes in our capitalization).

2. As of December 31, 2024, options to purchase 288,114 ordinary shares and restricted stock units covering 410,610 shares were outstanding under the Inducement Plan. All options granted under the Inducement Plan have a maximum term of ten years. The Inducement Plan, and awards thereunder, may be amended by the Board at any time or from time to time in accordance with the terms of the Inducement Plan and applicable law.

3. The weighted-average exercise price does not take into account the shares subject to outstanding restricted stock units which have no exercise price.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information relating to the beneficial ownership of our ordinary shares as of March 31, 2025, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding ordinary shares;
- each of our directors and each nominee for director;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

Beneficial ownership is based upon 46,101,785 ordinary shares issued and outstanding as of March 31, 2025 and determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Unless otherwise indicated, we believe that the persons or entities identified in this table have sole voting and investment power with respect to all shares shown beneficially owned by them, subject to applicable community property laws. Ordinary shares issuable upon vesting of outstanding equity awards that are exercisable or subject to vesting within 60 days after March 31, 2025 are deemed beneficially owned and such shares are used in computing the percentage ownership of the person holding the awards but are not deemed outstanding for the purpose of computing the percentage ownership of any other person. The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose, and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares.

Unless otherwise noted below, the address of each shareholder, director and executive officer is c/o UroGen Pharma Ltd., 400 Alexander Park Drive, 4th Floor, Princeton, New Jersey 08540.

Name of Beneficial Owner	Number	Percent
Greater than 5% Shareholders		
RTW Investments, LP [1]	3,787,347	8.2%
RA Capital Management, L.P. [2]	3,206,271	7.0%
Adage Capital Management, L.P. [3]	2,928,086	6.4%
BlackRock, Inc. [4]	2,497,943	5.4%
Directors and Named Executive Officers		
Elizabeth Barrett [5]	1,032,456	2.2%
Chris Degnan	—	*
Jason Smith [6]	172,180	*
Don Kim [7]	100,420	*
Arie Belldegrun M.D., FACS [8]	496,193	1.1%
Cynthia M. Butitta [9]	117,500	*
Stuart Holden, M.D. [10]	77,500	*
Leana Wen, M.D., M.SC. [11]	34,166	*
Daniel G. Wildman [12]	34,166	*
James A. Robinson Jr. [13]	29,166	*
All current directors and executive officers as a group (10 persons) [14]	2,232,431	4.7%

* Indicates beneficial ownership of less than 1% of the total ordinary shares outstanding.

1) Represents ordinary shares beneficially owned as of September 30, 2024, based on a Schedule 13G/A filed on November 14, 2024, by RTW Investments, LP. In such filing, RTW Investments LP lists its address as 40 10th Avenue, Floor 7, New York, New York 10014, and indicates that it has shared voting power with respect to 4,930,204 ordinary shares, including 1,142,857 ordinary shares issuable upon exercise of warrants, and shared dispositive power with respect to 4,930,204 ordinary shares, including 1,142,857 ordinary shares issuable upon exercise of warrants.

2) Represents ordinary shares beneficially owned as of September 30, 2024, based on a Schedule 13G/A filed on November 14, 2024, by RA Capital Management, L.P. In such filing, RA Capital Management, L.P. lists its address as RA Capital Management, L.P., 200 Berkeley Street, 18th Floor, Boston MA 02116, and indicates that it has shared voting power with respect to 3,206,271 ordinary shares and shared dispositive power with respect to 3,206,271 ordinary shares.

3) Represents ordinary shares beneficially owned as of December 31, 2024, based on a Schedule 13G/A filed on February 12, 2025, by Adage Capital Management, L.P. In such filing, Adage Capital Management, L.P. lists its address as 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116, and indicates that it has shared voting power with respect to 2,928,086 ordinary shares and shared dispositive power with respect to 2,928,086 ordinary shares.

4) Represents ordinary shares beneficially owned as of September 30, 2024, based on a Schedule 13G filed on November 8, 2024, by BlackRock, Inc. In such filing, BlackRock, Inc. lists its address as BlackRock, Inc., 50 Hudson Yards, New York, NY 10001, and indicates that it has shared voting power with respect to 2,453,286 ordinary shares and shared dispositive power with respect to 2,497,943 ordinary shares.

5) Consists of 326,691 ordinary shares and 705,765 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2025.

6) Consists of 32,514 ordinary shares and 139,666 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2025.

7) Consists of 45,087 ordinary shares (based on Mr. Kim's Form 4 filed on September 12, 2024 and subsequent vesting of his restricted shares) and 55,333 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2025.

8) Consists of 408,693 ordinary shares and 87,500 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2025.

9) Consists of 117,500 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2025.

10) Consists of 77,500 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2024.

11) Consists of 34,166 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2025.

12) Consists of 34,166 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2025.

13) Consists of 29,166 ordinary shares issuable upon exercise of options or upon settlement of restricted stock units within 60 days following March 31, 2025.

14) Includes the shares described in notes (5), (6) and (8) through (13) and 239,104 ordinary shares (which includes 90,564 ordinary shares issuable upon the exercise of options or upon settlement of restricted stock units within 60 days of March 31, 2025) beneficially owned by an additional executive officer who is not named in the table above.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

TRANSACTIONS WITH RELATED PERSONS

Certain Related-Person Transactions

Described below are all transactions occurring since January 1, 2023 to which we were a party and in which (i) the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and (ii) a director, executive officer, holder of more than 5% of our outstanding ordinary shares, or any member of such person's immediate family had or will have a direct or indirect material interest, other than the equity and other compensation agreements that are described under "Executive Compensation" and "Director Compensation" or that are not required to be described under this item pursuant to the instructions to Item 404(a) of Regulation S-K. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, in arm's-length transactions with unrelated third parties.

On July 26, 2023, we entered into a securities purchase agreement with certain institutional and other accredited investors (the "Purchasers"), pursuant to which the Company 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 (the "Private Placement").

Monograph Capital Partners I, L.P. ("Monograph"), a life sciences venture firm that is affiliated with Dr. Cohen, a former director of the Company, purchased 1,572,327 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.

On February 14, 2025, the Company entered into an Asset Purchase Agreement (the "Agreement") with IconOVir Bio, Inc. ("IconOVir"), pursuant to which the Company purchased and acquired certain assets of IconOVir, including the product candidate ICVB-1042 and certain contracts, intellectual property rights, regulatory applications, submissions and registrations, and data and other rights related thereto, and assumed certain liabilities and obligations of IconOVir arising under certain contracts of IconOVir acquired by the Company. As consideration for the acquired assets, the Company (i) issued 374,843 ordinary shares of the Company (the "Company Shares") to IconOVir, which represents a purchase price of $4.0 million divided by the volume-weighted average closing price of the Company Shares on The Nasdaq Stock Market over the 30 consecutive trading days ending on (and including) the trading day immediately prior to the closing of the acquisition, (ii) agreed to pay IconOVir a one-time payment of $15.0 million in cash upon the achievement of a cumulative aggregate worldwide net sales milestone for all products, including combination products, that incorporate or comprise ICVB-1042 ("ICVB Products"), (iii) agreed to pay IconOVir a low, single-digit percentage royalty, on an ICVB Product-by-ICVB Product basis, on the annual, worldwide net sales of such ICVB Product during the royalty term, subject to certain reductions as set forth in the Agreement, and (iv) agreed to assume certain immaterial liabilities arising under certain acquired contracts ((i), (ii), (iii), and (iv) collectively, the "Purchase Price").

Entities affiliated with Arie Belldegrun, M.D., the Chair of the Board of Directors of the Company, held certain promissory notes of IconOVir that may entitle such entities to receive, in the aggregate, approximately 28.3% of the Purchase Price.

Indemnification agreements

Our articles of association permit us to exculpate, indemnify and insure each of our directors and executive officers to the fullest extent permitted by the Israeli Companies Law. We have entered into indemnification agreements with each of our directors and executive officers, undertaking to indemnify them to the fullest extent permitted by Israeli law, to the extent that these liabilities are not covered by insurance. We have also obtained Directors and Officers insurance for each of our executive officers and directors.

Employment Agreements

We have entered into an employment agreement with our named executive officers. For more information regarding these agreements, see "Executive Compensation".

Equity Award Grants to Executive Officers and Directors

We have granted options to purchase our ordinary shares and restricted stock units to our directors and named executive officers as more fully described in the sections titled "Director Compensation" and "Executive Compensation," respectively.

Policies and Procedures for Transactions with Related Persons

We adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a "related person transaction" is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A "related person" is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our Audit Committee or, if Audit Committee approval would be inappropriate, to another independent body of our Board, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, interests, direct and indirect, of the related persons, benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our Audit Committee, or other independent body of our Board, is required to take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our Audit Committee, or other independent body of our Board, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our Audit Committee, or other independent body of our Board, determines in the good faith exercise of its discretion.

Independence of the Board of Directors

Applicable Nasdaq rules require a majority of a listed company's directors to be comprised of independent directors within one year of listing. In addition, Nasdaq rules require that, subject to specified exceptions, each member of a listed company's Audit, Compensation and Nominating and Corporate Governance Committees be independent and that Audit Committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. The Board consults with the Company's counsel to ensure that the Board's independence determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in the pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, the Board has determined that all of our directors, except Ms. Barrett, are independent directors, as defined under applicable Nasdaq listing standards. In making such determination, our Board considered the relationships that each such non-employee director has with the Company and all other facts and circumstances that our Board deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director.

Item 14. Principal Accountant Fees and Services.

Principal Accountant Fees and Services

The following table represents aggregate fees billed to us for the years ended December 31, 2024 and 2023, by PwC.

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Audit Fees[1]	$ 1,384	$ 1,195
Tax Fees[2]	—	80
All Other Fees[3]	2	1
	$ 1,386	$ 1,276

1) For the years ended December 31, 2024 and 2023, the aggregate audit fees were for professional services rendered for audits, quarterly reviews of our consolidated financial statements, statutory financial statements, registration statements and preparation of comfort letters.

2) For the years ended December 31, 2023, tax fees were tax transfer pricing services and tax consulting services.

3) For the years ended December 31, 2024 and 2023, all other fees were for accounting research subscription services.

All fees described above were pre-approved by the Audit Committee.

Pre-Approval Policies and Procedures

The Audit Committee must pre-approve all audit, audit-related and all permitted non-audit services, and related fees and terms, to be provided to the Company by the independent auditor under applicable law and regulations. Pre-approval may be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to the Audit Committee's Chairperson, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of services other than audit services by PwC US is compatible with maintaining the principal accountant's independence.

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 of the Form 10-K.

(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 Part II, Item 8 of the Form 10-K.

(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 (previously filed as Exhibit 4.2 to the Form 10-K).
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).
4.4	Form of June 2024 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 June 18, 2024).
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 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 8, 2024).
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 Performance Stock Award Grant Notice and Performance Stock Award Agreement under the UroGen Pharma Ltd. Israeli Sub-Plan to 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2024).
10.6	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).
10.7	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).
10.8	Amendment to Form of Restricted Stock Unit Grant Notice under the UroGen Pharma Ltd. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024)

10.9	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).
10.10	Amendment to Form of Performance-Based Restricted Stock Unit Grant Notice under the UroGen Pharma Ltd. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2024).
10.11*	UroGen Pharma Ltd. 2019 Inducement 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 August 13, 2024).
10.12	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).
10.13	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).
10.14	Amendment to Form of Restricted Stock Unit Grant Notice under the UroGen Pharma Ltd. 2019 Inducement Plan (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.15*	UroGen Pharma Ltd. 2024 Non-Employee Director and Officer Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 8, 2024).
10.16*	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).
10.17*	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).
10.18*	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).
10.19*	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).
10.20*	Amended Restricted Stock Unit Grant Notice by and between the Registrant and Elizabeth Barrett, dated as of December 20, 2023 (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.21*	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).
10.22*	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).
10.23*	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).

10.24*	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).
10.25*	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).
10.26*	Employment Agreement between the Company and Chris Degnan, dated October 7, 2024 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 9, 2024).
10.27*	Separation Agreement between the Company and Don Kim, dated October 7, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 9, 2024).
10.28†	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).
10.29	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).
10.30	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).
10.31†**	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).
10.32†**	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).
10.33†**	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).
10.34†**	Amendment 2 to Manufacturing & Supply Agreement, dated as of December 28, 2023 by and between UroGen Pharma Ltd. and Cenexi-Laboratoires Thissen s.a. (incorporated by reference to Exhibit 10.31 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.35†**	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. (incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
10.36	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 (incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).

10.37†**	Pre-Paid Forward Contract by and among the Registrant and RTW Investments ICAV for and on behalf of RTW Fund 2, dated as of March 18, 2021, as amended April 30, 2021 and August 14, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 6, 2024).
19.1	UroGen Pharma Ltd. Insider Trading Policy (previously filed as Exhibit 19.1 to the Form 10-K).
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 (previously filed as Exhibit 23.1 to the Form 10-K).
24.1	Power of Attorney (previously filed within the signature page of the Form 10-K).
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 (previously filed as Exhibit 31.1 to the Form 10-K).
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 (previously field as Exhibit 31.2 to the Form 10-K).
31.3	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
31.4	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
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 (previously filed as Exhibit 32.1 to the Form 10-K).
97	UroGen Pharma Ltd. Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 14, 2024).
101	The following financial information from the Annual Report on Form 10-K of UroGen Pharma Ltd. for the year ended December 31, 2024, 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 (previously filed as Exhibit 101.SCH, 101.CAL, 101.DEF, 101.LAB and 101.PRE to the Form 10-K).
104	The cover page to this Annual Report on Form 10-K/A 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.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to be signed on its behalf by the undersigned, thereunto duly authorized.

UROGEN PHARMA LTD.

April 30, 2025

By: /s/ Elizabeth Barrett
Elizabeth Barrett
President and Chief Executive Officer

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EXECUTIVE OFFICERS

Elizabeth Barrett
President, Chief Executive Officer and Director

Chris Degnan
Chief Financial Officer

Mark P. Schoenberg, M.D.
Chief Medical Officer

Jason Smith
General Counsel and Chief Compliance Officer

BOARD OF DIRECTORS

Arie Belldegrun, M.D., FACS
Chair of the Board

Elizabeth Barrett
President, Chief Executive Officer and Director

Cynthia M. Butitta

Stuart Holden, M.D.

James A. Robinson, Jr.

Leana S. Wen, M.D., M.Sc.

Daniel G. Wildman

CORPORATE HEADQUARTERS

400 Alexander Park Drive, Princeton, New Jersey 08540
Telephone: +1 (646) 768-9780
www.urogen.com

ORDINARY SHARES LISTING

Ticker Symbol: URGN, The Nasdaq Global Market

ANNUAL MEETING OF SHAREHOLDERS

The Annual Meeting of Shareholders of UroGen Pharma Ltd. will be held virtually via live audio webcast on Tuesday, August 26, 2025 at 10:00 a.m. ET.

TRANSFER AGENT AND REGISTRAR

Computershare Trust Company, N.A. 150 Royall Street, Canton, Massachusetts 02021. Telephone: (781) 575-2000
www.computershare.com/us

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

PricewaterhouseCoopers LLP

SHAREHOLDERS' INQUIRIES

Shareholders may obtain copies of our news releases, Securities and Exchange Commission filings, including Forms 10-K, 10-Q, and 8-K, and other company information by accessing our website at www.urogen.com. Shareholders may also contact Investor Relations at (646) 768-9780.

FORWARD-LOOKING STATEMENTS

Statements in this annual report and the accompanying letter from our Chief Executive Officer that are not strictly historical in nature are forward-looking statements. These statements include but are not limited to statements related to: the potential benefits of ZUSDURI to patients; the estimated U.S. market opportunity for ZUSDURI; the expected benefits to be gained from UroGen's existing infrastructure and experience; the belief that there is broad intent to adopt ZUSDURI in practice; the belief that certain JELMYTO metrics such as overall volume, patient enrollment forms, and new patient starts indicate positive momentum; plans to develop UGN-103 for LG-IR-NMIBC and other indications; statements related to the timing of UroGen's UGN-103 NDA submission and potential commercial launch; the potential applications of UGN-501 in treating bladder cancer as well as other types of cancers; and the belief that UroGen is well-positioned for sustained growth. Words such as "being," "continue," "estimate," "indicate," "may," "plan," "potential," "project," or other words that convey uncertainty of future events or outcomes are used to identify these forward-looking statements. These statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: clinical results may not be indicative of results that may be observed in the future, including in larger populations; potential safety and other complications related to UroGen's products; the ability to maintain regulatory approval; labeling limitations; competition in UroGen's industry; the scope, progress and expansion of developing and commercializing UroGen's products and product candidates; the size and growth of the market(s) therefor and the rate and degree of market acceptance thereof vis-à-vis alternative therapies or procedures, such as surgery; UroGen's ability to attract or retain key management, members of the board of directors and other personnel; UroGen's *RTGel* technology and ZUSDURI may not perform as expected; UroGen may not successfully develop and receive regulatory approval of any other product that incorporates *RTGel* technology; UroGen's financial condition and need for additional capital in the future; and the impacts of general macroeconomic and geopolitical conditions on UroGen's business and financial position. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section of UroGen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on May 12, 2025, the events and circumstances discussed in such forward-looking statements may not occur, and UroGen's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this annual report and the accompanying letter from our Chief Executive Officer, and are based on information available to UroGen as of such date.

UroGen® Pharma

UroGen Pharma Ltd.

ANNUAL REPORT

2024