UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)
☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2022

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 No.)**
400 Alexander Park Drive, Princeton, New Jersey	**08540**
(Address of principal executive offices)	**(Zip Code)**

(646) 768-9780

Registrant's telephone number, including area code

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

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, 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 3, 2022, the registrant had 22,693,170 ordinary shares, par value NIS 0.01 per share, outstanding.

UroGen Pharma Ltd.
Index

		Page
PART I.	FINANCIAL INFORMATION	1
Item 1.	Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations	2
	Condensed Consolidated Statements of Shareholders' Equity	3
	Condensed Consolidated Statements of Cash Flows	4
	Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	27
Item 4.	Controls and Procedures	29
PART II.	OTHER INFORMATION	30
Item 1.	Legal Proceedings	30
Item 1A.	Risk Factors	30
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	69
Item 3.	Defaults Upon Senior Securities	69
Item 4.	Mine Safety Disclosures	69
Item 5.	Other Information	69
Item 6.	Exhibits	70
	Signatures	71

Trademarks and Trade Names

Unless the context requires otherwise, references in this Quarterly Report to the "Company," "UroGen," "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 Quarterly Report. This Quarterly 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 Quarterly 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.

Part I—Financial Information

Item 1. Financial Statements.

UroGen Pharma Ltd.
Condensed Consolidated Balance Sheets
(unaudited; in thousands, except share amounts and par value)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 105,379	$ 44,360
Marketable securities	31,065	44,779
Restricted cash	550	1,226
Accounts receivable	9,499	11,717
Inventories	4,756	4,832
Prepaid expense and other current assets	9,275	7,476
Total current assets	160,524	114,390
Non-current assets:		
Property and equipment, net	1,777	1,967
Restricted deposit	223	223
Right of use asset	945	1,180
Marketable securities	674	675
Other non-current assets	1,572	1,311
Total Assets	$ 165,715	$ 119,746
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expense	$ 9,936	$ 12,102
Employee related accrued expense	5,146	6,948
Other current liabilities	4,009	3,330
Total current liabilities:	19,091	22,380
Non-current liabilities:		
Prepaid forward obligation	89,782	85,713
Long-term debt	70,797	—
Long-term lease liability	277	398
Uncertain tax positions liability	2,842	2,842
Total Liabilities	182,789	111,333
Commitments and contingencies (Note 18)		
Shareholders' equity:		
Ordinary shares, NIS 0.01 par value; 100,000,000 shares authorized at March 31, 2022 and December 31, 2021; 22,682,221 and 22,462,995 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	62	61
Additional paid-in capital	478,646	475,698
Accumulated deficit	(495,713)	(467,321)
Accumulated other comprehensive income (loss)	(69)	(25)
Total Shareholders' Equity (Deficit)	(17,074)	8,413
Total Liabilities and Shareholders' Equity (Deficit)	$ 165,715	$ 119,746

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

UroGen Pharma Ltd.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited; in thousands, except share and per share amounts)

	For the Three Months Ended March 31,	
	2022	**2021**
Revenue	$ 13,564	$ 7,485
Cost of revenue	1,525	897
Gross profit	12,039	6,588
Operating expense:		
Research and development expense	12,696	10,513
Selling, general and administrative expense	21,300	22,189
Operating loss	(21,957)	(26,114)
Financing on prepaid forward obligation	(5,826)	—
Interest expense on long-term debt	(282)	
Other income (expense)	(2)	179
Loss before income taxes	(28,067)	(25,935)
Income tax expense	(325)	—
Net Loss	$ (28,392)	$ (25,935)
Statements of Comprehensive Loss		
Net loss	$ (28,392)	$ (25,935)
Other comprehensive income		
Unrealized (loss) gain on marketable securities	(44)	(128)
Comprehensive Loss	$ (28,436)	$ (26,063)
Net loss per ordinary share basic and diluted	$ (1.25)	$ (1.17)
Weighted average number of shares outstanding used in computation of basic and diluted loss per ordinary share	22,631,509	22,242,375

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

UroGen Pharma Ltd.
Condensed Consolidated Statements of Shareholders' Equity
(unaudited; in thousands, except share amounts)

	Ordinary Shares					
	Number of Shares	Amount	Additional paid-in capital	Accumulated Deficit	Other comprehensive income (loss)	Total
Balance as of January 1, 2022	22,462,995	$ 61	$ 475,698	$ (467,321)	$ (25)	$ 8,413
Changes During the Three Months Ended March 31, 2022						
Exercise of options into ordinary shares	219,226	1	(1)			—
Share-based compensation			2,949			2,949
Other comprehensive income					(44)	(44)
Net loss				(28,392)		(28,392)
Balance as of March 31, 2022	22,682,221	$ 62	$ 478,646	$ (495,713)	$ (69)	$ (17,074)
Balance as of January 1, 2021	22,167,791	$ 60	$ 452,525	$ (356,501)	271	$ 96,355
Changes During the Three Months Ended March 31, 2021						
Exercise of options into ordinary shares	112,603	1	3			4
Share-based compensation			6,195			6,195
Other comprehensive income					(128)	(128)
Net loss				(25,935)		(25,935)
Balance as of March 31, 2021	22,280,394	$ 61	$ 458,723	$ (382,436)	$ 143	$ 76,491

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

UroGen Pharma Ltd.
Condensed Consolidated Statements of Cash Flow
(unaudited; in thousands)

	Three Months Ended March 31,	
	2022	**2021**
Cash Flows From Operating Activities		
Net loss	$ (28,392)	$ (25,935)
Adjustment to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	215	191
Accrued financing on prepaid forward obligation	4,289	—
Amortization on marketable securities	50	191
Share-based compensation	2,949	6,195
Interest expense on long-term debt	282	—
Amortization of right of use asset	241	237
Lease liability	(286)	(400)
Changes in operating assets and liabilities:		
Inventory	76	(1,367)
Accounts receivable	2,218	746
Prepaid expense and other current assets	(1,800)	(2,952)
Other non-current assets	(169)	—
Accounts payable and accrued expense	(2,169)	535
Employee related accrued expense	(1,801)	(4,842)
Other current liabilities	301	—
Net cash used in operating activities	(23,996)	(27,401)
Cash Flows From Investing Activities		
Maturities of marketable securities	13,621	15,311
Purchases of property and equipment	(25)	(287)
Net cash (used in) provided by investing activities	13,596	15,024
Cash Flows From Financing Activities		
Proceeds from exercise of options into ordinary shares	—	4
Proceeds from issuance of long-term debt	70,831	—
Issuance cost related to at-the-market issuances	(89)	—
Net cash provided by financing activities	70,742	4
Increase (Decrease) in Cash and Cash Equivalents	60,342	(12,373)
Cash, Cash Equivalents and Restricted Cash at Beginning of Period	45,587	54,090
Cash, Cash Equivalents and Restricted Cash at End of Period	$ 105,929	$ 41,717
Supplemental Disclosures of Non-Cash Activities		
Non-cash new lease liabilities	$ 6	$ (20)
Non-cash issuance cost	$ 3	$ —

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

UroGen Pharma Ltd.
Notes to the Unaudited Condensed Consolidated Financial Statements

Note 1 – Business and Nature of Operations

Nature of Operations

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

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

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

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

Note 2 – Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of the Company's management, the accompanying condensed consolidated financial statements contain all adjustments (consisting of normal recurring accruals and adjustments) necessary for fair statement of its financial position, results of operations and cash flows of the Company at the dates and for the periods indicated. Interim results are not necessarily indicative of results for the full fiscal year. The year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States. The unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission ("SEC") on March 21, 2022.

The Company has experienced net losses since its inception and has an accumulated deficit of $495.7 million and $467.3 million as of March 31, 2022 and December 31, 2021, 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. Based on management's cash flow projections the Company believes that its cash and cash equivalents and marketable securities are sufficient to fund the Company's planned operations for at least the next 12 months. The Company anticipates that it will need to raise additional capital in the future. There can be no assurances that the Company will be able to secure such additional financing if at all, or on terms that are satisfactory to the Company, and that it will be sufficient to meet its needs. In the event the Company is not successful in obtaining sufficient funding, this could force us to delay, limit, or reduce our product development, commercialization efforts or other operations.

Note 3 – Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results may differ from those estimates. As applicable to the unaudited condensed 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 condensed consolidated statements of operations as "Interest and other income, net."

Cash and Cash Equivalents; Marketable Securities

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents consist primarily of money market funds and bank money market accounts and are stated at cost, which approximates fair value. Restricted cash is related primarily to cash held to secure corporate credit cards; restricted deposits are related to cash held to secure leases.

Cash and cash equivalents and marketable securities totaled $137.1 million as of March 31, 2022. The Company classifies its 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 (expense), net. The cost of securities sold is based on the specific-identification method.

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.

Concentration of Credit Risk

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

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

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

Income Taxes

The Company provides for income taxes based on pretax income, if any, and applicable tax rates available in the various jurisdictions in which it operates, including Israel and the 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.

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 16 for further discussion related to income taxes.

Inventory

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

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

Property and Equipment

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

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

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

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

Prepaid Forward Obligation

The Company is party to a transaction with RTW Investments (the "RTW Transaction") in which the Company received funds to support the continued launch of *Jelmyto* and the development of UGN-102 in return for tiered, future cash payments based on net sales of *Jelmyto* and UGN-102, if approved by the FDA. The net proceeds received under the RTW Transaction were recognized as a long-term liability. The 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 condensed consolidated balance sheet. The Company recognizes capitalized financing expenses as a direct offset to the long-term debt on the Company's condensed consolidated balance sheet, and amortizes them over the term of the debt using the effective interest method. See Note 10 for further discussion related to long-term debt.

Leases

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

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

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

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

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

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

Revenue

Product sales from *Jelmyto* are recognized as revenue under ASC 606 at the point in time that control of the product has been transferred to the customer, generally at the point the product has been delivered to the treating physician. All product sales of *Jelmyto* are recognized through the Company's arrangement with a single customer, a third-party national specialty distributor. Net revenue recognized include 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, Medicaid drug rebate programs, and the Company's copay assistance program, which are estimated based on industry benchmarking studies as well as the Company's historical experience.

Research and Development Expense

Research and development costs are expensed as incurred and consist primarily of the cost of salaries, share-based compensation expense, 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 Expense

Selling, general and administrative expense consists 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. The fair value of options is determined using the Black-Scholes option-pricing model. The fair value of a restricted stock unit (“RSU”) equaled 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.

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.

Recently Issued Accounting Pronouncements

The Company has reviewed the Accounting Standards Updates recently issued by the Financial Accounting Standards Board, and determined that they are not applicable to the Company.

Note 4 – **Other Financial Information**

Accounts Payable and Accrued Expense

Accounts payable and accrued expense consists of the following as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Accounts payable	$ 4,234	$ 5,786
Accrued sales reserves	361	497
Accrued clinical expense	1,129	1,377
Accrued research and development expense	1,186	1,748
Accrued selling, general and administrative expense	2,042	1,965
Accrued other expense	984	729
Total accounts payable and accrued expense	$ 9,936	$ 12,102

Interest and Other Income (Expense), Net

Interest and other income (expense) consisted of the following as of March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Interest income	$ 2	$ 167
Other finance (expense), net	(4)	12
Total other income (expense)	$ (2)	$ 179

Note 5 – **Inventories**

Inventories consist of the following as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Raw materials (1)	$ 3,663	$ 3,894
Finished goods	2,365	1,958
Total inventories	$ 6,028	$ 5,852

(1) $1.3 million and $1.0 million of raw materials are included within other non-current assets on the condensed consolidated balance sheets at March 31, 2022 and December 31, 2021, respectively .

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 and cash equivalents, 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 instruments. The carrying value of the prepaid forward obligation (See Note 9 - Prepaid Forward Obligation) approximates its fair value as the effective interest rate approximates the market rate for loans with similar terms and risk characteristics. Likewise, the carrying value of long-term debt on the Company's balance sheet (see Note 10 – Long-Term Debt), approximates its fair value as the interest rate approximates the market rate for loans with similar terms and risk characteristics. No transfers between levels have occurred during the periods presented.

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

		Fair Value Measurements Using	
	Balance as of March 31, 2022	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Marketable securities:			
US government	$ 19,251	$ 19,251	
Corporate bonds	5,296		5,296
Commercial paper	5,192		5,192
Certificates of deposit	2,000		2,000
Total marketable securities	$ 31,739	$ 19,251	$ 12,488

Additionally, as of March 31, 2022 there were approximately $75.0 million of money market funds included within cash and cash equivalents on the condensed consolidated balance sheet that are measured at fair value based on Level 1 fair value measurement criteria.

Assets and liabilities measured at fair value on a recurring basis based on Level 1 and Level 2 fair value measurement criteria as of December 31, 2021 are as follows (in thousands):

		Fair Value Measurements Using	
	Balance as of December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Marketable securities:			
US government	$ 19,307	$ 19,307	$ —
Corporate bonds	8,652	—	8,652
Commercial paper	14,492	—	14,492
Certificates of deposit	3,003	—	3,003
Total marketable securities	$ 45,454	$ 19,307	$ 26,147

Additionally, as of December 31, 2021 there were approximately $21.4 million of money market funds included within cash and cash equivalents on the condensed consolidated balance sheet that are measured at fair value based on Level 1 fair value measurement criteria.

Table of Contents

Note 7 – Marketable Securities

The following table summarizes the Company's marketable securities (excluding cash and cash equivalents) as of March 31, 2022 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities:				
US government	$ 19,302		(51)	$ 19,251
Corporate bonds	5,305		(9)	5,296
Commercial paper	5,198		(6)	5,192
Certificates of deposit	2,003		(3)	2,000
Total marketable securities	$ 31,808	$ —	$ (69)	$ 31,739

The Company classifies its marketable securities as available-for-sale and they consist of all debt securities. The amortized cost basis as of March 31, 2022 includes $0.1 million of accrued interest receivable. As of March 31, 2022 marketable securities were in a net unrealized loss position. Unrealized gains and losses on available-for-sale debt securities are included as a component of comprehensive loss.

As of March 31, 2022, the aggregate fair value of marketable securities held by the Company in an unrealized loss position was $31.7 million which consisted of 17 securities. The unrealized loss was primarily driven by minor fluctuations in the fair value of corporate bonds driven by changes in market 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 March 31, 2022, the Company believes the cost basis for its marketable securities were recoverable in all material aspects and no credit losses were recognized in the period.

The Company's marketable securities as of March 31, 2022 mature at various dates through July 2023. The fair values of marketable securities by contractual maturity consist of the following (in thousands):

	March 31, 2022	December 31, 2021
Maturities within one year	$ 31,065	$ 44,779
Maturities after one year through three years	674	675
Total marketable securities	$ 31,739	$ 45,454

Note 8 – Property and Equipment

Property and equipment, consists of the following as of March 31, 2022 and December 31, 2021 (in thousands):

	March 31, 2022	December 31, 2021
Laboratory equipment	$ 374	$ 360
Computer equipment and software	2,072	2,064
Furniture	597	597
Leasehold improvements	617	617
Manufacturing equipment	558	555
	4,218	4,193
Less: accumulated depreciation and amortization	(2,441)	(2,226)
Property and equipment, net	$ 1,777	$ 1,967

Depreciation and amortization expense was $0.2 million for the three months ended March 31, 2022 and $0.2 million for the three months ended March 31, 2021.

Note 9 – Prepaid Forward Obligation

In March 2021, the Company entered into a prepaid forward agreement with RTW Investments ("RTW"). Under the terms of the RTW Transaction, the Company received $75.0 million ($72.4 million net of transaction costs) to support the continued launch of *Jelmyto* and the development of UGN-102. In return for the transferred funds, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of *Jelmyto* in an amount equal to: (i) 9.5% of annual net sales up to $200 million, (ii) 3.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 1.0% of annual net sales for annual net sales above $300 million. If certain revenue thresholds for *Jelmyto* aggregate worldwide annual net sales are not met, the future cash payments to RTW with respect to *Jelmyto* annual net sales up to $200 million will increase by 3.5%, and may decrease back to 9.5% dependent on the Company meeting certain subsequent *Jelmyto* aggregate worldwide annual net sales thresholds. The rate in effect for the three months ended March 31, 2022 for annual sales up to $200 million was 13.0%.

In addition, subject to FDA approval of UGN-102, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of UGN-102 in an amount equal to: (i) 2.5% of annual net sales up to $200 million, (ii) 1.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 0.5% of annual net sales for annual net sales above $300 million. If the Company does not receive FDA approval for UGN-102 by a specified date, the future cash payments to RTW with respect to aggregate worldwide annual net sales of *Jelmyto* across all *Jelmyto* annual net sales tiers will increase by 1.5%. The rate in effect for 2022 for sales up to $200 million is 13%.

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

In May 2021, following the receipt of necessary regulatory approvals, the Company received the $75.0 million prepaid forward payment ($72.4 million net of transaction costs) from RTW and recognized an associated prepaid forward obligation liability. Each period the Company makes a payment to RTW, an expense is recognized related to financing on the prepaid forward obligation based on an imputed rate derived from the expected future payments. Management reassesses the effective rate each period based on the current carrying value of the obligation and the revised estimated future payments. Changes in future payments from previous estimates are included in current and 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, in thousands:

Prepaid forward obligation at closing of RTW Transaction	$	75,000
Capitalized closing costs		(2,599)
Financing on prepaid forward obligation		17,291
Amounts paid and payable		(3,979)
Carrying value of prepaid forward obligation as of December 31, 2021		85,713
Financing on prepaid forward obligation		5,826
Amounts paid and payable		(1,757)
Carrying value of prepaid forward obligation as of March 31, 2022	$	89,782

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. At its option, the Company may draw up to an additional $25 million before December 31, 2022, subject to customary bring down conditions and deliverables. The facility will mature five years from initial funding and can be prepaid in whole at the Company's discretion, at any time, subject to prepayment premiums and makewhole amounts. The loan will require interest-only payments for the first 48 months followed by principal and interest payments with interest accruing using 3-month London Inter-Bank Offered Rate ("LIBOR") (with a 1.25% floor) plus 8.25%. In the event of the cessation of LIBOR, the benchmark governing the interest rate will be replaced with a rate based on the secured overnight financing rate published by the Federal Reserve Bank of New York. The Company is not required to maintain any financial covenants.

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

The following table shows the activity with respect to the carrying value of the long-term debt, in thousands:

Long-term debt at closing of Pharmakon loan	$ 75,000
Capitalized costs and discounts	(4,169)
Interest expense	282
Amounts paid and payable	(316)
Carrying value of Pharmakon loan as of March 31, 2022	70,797

Note 11 – Leases

Operating Leases

The Company has the following office and laboratory facility leases:

- 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 until 2019. In March 2019, UPL utilized the agreement extension option and extended the rent period for additional three years until August 2022.

- In September 2017, UPI entered into a new lease agreement for its office space in New York, which the Company previously used as its headquarters. The lease agreement commenced in October 2017 and terminated in February 2021.

- 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 terminates in March 2024. The landlord provided a tenant allowance for leasehold improvements of $0.2 million that was accounted for as a lease incentive. The Company's remaining contractual obligation under this lease is approximately $0.6 million as of March 31, 2022. In November 2019, UPI entered into a sublease for this office space, with a lease commencement date of January 1, 2020 and continuing 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 remaining rental payments to be received over the lease term is approximately $0.5 million as of March 31, 2022. The Company accounts for the sublease as on operating lease in accordance with ASC 842-10-25-2 and ASC 842-10-25-3. The main lease was considered for impairment and the amount was determined to be immaterial.

- 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 and the lease term is 38 months. The Company's remaining contractual obligation under this lease is approximately $0.5 million as of March 31, 2022.

In addition, the Company has other operating office equipment and vehicle leases. The Company's operating leases may require minimum rent payments, contingent rent payments adjusted periodically for inflation, or rent payments equal to the greater of a minimum rent or contingent rent. The Company's leases do not contain any residual value guarantees or material restrictive covenants. The Company's leases expire at various dates from 2022 through 2024, with varying renewal and termination options.

The components of lease cost for the three months ended March 31, 2022 and 2021 were as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Operating lease cost	$ 259	$ 267
Sublease income	(56)	(56)
Variable lease cost	17	22
	$ 220	$ 233

The amounts recognized as of March 31, 2022 and December 31, 2021 were as follows (in thousands):

	March 31, 2022	December 31, 2021
Right of use asset	$ 945	$ 1,180
Long-term lease liabilities	277	398
Other current liabilities	930	1,089

As of March 31, 2022, no impairment losses have been recognized to date.

Supplemental information related to leases for the three months ended March 31, 2022 and 2021 is as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	3,322	2,157
Right-of-use assets obtained in exchange for new operating lease liabilities	144	135
Weighted-average remaining lease term of operating leases (in years)	1.28	2.13
Weighted-average discount rate of operating leases	5.78%	5.36%

As of March 31, 2022, maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
Remainder of 2022	$ 841
2023	358
2024	58
2025	—
2026 and thereafter	—
Total future minimum lease payments	$ 1,257
Less: Interest	50
Present value of lease liabilities	$ 1,207

Subleases

As of March 31, 2022, undiscounted cash flows to be received under the Company's operating sublease on an annual basis were as follows (in thousands):

	Operating Leases
Years ending December 31,	
Remainder of 2022	$ 182
2023	243
2024	251
2025	49
2026 and thereafter	—
	$ 725

Sublease income is recognized net within operating expense. Sublease income for the three months ended March 31, 2022 and 2021 was as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Sublease income from fixed lease payments	$ 56	$ 56

Note 12 – Revenue From Product Sales

Net product sales consist of the following for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Jelmyto	$ 13,564	$ 7,485

Net revenue recognized includes 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, Medicaid drug rebate programs, and the Company's copay assistance program, which are estimated based on industry benchmarking studies as well as the Company's historical experience. Reserves related to items that are contractually able to be net settled are recognized as contra accounts receivables. The following table shows the activity with respect to sales reserves for period ended March 31, 2022 (in thousands):

	Reserves related to government sponsored programs	Other reserves	Total accrued sales reserves
Balance as of December 31, 2021	373	1,335	1,708
Changes during Q1 22			
Accruals	873	1,220	2,093
Utilizations	(1,001)	(1,411)	(2,412)

Balance as of March 31, 2022	245	1,144	1,389

Note 13 – **License and Collaboration Agreements**

Agenus Agreement

In November 2019, the Company entered into a license agreement with Agenus Inc., 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 antibody of Agenus known as AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. AGEN1884 is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients and in combination with Agenus' anti-PD-1 antibody in solid tumors. Initially, the Company plans to develop AGEN1884 in combination with UGN-201 for the treatment of high-grade NMIBC.

Pursuant to the license agreement, the Company paid Agenus an upfront fee of $10.0 million and has agreed to pay Agenus up to $115.0 million upon achieving certain clinical development and regulatory milestones, up to $85.0 million upon achieving certain commercial milestones, and royalties on net sales of licensed products in the 14%-20% range. The Company will be responsible for all development and commercialization activities. Under the terms of the license agreement, Agenus has agreed to use commercially reasonable efforts to supply AGEN1884 to the Company for use in preclinical studies or clinical trials.

Unless earlier terminated in accordance with the terms of the license agreement, the license agreement will expire on a product-by-product and country-by-country basis at the later of (a) the expiration of the last to expire valid claim of a licensed patent right that covers the licensed product in such country or (b) 15 years after the first commercial sale of the licensed product in such country. The Company may terminate the license agreement for convenience upon 180 days' written notice to Agenus. Either party may terminate the license agreement upon 60 days' notice to the other party if, prior to the first commercial sale of a licensed product, the Company substantially ceases to conduct development activities of the licensed products for nine consecutive months (and during such period, Agenus has complied with its obligations under the license agreement) other than in response to a requirement of an applicable regulatory authority or an event outside of the Company's control. In addition, either party may terminate the license agreement in the event of an uncured material breach of the other party.

MD Anderson Agreement

In January 2021, the Company announced that it entered into a three-year strategic research collaboration agreement with MD Anderson focusing on the sequential use of UGN-201 and UGN-301 as an investigational treatment for high-grade NMIBC. Under the agreement, MD Anderson and the Company will collaborate on the design and conduct of non-clinical and clinical studies with oversight from a joint steering committee. The Company will provide funding, developmental candidates, and other support. Pursuant to the agreement, the Company makes bi-annual payments to MD Anderson to fund the collaboration. As of March 31, 2022, the Company has made payments to MD Anderson of $1,000,000 recognized evenly over the associated period through research and development expense.

Note 14 – **Shareholders**' **Equity**

The Company had 100.0 million ordinary shares authorized for issuance as of March 31, 2022 and December 31, 2021. The Company had 22.7 million and 22.5 million ordinary shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively. Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors (the "Board"). Since its inception, the Board has not declared any dividends.

Note 15 – Share-Based Compensation

In October 2010, the Board approved a share option plan (the “Plan”) for grants to Company employees, consultants, directors, and other service providers.

The grant of options to Israeli employees under the Plan 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 Plan 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 Plan, 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 Plan is subject to Section 3(i) of the Israeli Income Tax Ordinance.

Employees are typically granted stock options and/or restricted stock units ("RSUs"), upon commencement of employment. Also, eligible employees may receive an annual grant of options or RSUs. Non-employee members of the Board typically receive a grant of stock options and/or RSUs annually. The term of any option granted under the Plan cannot exceed 10 years. Options shall not have an exercise price less than 100% of the fair market value of the Company’s ordinary shares on the grant date, and generally vest over a period of three years. If the individual possesses more than 10% of the combined voting power of all classes of equity of the Company, the exercise price shall not be less than 110% of the fair market value of an ordinary share on the date of grant.

The Company’s RSU and option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including a termination in connection with a change in control. RSUs generally vest in a 33% increment upon the first anniversary of grant, and in either equal quarterly or annual amounts for the two years following the one-year anniversary of the grant date. Options generally vest in a 33% increment upon the first anniversary of the grant date, and in either equal quarterly or annual amounts for the two years following the one-year anniversary of the grant date.

The expected volatility is based on a mix of the Company’s historical volatility, and the historical volatility of comparable companies with similar attributes to the Company, including industry, stage of life cycle, size and financial leverage. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted. The expected term is the length of time until the expected dates of exercising the options and is estimated for employees using the simplified method due to insufficient specific historical information of employees’ exercise behavior, and for non-employees, and directors using the contractual term.

In March 2017, the Board adopted the 2017 Equity Incentive Plan (the "2017 Plan"), 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 maximum number of ordinary shares that was initially authorized for issuance under the 2017 Plan is 1,400,000. On January 1, 2018, the share reserve increased by 250,167 to 1,650,167. On October 12, 2018, the Company increased the amount of registered ordinary shares of the Company’s 2017 Plan by 1,900,000 to 3,550,167. On June 8, 2020 the Company’s shareholders approved an increase to the amount of registered ordinary shares of the Company’s 2017 Plan by 400,000 to 3,950,167. On June 7, 2021, the Company’s shareholders approved an increase of the amount of registered ordinary shares of the Company’s 2017 Plan by 400,000 to 4,350,167.

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 awards issued under the Inducement Plan. The only persons eligible to receive grants of Awards (as defined below) under the 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. Under the Inducement Plan, an “Award” is a nonstatutory stock option, RSU or other right to receive ordinary shares pursuant to the Inducement Plan. In December 2021, the Board approved a 300,000 increase in the share reserve of the Inducement Plan.

As of March 31, 2022, 3,949,544 ordinary shares are subject to outstanding awards under the Company's share-based compensation plans and 722,810 ordinary shares remain available for future awards.

The following table illustrates the effect of share-based compensation on the condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development expense	$ 726	$ 1,107
Selling, general and administrative expense	2,223	5,088
	$ 2,949	$ 6,195

The total unrecognized compensation cost of options and RSUs at March 31, 2022 is $17.5 million with a weighted average recognition period of 1.96 years.

Note 16 – **Income Taxes**

UroGen Pharma Ltd. is taxed under Israeli tax laws. As of March 31, 2022, the Company continues to maintain a full valuation allowance against deferred tax assets for all jurisdictions. In evaluating the need for a valuation allowance, the Company considers all sources of taxable income available to realize the deferred tax asset, including the future reversal of existing temporary differences, forecasts of future taxable income, and tax planning strategies. The Company has cumulative global pretax losses for the years ended 2021, 2020 and 2019, and for the three months ended March 31, 2022. The Company will continue to assess the extent to which its deferred tax assets may be realized in the future and will adjust the valuation allowance as needed.

The Company has a liability for uncertain tax positions of $2.8 million as of March 31, 2022, for tax positions relating to transfer pricing between affiliated entities. The Company recognizes interest accrued and penalties related to uncertain tax positions as a component of income tax expense. As of March 31, 2022, the Company's liability for uncertain tax positions includes $0.9 million of accrued interest and penalties.

The Company operates on a global basis and is subject to tax laws and regulations in the U.S. and Israel. The estimate of the Company's tax liabilities relating to uncertain tax positions requires management to assess uncertainties and to make judgments about the application of complex tax laws and regulations, expectations regarding the outcome of tax authority examinations, as well as the ultimate measurement of potential liabilities.

The uncertain tax positions are reviewed quarterly and adjusted as events occur that could affect potential liabilities for additional taxes, including lapsing of applicable statutes of limitations, correspondence with tax authorities, proposed assessments by tax authorities, identification of new issues, and issuance of new legislation or regulations. The Company believes that adequate amounts of tax have been provided in income tax expense for any adjustments that may result from its uncertain tax positions. Based upon the information currently available, the Company does not reasonably expect changes in its existing uncertain tax positions in the next 12 months and has recorded the gross uncertain tax positions as a long-term liability.

Note 17 – **Related Parties**

There were no related party transactions for the three months ended March 31, 2022 or 2021.

Note 18 – **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 March 31, 2022 and December 31, 2021. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Leases

See Note 11 for further discussion regarding lease commitments.

Note 19 – **Subsequent Events**

The Company has evaluated and determined there were no subsequent events through May 10, 2022.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report and the audited financial statements and notes thereto as of and for the year ended December 31, 2021 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2021("Annual Report"), which was filed with the SEC on March 21, 2022. The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, ("Exchange Act"), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Overview

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

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

RTGel is a novel proprietary polymeric biocompatible, reverse thermal gelation hydrogel, 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 disintegrates 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 mitomycin water formulation, currently used as adjuvant treatment, in the upper urinary tract is approximately five minutes, compared to approximately six hours when mitomycin is formulated with *RTGel*;

- administering higher doses of an active drug than would otherwise be possible using standard water-based formulations. For instance, it is only possible to dissolve 0.5 mg of mitomycin in 1 mL of water while it is possible to formulate up to 8 mg of mitomycin with 1 mL of *RTGel*; and

- maintaining the active drug's molecular structure and mode of action.

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

Jelmyto

On April 15, 2020, the FDA approved our 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* exists through April 15, 2023, Orphan Drug exclusivity through April 15, 2027, as well as a composition of matter patent through 2031. The main patents that protect Jelmyto in the United States are set to expire on January 20, 2031. These patents were listed in the FDA's Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

Low-grade UTUC is a rare cancer that develops in the lining of the upper urinary tract, ureters and kidneys. In the United States, there are approximately 6,000 - 7,000 new or recurrent low-grade UTUC patients annually. It is a challenging condition to treat due to the complex anatomy of the urinary tract system. Prior to *Jelmyto*, the current standard of care included endoscopic resection(s) and radical nephroureterectomy, 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 radical nephroureterectomy.

The FDA approval is 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 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 using well established treatments. No treatment-related deaths occurred.

In June 2020, we initiated our commercial launch of *Jelmyto* in the United States. We have staffed, trained and prepared a customer-facing team comprising territory business managers with deep experience in both urology and oncology. These territory business managers are led by seven regional business managers. 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. In addition, our organization includes seven medical science liaisons who appropriately engage with physicians interested in learning more about UroGen, *Jelmyto* and our technology, both in person and virtually. In total, our customer-facing team comprises approximately 80 representatives
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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. The majority of large commercial plans have policies in place, 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 safe and seamless for practitioners and patients, including entering into an agreement with a major national specialty pharmacy under which the pharmacy, following receipt of a patient prescription, prepares the *Jelmyto* admixture on our behalf. 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. We are also launching a registry to capture data and evaluate real world outcomes in patients with UTUC that have been or will be treated with Jelmyto. The purpose of the registry is to study the use of Jelmyto in clinical practice in the United States and address specific clinical questions.

UGN-102

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

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. Consistent with our previous reports showing that 65%, or 41 out of 63 patients, treated with UGN-102 achieved a complete response 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 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.

Urothelial cancer, which is comprised of bladder cancer and UTUC, affects a large, and what we believe to be, an underserved patient population. Annual expenditures for Medicare alone in the United States for the treatment of urothelial cancer were estimated to be at least $5.0 billion in 2020. The majority of the expenditures are spent on tumor resection surgeries such as transurethral resection of bladder tumor ("TURBT"). The prevalence of bladder cancer in the United States based on most recently published data was approximately 724,000 and estimated 2021 annual incidence of bladder cancer was approximately 85,000. We estimate based upon a review of peer-reviewed literature and publicly available data that there are approximately 80,000 low-grade intermediate risk NMIBC patients in the U.S. annually. We believe that UGN-102 has the potential to be a new therapeutic option for the treatment of low-grade intermediate risk NMIBC patients.

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 same-day treatment, in comparison with TURBT or similar surgical procedures, which are operations conducted under general anesthesia and may require an overnight stay. 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 removing the need for surgery, patients may avoid potential complications associated with surgery.

We initiated the Phase 3 ATLAS trial in December 2020 and until November 2021, were enrolling patients in this trial assessing UGN-102 with or without TURBT compared to standard of care. 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 new 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 for the Phase 3 ENVISION trial is similar to our Phase 2 OPTIMA II trial in that the patient population will have similar clinical characteristics, receive the same treatment regimen and undergo the same efficacy and safety assessments and qualitative follow-up. Study participants will receive six once-weekly intravesical instillations of UGN-102. The planned primary endpoint will evaluate the complete response rate at three months after the first instillation, and the key secondary endpoint will evaluate durability over time in patients who achieve complete response at the three-month assessment.

In February 2022, we announced the initiation of the Phase 3 ENVISION trial, which is expected to enroll approximately 220 patients across 90 sites, with completion of enrollment expected by the end of 2022. Assuming positive findings, we anticipate submitting an NDA for UGN-102 in 2024. As a result of the FDA's acceptance of a single arm approach, we have stopped enrollment of the Phase 3 ATLAS study. However, at the time enrollment was stopped, any patients who had signed an informed consent were able to complete screening, and if eligible were randomized into the trial. Patients continue to be followed in the Phase 3 ATLAS study, and clinical results from these patients are expected to generate additional safety data and other insights in our evaluation of UGN-102 as a primary therapy in the treatment of low-grade intermediate risk NMIBC.

We have also initiated a Phase 3b study with the objective of demonstrating whether UGN-102 can be administered at home by a qualified home health professional, avoiding the need for repeated visits to a healthcare setting for instillation. Patients in the ongoing Phase 3b study will receive six once-weekly intravesical instillations of UGN-102. The Phase 3b study aims to enroll up to 10 patients across four centers. The initial treatment visit will occur at the investigative site and instillation will be performed by a qualified physician. Treatment visits two to six will take place at the patient's home and instillation will be performed by a properly trained and qualified home health professional. The primary endpoint of the study is the incidence of treatment-emergent adverse events ("TEAEs"), serious TEAEs, TEAEs of special interest, discontinuations from at home study treatment, and clinically significant abnormalities in laboratory tests (hematology, serum chemistry, and urinalysis). We believe the ease and convenience of home instillation has the potential to transform care and facilitate alternative access to treatment.

UGN-301

Our immuno-uro-oncology pipeline includes UGN-301, an anti-CTLA-4 antibody, which we intend to study as a combination therapy with multiple potential agents. The completion of non-human primate toxicity studies support the initiation of a multi-arm Phase 1 study of UGN-301 in combination with other agents. We believe that this approach leverages our unique drug delivery technology and provides an opportunity to evaluate intravesical delivery of UGN-301 in combination with other immuno-modulators, chemotherapies, gene therapy and innate immune stimulators.

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

The first combination we are seeking to investigate clinically involves the sequential use of UGN-201 (imiquimod), a toll-like receptor-7 ("TLR 7") agonist, and UGN-301 in high-grade NMIBC ("high-grade NMIBC"). UGN-201 is a liquid formulation of imiquimod for intravesical administration that has been optimized for delivery in the urinary tract. We believe that UGN-201 may elicit an adaptive immune response in the presence of released bladder cancer antigens, which may translate into a long lasting acquired immune response. We believe the combination of UGN-301 and UGN-201 could further increase the adaptive 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. In November 2019, we entered into a worldwide license agreement with Agenus Inc. to develop and commercialize zalifrelimab via intravesical delivery in combination with UGN-201 for the treatment of urinary tract cancers, initially in high-grade NMIBC. We believe that the combination treatment makes 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 Investigational New Drug application ("IND") to begin a novel Phase 1 clinical study of UGN-301 in patients with recurrent NMIBC. The novel study design will utilize 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 the Company 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 was initiated in April 2022 and is expected support the development of UGN-301 in high-grade NMIBC.
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Our Research and Development and License Agreements

Agenus Agreement

In November 2019, we entered into a license agreement with Agenus Inc. (“Agenus”). Pursuant to the agreement, Agenus granted us an exclusive, worldwide license (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 antibody of Agenus known as AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. AGEN1884 is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients and in combination with Agenus’ anti-PD-1 antibody (AGEN2034) in solid tumors. UGN-301 is a formulation of *RTGel* and zalifrelimab that is in early-stage development for high-grade NMIBC.

MD Anderson Agreement

Based on nonclinical studies conducted by us, UGN-201 in combination with anti-CTLA-4 antagonists have shown encouraging results for the potential treatment of high-grade NMIBC. In January 2021, we announced that we entered into a three-year strategic research collaboration agreement with MD Anderson focusing on the sequential use of UGN-201 and UGN-301 as an investigational treatment for high-grade NMIBC. Under the agreement, we will collaborate with MD Anderson on the design and conduct of non-clinical and clinical studies with oversight from a joint steering committee. We will provide funding, developmental candidates, and other support.

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

Impact of COVID-19 Pandemic

In the event of a prolonged disruption related to COVID-19, there could be detrimental impact to our ongoing and future clinical trials, our ongoing commercial launch and future commercialization activities for *Jelmyto*, and our ability to access capital markets.

According to the Centers for Disease Control and Prevention, as of April 2022, over 75% of the U.S. population has had at least one dose of the COVID-19 vaccine, and over 65% are fully vaccinated. However, as circumstances evolve, in particular related to the emergence of variants, it will be important to understand potential impacts to patients and the hospital system, and the ability for patients to access *Jelmyto.* While it is difficult to predict the impact of the ongoing COVID-19 pandemic, including associated variants, on our business and the healthcare industry, we continue to monitor the evolving COVID-19 situation, and the potential further impacts that the pandemic and related government response may have on our business.

Components of Operating Results

Revenue

During the three months ended March 31, 2022 and 2021 we recognized $13.6 million and $7.5 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*. In periods prior to receiving FDA approval for *Jelmyto*, we recognized inventory and related costs associated with the manufacture of *Jelmyto* as research and development expense.

Research and Development Expense

Research and development expense, net consists primarily of:

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

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 accrue for 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.

We are currently focused on advancing our product candidates, and our future research and development expense will depend on their clinical success. Research and development expense will continue to be significant and will increase over at least the next several years as we continue to develop our product candidates and conduct nonclinical studies and clinical trials of our product candidates.

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 expense required for us to reach commercialization of our product candidates. Due to the inherently unpredictable nature of nonclinical and clinical development, we are unable to estimate with certainty the costs we will incur and the timelines that will be required in the continued development and approval of our product candidates. Clinical and nonclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, if and when such arrangements will be entered into, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We expect our research and development expense to increase over the next several years as our clinical programs progress and as we seek to initiate clinical trials of additional product candidates. We also expect to incur increased research and development expense as we selectively identify and develop additional product candidates.

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

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- delays or operational challenges resulting from the ongoing COVID-19 pandemic;
- 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 is still in clinical development and our other product candidates are in nonclinical development, and the outcome of these efforts is uncertain. 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 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 when achieved, in the case of milestones, if it is determined at that point that they have no established alternative future use.

Selling and Marketing Expense

To date, selling and marketing expense consists primarily of commercial personnel costs (including share-based compensation) along with pre-commercialization and commercialization activities related to *Jelmyto*, formerly known as UGN-101. We anticipate that our selling and marketing expense remain relatively consistent for the remainder of 2022.

General and Administrative Expense

General and administrative expense consists 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.

We anticipate that our general and administrative expense will remain relatively consistent for the remainder of 2022, and may increase in the future to support the potential approval and commercialization of our product candidates and our continued research and development programs.

Financing on prepaid forward obligation

Financing on prepaid forward obligation is comprised of financing expense related to the RTW Transaction (as defined in Note 3 to our condensed consolidated financial statements included in this Quarterly Report).

Interest expense

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

Interest and Other Income, Net

Interest and other income, net, consisted primarily of interest income.

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 $335.8 million as of December 31, 2021. 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 16 to the condensed consolidated financial statements for further information.

Critical Accounting Policies and Estimates

The preparation of our unaudited condensed consolidated 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, and the revenue and expense incurred during the reported periods. In accordance with GAAP, we base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ from these estimates under different assumptions or conditions. We discussed the critical accounting policies used in the preparation of our financial statements in *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our Annual Report as well as in the Note 3 to the condensed consolidated financial statements included in this Quarterly Report.

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

The following table sets forth our results of operations for the three months ended March 31, 2022 and 2021.

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Revenue	$ 13,564	$ 7,485	$ 6,079
Cost of revenue	1,525	897	628
Gross profit	12,039	6,588	5,451
Operating expense:			
Research and development	12,696	10,513	2,183
Selling and marketing	13,351	11,435	1,916
General and administrative	7,949	10,754	(2,805)
Total operating expense	33,996	32,702	1,294
Operating loss	(21,957)	(26,114)	4,157
Financing on prepaid forward obligation	(5,826)	—	(5,826)
Interest expense	(282)	—	(282)
Interest and other income, net	(2)	179	(181)
Loss before income taxes	(28,067)	(25,935)	(2,132)
Income tax expense	(325)	—	(325)
Net loss	$ (28,392)	$ (25,935)	$ (2,457)

Revenue

Revenue was $13.6 million and $7.5 million for the three months ended March 31, 2022 and 2021, respectively. The increase in revenue of $6.1 million reflects the increased volume of sales of our product *Jelmyto*.

Cost of Revenue

Cost of revenue was $1.5 million and $0.9 million for the three months ended March 31, 2022 and 2021, respectively. In periods prior to receiving FDA approval for *Jelmyto*, we recognized inventory and related costs associated with the manufacture of *Jelmyto* as research and development expense. We expect this to continue to impact cost of revenue through the first quarter of 2023 as we produce *Jelmyto* at costs reflecting the full cost of manufacturing and as we deplete inventories that we had expensed prior to receiving FDA approval. Gross margin would have been approximately 88.2% versus 88.7% for the three months ended March 31, 2022, if we had not sold *Jelmyto* units that were expensed prior to regulatory approval.

Research and Development Expense

Research and development (R&D) expense was $12.7 million and $10.5 million for the three months ended March 31, 2022 and 2021, respectively. The overall increase of $2.2 million is primarily attributable to the Phase 3 ENVISION study for UGN-102, and commencement of Phase 1 study for UGN-301.

Selling and Marketing Expense

Selling and marketing expense was $13.4 million and $11.4 million for the three months ended March 31, 2022 and 2021, respectively. The increase in selling and marketing expense of $2.0 million is primarily attributable to expenses related to our annual sales meeting held in March 2022 which did not occur during the first quarter of 2021.

General and Administrative Expense

General and administrative expense was $7.9 million and $10.8 million for the three months ended March 31, 2022 and 2021, respectively. The decrease in general and administrative expense of $2.9 million resulted primarily from a decrease in compensation expenses in 2022.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation was $5.8 million and $0 for the three months ended March 31, 2022 and 2021, respectively. The cost in 2022 relates to the financing cost of the RTW Transaction which closed in May 2021.

Interest Expense

Interest expense was $0.3 million and $0.0 for the three months ended March 31, 2022 and 2021, respectively. The cost in 2022 relates to the Pharmakon loan which closed in March 2022.

Interest and Other Income, Net

Interest and other income, net was $0.0 million and $0.2 million for the three months ended March 31, 2022 and 2021, respectively. The decrease in interest and other income, net of $0.2 million was primarily due to lower interest earned on cash and marketable securities.

Liquidity and Capital Resources

As of March 31, 2022, we had $137.1 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. Based on our cash flow projections, we believe that our current cash and cash equivalents and marketable securities are sufficient to fund our planned operations beyond the next 12 months.

Through March 31, 2022, we funded our operations primarily through public equity offerings, private placements of equity securities and our funding arrangement with RTW Investments (“RTW”).

In December 2019, we entered into a sales agreement (the “ATM Sales Agreement”) with Cowen and Company, LLC (“Cowen”) pursuant to which we may from time to time offer and sell our ordinary shares having an aggregate offering price of up to $100.0 million. The shares are offered and will be sold pursuant to a shelf registration statement on Form S-3 which was declared effective by the SEC on January 2, 2020.

During the second quarter of 2020, we sold 700,000 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $16.6 million. The net proceeds to us after deducting sales commissions to Cowen and other issuance expenses were approximately $15.8 million. The remaining capacity under the ATM Sales Agreement is approximately $83.4 million.

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

On March 7, 2022, we entered into a loan agreement ("Loan Agreement") with Pharmakon for a senior secured term loan of up to $100 million in two tranches. The first tranche of $75 million ($72.6 million net of transaction costs) was funded in March 2022. At our option, we may draw up to an additional $25 million before December 31, 2022, subject to customary bring down conditions and deliverables. The Pharmakon loan will mature five years from initial funding and can be prepaid in whole at our discretion, at any time, subject to prepayment premiums and makewhole amounts. The Pharmakon loan will require interest-only payments for the first 48 months followed by principal and interest payments with interest accruing using 3-month LIBOR (with a 1.25% floor) plus 8.25%. In the event of the cessation of LIBOR, the benchmark governing the interest rate will be replaced with a rate based on the secured overnight financing rate published by the Federal Reserve Bank of New York.

We have incurred losses since our inception and negative cash flows from our operations, and as of March 31, 2022 we had an accumulated deficit of $495.7 million. We anticipate that we will continue to incur losses for the reasonably foreseeable future. Our primary uses of capital are, and we expect will continue to be, commercialization activities, research and development expense, including third-party clinical research and development services, laboratory and related supplies, clinical costs, including manufacturing costs, legal and other regulatory expense and general and administrative costs, partially offset by proceeds from sales of *Jelmyto*.

We cannot estimate the actual amounts necessary to successfully commercialize any approved products, including *Jelmyto*, 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. There can be no assurances that we will be able to secure such additional financing if at all, or on terms that are satisfactory to us, and that it will be sufficient to meet its needs. In the event we is not successful in obtaining sufficient funding, this could force us to delay, limit, or reduce our product development, commercialization efforts or other operations.

Funding and Material Cash Requirements

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

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

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

We may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants that further limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, the terms of the Forward Contract and 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 Part II, Item 1A – 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 April 2018, we entered into a new lease agreement for an office in Los Angeles, CA. The lease commencement date was July 10, 2018 and terminates in March 2024. In November 2019, we subleased our offices in Los Angeles, CA. The lease commencement date was January 1, 2020 and terminates in March 2024. The subtenants exercised their early access clause and moved into the premises at the end of November 2019.

Also, in November 2019, we entered into a new lease agreement, dated effective October 31, 2019, for an office in Princeton, NJ. The lease commencement date was November 29, 2019 and the lease term is 38 months.

The total obligation for future minimum lease payments under our operating leases is $1.6 million as of December 31, 2021. See Note 11 to the Consolidated Financial Statements for further information.

In March 2022, UroGen Pharma Ltd., the Borrower and the Guarantors party thereto from time to time entered into the Loan Agreement with the Lenders and Collateral Agent pursuant to which the Lenders agreed to make the Term Loans to the Borrower in an aggregate principal amount of up to $100 million to be funded in two tranches: (i) the Tranche A Loan of $75 million was advanced in March, 2022 and (ii) the Tranche B Loan of $25 million will be advanced at Borrowers election, subject to certain conditions, subject to the customary bring down conditions and deliverables, and in no event later than December 31, 2022. The Term Loans will mature on the fifth-year anniversary of the Tranche A Closing Date (the “Maturity Date”). The Term Loans bear interest at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.25%. In the event of the cessation of LIBOR, the benchmark governing the interest rate will be replaced with a rate based on the secured

overnight financing rate published by the Federal Reserve Bank of New York as described in the Loan Agreement. Interest is payable quarterly in arrears. Repayment of outstanding principal of the Term Loans will be made in four equal quarterly payments of principal commencing after the 17th-quarter anniversary of the Tranche A Closing Date. The obligations of the Borrower under the Loan Agreement are guaranteed on a full and unconditional basis by UroGen Pharma Ltd. and the other Guarantor and are secured by substantially all of the respective Credit Parties' tangible and intangible assets and property, including intellectual property, subject to certain exceptions.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (23,996)	$ (27,401)
Investing activities	13,596	15,024
Financing activities	70,742	4
Net change in cash and cash equivalents	$ 60,342	$ (12,373)

Operating Activities

Net cash used in operating activities was $24.0million during the three months ended March 31, 2022, compared to $27.4 million during the three months ended March 31, 2021. The $3.4 million decrease was attributable primarily to financing payments related to the prepaid forward obligation and timing of certain accruals, partially offset by increased collections of accounts receivables.

Investing Activities

Net cash used in investing activities was $13.6 million during the three months ended March 31, 2022, compared to $15.0 million provided by investing activities during the three months ended March 31, 2021. The net decrease of $1.4 million is primarily related to a decrease in maturities of marketable securities, as compared to the prior year.

Financing Activities

Net cash provided by financing activities was $70.7 million during the three months ended March 31, 2022, compared to $0.0 million during the three months ended March 31, 2021. The increase is related to the proceeds from the Pharmakon loan in the current year.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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 and marketable securities. As of March 31, 2022 we had $137.1 million of cash and cash equivalents and marketable securities. We invest our cash primarily in money market accounts, but also invest in commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. 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 March 31, 2022, this change would not have had a material effect on the fair value of our cash and cash equivalents and marketable securities as of that date.

Inflation Risk

Inflation generally may affect us by increasing our cost of labor and clinical trial costs. Inflation has not had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2022.

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 the New Israeli Shekel ("NIS") . As a result, we are exposed to the risk that 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 depreciated against the NIS during 2021 by a total of 3.2%. 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. If a 10% change in NIS-to-Dollar exchange rates were to have occurred during the three months ended March 31, 2022, this change would not have had a material effect on our operating expenses.

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 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive and financial officers (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosures controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2022. 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.

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 March 31, 2022, 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.

Changes in Internal Control over Financial Reporting

Changes in our internal control over financial reporting may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes. There were no changes in our internal control over financial reporting during the quarter ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.
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Part II—Other Information

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Risk Factor Summary

Below is a summary of the principal 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 Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our ordinary shares.

- 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.
- Our indebtedness resulting from our Loan Agreement could adversely affect our financial condition or restrict our future operations.
- 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.
- 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-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 and UGN-201, if approved, as well as UGN-301 if approved as a monotherapy or for any approved product that includes UGN-301.
- There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers, including single-source suppliers. Furthermore, our existing third-party subcontractors and single-source suppliers may not be able to meet the increased need for certain raw materials, compounds and components that may result from our commercialization efforts. This increases the risk that we will not have sufficient quantities of *Jelmyto*, UGN-102 , UGN-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.
- Our business could be adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic.
- 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 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.
- 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.
- 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.

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

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

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

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 Business and Strategy

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

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

Successful commercialization of *Jelmyto* is subject to many risks. We initiated our commercial launch of *Jelmyto* in June 2020, and prior to that, we had never, as an organization, launched or commercialized any product. There is no guarantee that our ongoing commercial launch of *Jelmyto* or our future 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 launch and commercialization of *Jelmyto*. Even if we are successful in maintaining and further developing our commercial team, there are many factors that could cause the ongoing launch and commercialization of *Jelmyto* to be unsuccessful, including a number of factors that are outside our control. We must also properly educate physicians and nurses on the skillful preparation and administration of *Jelmyto*, and develop a broad experiential knowledge base of aggregated clinician feedback from which we can refine appropriate procedures for product administration, without which there could be a risk of adverse events.

Because no drug has previously been approved by the FDA for the treatment of low-grade UTUC, it is especially difficult to estimate *Jelmyto*'s market potential. The commercial success of *Jelmyto* depends on the extent to which patients and physicians accept and adopt *Jelmyto* as a treatment for low-grade UTUC, and we do not know whether our or others' estimates in this regard will be accurate. For example, if the patient population suffering from low-grade UTUC is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to be treated with *Jelmyto* due to label warnings, adverse events associated with product administration or other reasons, the commercial potential of *Jelmyto* will be limited. At this time, we have only limited information regarding how physicians, patients and payors will respond to the pricing of *Jelmyto*. 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 ongoing commercial launch of *Jelmyto* and subsequent commercialization efforts could be hindered by the COVID-19 pandemic, although we are currently not able to predict or quantify any such potential impact with any degree of certainty.

If the launch or commercialization of *Jelmyto* is unsuccessful or perceived as disappointing, 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. Following the initiation of our commercial launch in June 2020, Jelmyto is now available to a much larger number of patients and in broader populations, and we do not know whether the results of Jelmyto use in such 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 successful 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, we do not know whether the results when a large number of patients and broader populations are exposed to *Jelmyto*, including results related to safety and efficacy, will be consistent with the results from earlier clinical studies of *Jelmyto* that served as the basis for the approval of *Jelmyto*. New data relating to *Jelmyto*, including from spontaneous adverse event reports and post-marketing studies in the United States, and from other ongoing clinical studies, may result in changes to the product label and may adversely affect sales, or result in withdrawal of *Jelmyto* from the market. The FDA and regulatory authorities in other jurisdictions may also consider the new data in reviewing potential marketing applications in other jurisdictions, or imposing post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales revenues.

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

Our strategy is to build and maintain a fully integrated biotechnology company to successfully execute the commercialization of *Jelmyto* in the United States. *Jelmyto* is our only product that has been approved for sale by any regulatory body, and it became available in the United States in June 2020. While we have established a commercial management team and have also established a field-based organization comprised of approximately 80 individuals, including a sales team, reimbursement support team, clinical nurse educators, national account managers and medical science liaisons, we currently have very limited experience commercializing pharmaceutical products as an organization. In order to successfully commercialize *Jelmyto*, we must continue to develop our sales, marketing, managerial, compliance and related capabilities or make arrangements with third parties to perform these services. This involves many challenges, such as recruiting and retaining talented personnel, training employees, setting the appropriate system of incentives, managing additional headcount and integrating new business units into an existing corporate infrastructure. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully further develop these capabilities. Additionally, we will need to maintain and further develop our sales force, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to effectively develop and maintain our commercial team, including our sales force, our ability to effectively commercialize *Jelmyto* would be limited, and we would not be able to generate product revenues successfully. If we fail to establish and maintain an effective sales and marketing infrastructure, we will be unable to successfully commercialize our product candidates, which in turn would have an adverse effect on our business, financial condition and results of operations.

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

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

Additionally, in light of the COVID-19 pandemic, we have developed digital materials and programs for our sales force to use in order to engage virtually with their target physicians when in-person engagement is not safe or feasible. Beginning in the second quarter of 2021, our territory business managers have been able to engage in higher levels of in-person physician interaction than they were previously during the pandemic. However, there can be no assurance that our territory business managers will continue to have in-person access to physicians as a result of the ongoing evolution of the COVID-19 pandemic (including the emergence of variants), 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 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 candidates with the goal of replacing surgery as the standard of care for certain urothelial cancers. However, there is no guarantee that our product candidates, if approved, would be approved for first-line or even later lines of therapy, and that prior to any such approvals, we will not have to conduct additional clinical trials.

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, physicians may choose 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; and
- 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.

If *Jelmyto*, UGN-102 or any of our other product candidates are approved for use but fails 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.

The FDA has approved five immunotherapy drugs known as checkpoint inhibitors; Tecentriq (atezolizumab), Bavencio (avelumab), Imfinzi (durvalumab), Opdivo (nivolumab) and Keytruda (pembrolizumab) for the treatment of locally advanced or metastatic bladder cancer, a form of muscle invasive bladder cancer.

We are aware of several pharmaceutical companies that are developing drugs in the fields of urology and uro-oncology, such as Roche, Vyriad, GSK, Celgene, Samyang biopharma, Merck Sharp & Dohme Corp., Sesen Bio, Viralytics Limited, AADi, LLC, Biocancell Ltd., ImmunityBio, Seagen Inc., Steba Biotech Ltd., FKD Therapies Oy and Janssen. We are aware of a company called Steba Biotech with an IND granted in December 2020 who has initiated a Phase 3 study of padeliporfin ImPACT for the treatment of adult patients with low-grade and unifocal high-grade UTUC in the first quarter of 2021. We are also aware that other companies, such as Janssen and Lipac are conducting, or have recently conducted clinical trials for product candidates for the treatment of low-grade intermediate risk NMIBC. 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 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-201 and UGN-301 for the treatment of various forms of bladder cancer. The FDA and other applicable regulatory agencies will restrict our ability to market or advertise our products to the scope of the approved label for the applicable product and for no other indications, which could limit physician and patient adoption. We may attempt to develop and, if approved, promote and commercialize new treatment indications for our products in the future, but we cannot predict when or if we will receive the regulatory approvals required to do so. Failure to receive such approvals will prevent us from promoting or commercializing new treatment indications. In addition, we would be required to conduct additional clinical trials or studies to support approvals for additional indications, which would be time consuming and expensive, and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

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

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

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

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

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

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

- the FDA's acceptance of our parameters for regulatory approval relating to UGN-102 and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways, and proposed labeling and packaging;
- our ability to successfully complete the FDA requirements related to chemistry, manufacturing and controls ("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. Without such IND acceptances, we will be unable to commence clinical trials in the United States;
- the FDA's acceptance of the number, 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 that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's need to schedule an advisory committee meeting, and to conduct such meeting, in a timely manner to evaluate and decide on the approval of our potential future NDA for UGN-102;
- if applicable, the recommendation of the FDA's advisory committee to approve our applications to market UGN-102 and our other product candidates in the United States, without limiting the approved labeling, specifications, distribution or use of the products, or imposing other restrictions;
- the FDA's determination of safety and efficacy of our product candidates;
- the FDA's determination that the 505(b)(2) regulatory pathway 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 supply of the raw materials from TAPI (Teva Active Pharmaceutical Ingredients) or other suppliers for our product candidates to support clinical trials and commercial use;
- our ability to manufacture or secure finished product from third-party suppliers for product candidates, including UGN-102, if approved;
- our ability to obtain, protect and enforce our intellectual property rights with respect to our product candidates;
he 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;
- 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 have been amplified by the ongoing COVID-19 pandemic, 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.

To date we have only generated limited clinical data for our investigational product candidates.

Positive results in nonclinical testing and early clinical trials do not ensure that later clinical trials will be successful. A number of pharmaceutical companies have suffered significant setbacks in clinical trials, including in Phase 3 clinical trials, after promising results in nonclinical testing and early clinical trials. These setbacks have included negative safety and efficacy observations in later clinical trials, including previously unreported adverse effects. To date, our clinical trials and other programs have involved small patient populations and because of the small sample size, the results of these clinical trials may be subject to substantial variability and may not be indicative of future results. We initiated the Phase 3 ATLAS trial in December 2020 and until recently were enrolling patients in this trial assessing UGN-102 with or without TURBT compared to standard of care, TURBT. Following discussions with the FDA, we initiated our Phase 3 ENVISION trial, a new single-arm Phase 3 trial of UGN-102 in low-grade, intermediate-risk, NMIBC in the first quarter of 2022. The design for the Phase 3 ENVISION trial is similar to our Phase 2 OPTIMA II trial in that the patient population will have similar clinical characteristics, receive the same treatment regimen and undergo the same efficacy and safety assessments and qualitative follow-up. However, there can be no assurance that the Phase 3 ENVISION trial will have a higher probability of clinical or regulatory success notwithstanding similarities in its design to our Phase 2 OPTIMA II trial. If our clinical trials do not ultimately indicate that our product candidates are safe and effective for their intended use, the FDA may not approve any NDA that we may submit to market such product candidates, and our business would not be able to generate revenue from the sale of any such product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These risks and uncertainties impact all of our nonclinical programs that we pursue and have been amplified by the recent COVID-19 pandemic, as described below. 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 report and our other filings with the SEC. Accordingly, we cannot assure you that we will be able to develop, obtain regulatory approval for, commercialize or generate significant revenue from our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may continue to 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 complete responses enrolled in the Phase 3 OLYMPUS trial. With respect to our current and future candidates, even if we complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA or applicable foreign regulatory agency may grant approval contingent on the performance of additional costly post-approval clinical trials, risk mitigation requirements and surveillance requirements to monitor the safety or efficacy of the product, which could negatively impact us by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. Absence of long-term safety data may further limit the approved uses of our products, if any.

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

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

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

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

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

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

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

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

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

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

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

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

Collaborations may not lead to development or commercialization of product candidates in the most efficient manner, or at all, and may otherwise experience challenges. For example, in August 2020, we announced that the Phase 2 APOLLO trial 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 the arrangement 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-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 and UGN-201, if approved, as well as UGN-301 if approved as a monotherapy or for any approved product that includes UGN-301. There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers, including single-source suppliers. Furthermore, our existing third-party subcontractors and single-source suppliers may not be able to meet the increased need for certain raw materials, compounds and components that may result from our commercialization efforts. This increases the risk that we will not have sufficient quantities of Jelmyto, UGN-102, UGN-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-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 ("Teva"), as our single-source supplier of mitomycin active pharmaceutical ingredient ("API") for *Jelmyto* and UGN-102. We rely on Cenexi-Laboratoires Thissen s.a., and Isotopia Molecular Imaging Ltd. as our sole suppliers for the mitomycin and gel contained in *Jelmyto* and UGN-102, respectively. We also currently depend on a single source supplier for imiquimod for UGN-201 and zalifrelimab for UGN-301. 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*. We do not have any control over the availability of raw materials. If we or our suppliers and manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development and commercialization of our product candidates or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of *Jelmyto* or any other approved products.

We expect to continue to rely on these or other subcontractors and suppliers to support our commercial requirements for *Jelmyto*, as well as UGN-102 or any of our other product candidates if approved for marketing by the FDA or foreign regulatory authorities. We also rely on a single third-party manufacturer to produce our proprietary drug product, or final mitomycin formulation, necessary for our clinical trial and commercial requirements. We plan to continue to rely on third parties for the production of mitomycin API, the gel contained in *Jelmyto,* UGN-102 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 ongoing commercial launch and commercialization of *Jelmyto* 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, depending on the duration of the COVID-19 pandemic and whether further disruptions occur, we may face such delays or costs in future years. Although we believe we have sufficient quantities of mitomycin API for planned manufacturing operations during 2022, 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 the ongoing COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture and distribute *Jelmyto* for commercial sales and our product candidates for our clinical trials and research and development operations.

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

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

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

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

We rely on third party transportation to deliver materials to our facilities and ship products to our customers. Transport operators are exposed to various risks, such as extreme weather conditions, natural disasters, work stoppages, personnel shortages, and operating hazards, as well as interstate and international transportation requirements. In addition, transport operators have been affected by the impact of the COVID-19 pandemic and related shipping crisis and backlog, which has led to increased shipping costs and supply chain 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. For example, have entered into an exclusive license agreement with Neopharm Ltd. ("Neopharm"), pursuant to which Neopharm is leading the process for seeking regulatory approval of *Jelmyto* in Israel. Neopharm initiated the regulatory approval process in June 2021. Although the submission is supported by the results from our Phase 3 OLYMPUS trial, there can be no assurance that *Jelmyto* will be approved for marketing in Israel in the timeframe we expect, or at all. Even if *Jelmyto* is approved for marketing in Israel, there can be no assurance that it will achieve the broad degree of physician adoption and use 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 our 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 have recently increased the size of our organization and 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 March 31, 2022, we had 192 employees, of whom 42 are based in Israel and 150 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 ongoing commercial launch of *Jelmyto*, we will evaluate, and may implement, changes to our organization that may be appropriate in order to properly manage and direct our growth and transformation into a commercial-stage company. Due to our limited financial resources and our limited experience in managing a larger company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, the ongoing COVID-19 pandemic could make recruiting and training more difficult. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion or other significant changes to our organization could delay the execution of our development, commercialization and strategic objectives or disrupt our operations; and if we are not successful in commercializing our approved product or any of our product candidates that may receive regulatory approval, either on our own or through collaborations with one or more third parties, our revenues will suffer, and we would incur significant additional losses.

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

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

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

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

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

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

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

If our security measures are compromised, or our information technology systems or those of our vendors, and other relevant third parties fail or suffer security breaches, loss or leakage of data, and other disruptions, this could result in a material disruption of our drug development program, compromise sensitive information related to our business, harm our reputation, trigger our breach notification obligations, prevent us from accessing critical information, and expose us to liability or other adverse effects to our business.

In the ordinary course of our business, we may collect, process and store proprietary, confidential and sensitive information, including personal information (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. We face several risks relative to protecting the security, confidentiality, integrity and availability of this critical information, including loss of access risk, inappropriate use or disclosure, inappropriate modification, and the risk of being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third-party service providers who handle elements of our operations and data processing.

We, our CROs and other contractors, consultants, and other third parties on which we rely, depend on information technology, telecommunication systems and data processing for significant elements of our operations, including, for example, systems handling human resources, financial reporting and controls, regulatory compliance and other infrastructure operations. Notwithstanding the implementation of security measures, these information technology systems are potentially vulnerable to breakdown, service interruptions, system malfunction, natural disasters, fire, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our personnel, third-party vendors, contractors, consultants, business partners, or third parties, or from cyber-attacks by malicious third parties (including the deployment of malware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information), which may compromise our information technology, telecommunication systems and data, or that of our third-party vendors and other contractors and consultants, or lead to data leakage. The risk of a security breach or disruption, particularly through accidental actions or omissions by trusted insiders, cyber-attacks or cyber intrusions has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. 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. The COVID-19 pandemic and our remote workforce also poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. 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.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. 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. A security incident could compromise our networks and the information stored there could be accessed by parties, manipulated, publicly disclosed, lost, destroyed, altered, encrypted or stolen. Any event that leads to unauthorized access, use or disclosure of personal information could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign equivalents, subject us to mandatory corrective action, which could result in significant costs and reputational damage or otherwise have an adverse effect on our business.

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 or confidential 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. For example, 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 breach 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 breaches, 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.

Additionally, applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including

personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms.

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

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

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

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

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

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

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

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

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

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

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

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

The U.S. dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in New Israeli Shekels ("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 depreciated against the NIS during 2021 by a total of 3.2%. 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 or epidemics, including the ongoing COVID-19 pandemic.*

A pandemic, including the ongoing COVID-19 pandemic or other public health epidemics, poses 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. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the COVID-19 pandemic and mitigation measures have had and may in the future 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 taken or that may be taken by various governments, in response to COVID-19 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 and have a material adverse effect on our business, financial condition and results of operations. In addition, we and many of our potential customers and partners worldwide have in the past and may in

the future be subject to stay-at-home orders as a result of the COVID-19 pandemic. In addition, our ongoing commercial launch of *Jelmyto* and subsequent commercialization activities could be hindered by the COVID-19 pandemic, although we are currently not able to predict or quantify any such potential impact with any degree of certainty. However, the worldwide spread of the COVID-19 virus has previously resulted and may in the future result in a varying degree of interruption or slowdown of economic activity, thereby impacting demand for a broad variety of goods and services, including potentially for *Jelmyto*, while also disrupting sales channels and marketing activities for an unknown period of time until the disease is contained.

The timelines and conduct of our ongoing clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic and patients' ability or willingness to participate in clinical trials. For those patients who are enrolled and desire to continue in the clinical trials, some patients may not be able or willing to comply with clinical trial protocols if quarantines or governmental orders impede patient movement or interrupt healthcare services. Similarly, we may face increased challenges with the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, which could adversely impact our clinical trial operations, timelines and outcomes. While we remain in close contact with our clinical sites and suppliers to attempt to assess the impacts that COVID-19 may have on our clinical trials and projected timelines and we have reviewed and acknowledged recent FDA guidance in our protocols, and follow such guidance where possible, with in an effort to ensure the ongoing safety of the patients in our clinical trials and the continued collection of high quality data, there is no guarantee that such efforts will be successful. As challenging as conducting clinical trials is during normal times, the risks, operational challenges and costs of conducting clinical trials have increased substantially during the pandemic.

Additionally, during most of the COVID-19 pandemic, our sales force has had physical access to hospitals, surgery centers, clinics, healthcare providers and pharmacies curtailed, which we believe has affected our sales to date and may in the future have a material adverse effect on our future sales. Beginning in the second quarter of 2021, our territory business managers have been able to engage in higher levels of in-person physician interaction than they were previously during the pandemic. However, there can be no assurance that our territory business managers will continue to have in-person access to physicians as a result of the ongoing evolution of the COVID-19 pandemic (including the emergence of variants). In addition, while we have developed digital materials and programs for our sales force to use in order to engage virtually with their target physicians when in-person engagement is not safe or feasible, digital materials and virtual engagement may not be effective at growing and maintaining prescription levels of *Jelmyto*. Additionally, patients who are currently using *Jelmyto* or who are eligible to use *Jelmyto*, may be unable to meet with their healthcare providers in person, which may reduce the number of new patient starts and hinder the ability of healthcare providers to complete the recommended number of *Jelmyto* instillations, affecting our revenues both in our currently approved indication and potentially impacting our anticipated launches in other indications, if approved.

Moreover, the COVID-19 pandemic continues to evolve, including as a result of the emergence of SARS-CoV-2 variants, and the extent to which the COVID-19 pandemic may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the number of cases and the severity of those cases, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain, prevent and treat the disease.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in the "Risk Factors" section of this report.

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

Certain of our clinical trials, such as the Phase 3 ATLAS trial, are operated outside of the U.S., including in the Ukraine and Russia. We continue to follow patients in ATLAS from Russia, but not Ukraine, however, due to ongoing military instability, we may not have the ability to continue follow up of these patients. The failure to identify and operationalize any alternative clinical sites may have an adverse effect on patient enrollment, and could result in delays in enrolling, carrying out, and/or completing our clinical trials. 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 U.S. Foreign Corrupt Practices Act ("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 U.S. Our business activities in these foreign countries may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently the SEC and U.S. Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business.

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

Risks Related to Our 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 $110.8 million and $128.5 million for the years ended December 31, 2021 and 2020, respectively. As of March 31, 2022, we had an accumulated deficit of $495.7 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* and we have not commercialized any of our products or generated any revenue from product sales.

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

On March 7, 2022, UroGen Pharma Ltd., UroGen Pharma, Inc., as the borrower ("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 ("Loan Agreement") with funds managed by Pharmakon Advisors, L.P., including BPCR Limited Partnership (as a "Lender"), BioPharma Credit Investments V (Master) LP (as a "Lender"), and BioPharma Credit PLC, as collateral agent for the Lenders (in such capacity, "Collateral Agent), pursuant to which the Lenders agreed to make term loans to the Borrower in an aggregate principal amount of up to $100 million ("Term Loans"), to be funded in two tranches: (i) the first tranche ("Tranche A Loan") was advanced in the amount of $75 million, in March, 2022 ("Tranche A Closing Date") and (ii) the second tranche ("Tranche B Loan") of $25 million will be advanced at the Borrower's election, subject to the customary bring down conditions and deliverables, and in no event later than December 31, 2022. There is no assurance that the Tranche B Loan will be funded as expected or at all.

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

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

- sell or dispose of assets, including certain intellectual property;
- amend, modify or waive certain material 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 makewhole 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.

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.*

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 March 31, 2022, we had cash and cash equivalents and marketable securities of $137.1 million. In January 2019, we completed an underwritten public offering in which we received net proceeds of approximately $161.4 million, after deducting the underwriting discounts and commissions and payment of other offering expenses. During the second quarter of 2020, we sold 700,000 ordinary shares under the sales agreement ("ATM Sales Agreement") with Cowen and Company, LLC ("Cowen"), for gross proceeds of approximately $16.6 million. The net proceeds to us after deducting sales commissions to Cowen and other issuance expenses were approximately $15.8 million. The remaining capacity under the ATM Sales Agreement is approximately $83.4 million. In March 2021, we announced a transaction with RTW Investments ("RTW") totaling $75 million in funding for our company, which was received in May 2021, to support the launch of *Jelmyto* and the development of UGN-102. In return for the upfront cash payment, RTW is entitled to receive tiered future payments based on global annual net product sales of *Jelmyto* and UGN-102, if approved. In addition, in March 2022, we entered into the Loan Agreement, pursuant to which the Lenders agreed to make the Term Loans to Borrower in an aggregate principal amount of up to $100 million to be funded in two tranches.

Based on our cash flow projections, we believe that our current cash and cash equivalents and marketable securities are sufficient to fund our planned operations for at least the next 12 months. We will require additional capital to complete clinical trials, obtain regulatory approval for and commercialize our product candidates. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity financings, convertible debt or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. In any event, we will require additional capital to pursue nonclinical and clinical activities, and pursue regulatory approval for, and to commercialize, our pipeline product candidates. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

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 terms acceptable to us, 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.

Covenants under our Pre-Paid Forward Contract with RTW restrict our ability to borrow additional capital.

In March 2021, we entered into a Pre-Paid Forward Contract (the "Forward Contract") with RTW, pursuant to which we are obligated to make tiered cash payments to RTW, based on the worldwide annual net product sales of *Jelmyto* and, subject to FDA approval, UGN-102 (together, the "Products"), subject to an aggregate revenue cap of $300 million.

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

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

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

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

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

Risks Related to Our Intellectual Property

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

Our commercial success depends in part upon our ability to obtain and maintain patent protection and utilize trade secret protection for our intellectual property and 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 urothelial cancer using hydrogel-based compositions, the method for treating overactive bladder topically without the need for injections, an in-dwelling ureter catheter system for optimal delivery of a drug into the renal cavity, and pharmaceutical compositions comprising an imidazoquinolin (amine) and lactic acid for use in a method for the treatment of bladder diseases, as well as other intellectual property advancements.

We seek patent protection for our product candidates, and we hold a broad collection of intellectual property comprised of issued patents, pending patent applications and trademarks covering our proprietary *RTGel* technology, the pharmaceutical compositions, methods of use and manufacturing aspects of our product candidates. In the United States, we currently hold 18 granted patents that are directed to protect our approved product, *Jelmyto* and our lead product candidate, UGN-102, a proprietary *RTGel* technology, local compositions comprising different active ingredients, inter alia compositions comprising a Botulinum Toxin, UGN-201, UGN-302 (the sequential use of UGN-201 and UGN-301) and our future product candidates that are under company research. These IP rights relate to certain aspects of cancer treatment. These issued patents are set to expire between 2024 and 2037. In total, our IP portfolio includes 40 granted patents worldwide, and more than 45 pending patent applications filed in the US, Europe, Israel, Japan, Canada, China, Mexico and Australia that are directed to cover various methods, systems and compositions for treating cancer locally, by intravesical means, utilize various active ingredients and the combinations thereof. These patent applications, if issued, are set to expire between 2031 and 2041.

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

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

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

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

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

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

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

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

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

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

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

Our trade secrets may not have sufficient intellectual property protection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We filed applications for trademarks (*Jelmyto* ®, *RTGel*™, UroGen ® and Cystoject ™) 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. If we file an infringement action against such 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.

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

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

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

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

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

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

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

A significant portion of our intellectual property has been developed by our employees during their employment. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee during the scope of his or her employment with a company are regarded as "service inventions." The Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law, has previously held, in certain cases, that employees may be entitled to remuneration for service inventions that they develop during their service for a company despite their explicit waiver of such right. Therefore, although we enter into agreements with our employees pursuant to which they waive their right to special remuneration for service inventions created in the scope of their employment or engagement and agree that any such inventions are owned exclusively by us, we may face claims by employees demanding remuneration beyond their regular salary and benefits.

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

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

For example, in March 2010, President Obama signed into law the ACA laws intended, among other things, to broaden access to health insurance, improve quality of care, and reduce or constrain the growth of healthcare spending.

Provisions of the ACA relevant to the pharmaceutical industry included the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price ("AMP") for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report annually certain financial arrangements with physicians and teaching hospitals; as defined in the ACA and its implementing regulations, including reporting any payment or "transfer of value" provided to physicians, as defined by such law, and teaching hospitals and any ownership and investment interests held by such physicians and their immediate family members during the preceding calendar year, which will be expanded beginning in 2022 to include reporting obligations with respect to financial relationships with certain additional healthcare providers;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

There have been judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear any such challenges, other litigation and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which started in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will stay in effect through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's AMP, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures

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, the former Trump Administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump Administration announced several executive orders related to prescription drug pricing that attempted to implement several of the Administration's proposals. The FDA concurrently released a final rule and guidance in September 2020, implementing a portion of President Trump's importation executive order announced in July 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health & Human Services ("HHS") finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this rule has been delayed by the Biden administration until January 1, 2026. On November 20, 2020, the Centers for Medicare & Medicaid Services ("CMS") issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. As a result of litigation challenging the Most Favored Nation Model, on December 27, 2021, CMS published a final rule that rescinds the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. 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. In addition, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 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. Certain state and local laws also require the registration of pharmaceutical sales representatives.

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

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

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

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

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

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

We are subject to stringent and changing privacy and data security laws, contractual obligations, self-regulatory schemes, government regulation, and standards related to data privacy and security. The actual or perceived failure by us, our customers, partners or vendors to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

We are or may become subject to numerous domestic and foreign laws and regulations regarding privacy, data protection, and data security, the scope of which is changing, subject to differing applications and interpretations and may be inconsistent among countries, or conflict with other rules. We are also subject to the terms of our contractual obligations to customers and third parties related to privacy, data protection and data security.

For example, the European Union ("EU") has established its own data security and privacy legal framework, including but not limited to the European General Data Protection Regulation ("GDPR"), which imposes onerous and comprehensive privacy, data protection, and data security obligations onto data controllers and processors, and contains provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. Our upcoming clinical trial will include sites in the EU, which will increase our exposure to potential liability under the GDPR. Penalties for non-compliance with the GDPR can be significant and include fines in the amount greater of €20 million or 4% of global turnover and restrictions or prohibitions on data processing, which could impair our ability to do business in the EU, interrupt our clinical trials, reduce demand for our services and adversely impact our business and results of operations. 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 GDPR. Assisting our customers, partners, and vendors in complying with the 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.

Moreover, many foreign laws, including the GDPR and data protection laws in the United Kingdom and Switzerland, impose restrictions on the transfer of personal information to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. The European Commission released a set of Standard Contractual Clauses ("SCCs") that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers
outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection, and certain countries outside Europe (e.g. China) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business. If we are unable to implement a valid compliance mechanism for cross-border personal data transfers, we may face increased exposure to regulatory actions, substantial fines and injunctions against processing or transferring personal data from Europe. Inability to import personal data from Europe to the United States may limit our ability to conduct clinical trial activities in Europe, limit our ability to collaborate with contract research organizations, service providers, contractors and other entities subject to European data protection laws, adversely impact our operations, product development and ability to provide our products, and require us to increase our data processing capabilities in Europe at significant expense.

Regulation of privacy, data protection and data security has also become more stringent in the United States. For example, California enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act ("CCPA"), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Effective January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 (“CPRA”) becomes fully operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, establish restrictions on the retention of personal information, and expand the types of data breaches subject to the CCPA’s private right of action. Additionally, Virginia recently passed its Consumer Data Protection Act, Colorado passed the Colorado Privacy Act, and Utah passed the Consumer Privacy Act, all of which differ from the CPRA and become effective in 2023. These laws demonstrate our vulnerability to the evolving regulatory environment related to personal information. As we expand our operations, these and similar laws may increase our compliance costs and potential liability.

Complying with these various laws, regulations and other obligations related to data privacy and protection could require us to incur substantial costs, take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, require us to change our business practices and compliance procedures in a manner adverse to our business, or, in some cases, impact our ability to operate in certain jurisdictions. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. The actual or perceived failure by us, our customers, our vendors, or other relevant third parties to address or comply with these laws, regulations, and obligations could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines, civil or criminal penalties, private litigation, cause regulators to reject, limit or disrupt our clinical trial activities, harm our reputation, and otherwise cause a material effect on our business, financial condition, and results of our operations. Moreover, inability to import personal information to the United States or other countries may disrupt or require us to change our business practices, interrupt our business operations, including clinical trials, and otherwise have a material financial impact on our business.

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

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

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

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

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of *Jelmyto*, UGN-102 and our other product candidates, if approved, will depend on the coverage and reimbursement policies of third-party payors, like government authorities, private health insurers, and managed care organizations. Third-party payors decide which medications they will cover and separately establish reimbursement levels. In October 2020, a Medicare C-Code was issued for *Jelmyto* and we have obtained pass-through status for two years, no more than three. CMS has established a permanent and product-specific J-code for *Jelmyto* that took effect on January 1, 2021.

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 observed 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. 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.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of UGN-102 or any of our other product candidates and to produce, market, and distribute Jelmyto or any of our product candidates that receive clearance or approval.

From time to time, legislation is drafted and introduced in Congress 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 regulations and guidance are often revised or reinterpreted by the FDA 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 UGN-102 or any of our other 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;
- change in protocol design;
- additional treatment arm (control);
- 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.

Risks Related to Ownership of Our Ordinary Shares

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

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

- the success of our launch and 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;
- our sale or proposed sale, or the sale by our significant shareholders, of our ordinary shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our ordinary shares; and
- general economic and market conditions and other factors, such as the COVID-19 pandemic, 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.

As of the date of this report, the holders of up to approximately 4.5 million ordinary shares are entitled to registration rights. In addition, our sale of additional ordinary shares or similar securities in order to raise capital might have a similar negative impact on the share price of our ordinary shares. A decline in the price of our ordinary shares might impede our ability to raise capital through the issuance of additional ordinary shares or other equity securities and may cause you to lose part or all of your investment in our ordinary shares.

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

In order to raise additional capital, we may in the future offer additional ordinary shares or other securities convertible into or exchangeable for our ordinary shares at prices that we determine from time to time, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. We may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. On December 20, 2019, we entered into the ATM Sales Agreement pursuant to which we may from time to time offer and sell our ordinary shares, having an aggregate offering price of up to $100.0 million, to or through Cowen, acting as sales agent or principal, in any manner deemed to be an “at-the market offering”. The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 filed with the SEC on December 20, 2019, which was declared effective on January 2, 2020. As of December 31, 2021, we had sold 700,000 shares under the sales agreement for total gross proceeds of $16.6 million, leaving up to $83.4 million available for sale under the ATM Sales Agreement.

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

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

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

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

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, for our current and future taxable years, 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 estimated income, estimated assets, activities and market capitalization, we do not believe that we were a PFIC for the taxable year ended December 31, 2021. 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 Internal Revenue Service 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. 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 U.S. tax expense.

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

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

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

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

We cannot provide any assurances that we will assist investors in determining whether we or any non-U.S. subsidiaries that we may form or acquire in the future would be treated as a CFC or whether such investor would be treated as a United States shareholder with respect to any such CFC. Further, we cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations discussed above. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. Holders 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 in tax years beginning after December 31, 2020, 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 facilities are located in Ra'anana, 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.

Political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, Hamas (an Islamist militia and political group that controls the Gaza Strip) and Hezbollah (an Islamist militia and political group based in Lebanon). 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.

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

Further, our operations could be disrupted by the obligations of our employees to perform military service. As of March 31, 2022, we had 42 employees based in Israel. Of these employees, some may be military reservists, and may be called upon to perform military reserve duty of up to 36 days per year (and in some cases more) until they reach the age of 40 (and in some cases, up to the age of 45 or older). Additionally, they may be called to active duty at any time under emergency circumstances. In response to increased tension and hostilities in the region, there have been, at times, call-ups of military reservists, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of these employees due to military service. Such disruption could harm our business and operating results.

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

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

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

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

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

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

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

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

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

Risks Related to Our Management and Employees

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

Our success depends upon the continued service and performance of our executive officers who are essential to our growth and development. The loss of one or more of our executive officers could delay or prevent the continued successful implementation of our growth strategy, could affect our ability to manage our company effectively and to carry out our business plan, or could otherwise be detrimental to us. As of March 31, 2022, we had 192 employees. Therefore, knowledge of our product candidates and clinical trials is concentrated among a small number of individuals. Members of our executive team as well as key clinical, scientific, technical and commercial personnel may resign at any time and there can be no assurance that we will be able to continue to retain such personnel. If we cannot recruit suitable replacements in a timely manner, our business will be adversely impacted.

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

General Risk Factors

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

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

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

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

Unstable market, economic and geo-political conditions may have serious adverse consequences on our business, financial condition and stock 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 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, or continued unpredictable and unstable market conditions. If the current 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 stock 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. While we cannot predict the broader consequences, the conflict 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 (ESG) matters or our reporting of such matters.*

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
3.1	Articles of Association of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Form 6-K (File No. 001-38079), filed with the SEC on May 18, 2017).
10.1	Loan Agreement, dated as of March 7, 2022, by and among UroGen Pharma Ltd. (the "Company"), UroGen Pharma, Inc., as the borrower, and certain direct and indirect subsidiaries of the Company party thereto from time to time, as guarantors, BPCR Limited Partnership, as a lender, BioPharma Credit Investments V (Master) LP, as a lender, and BioPharma Credit PLC, as collateral agent for the lenders.
10.2*	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.
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) or 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) or 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL

The information in Exhibits 32.1 and 32.2 shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Quarterly Report), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

* Certain portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Signatures

Pursuant to the requirements 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.

May 10, 2022 By: /s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer
(Principal Executive Officer)

May 10, 2022 By: /s/ Don Kim
Don Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)

LOAN AGREEMENT

Dated as of March 7, 2022

among

UROGEN PHARMA, INC.

(as ***Borrower***, and a ***Credit Party***),

UROGEN PHARMA LTD.

(as ***Parent***, and a ***Credit Party***),

THE OTHER GUARANTORS SIGNATORY HERETO OR OTHERWISE PARTY HERETO FROM TIME TO TIME

(as additional ***Credit Parties***),

BIOPHARMA CREDIT PLC

(as ***Collateral Agent***),

BPCR LIMITED PARTNERSHIP

(as a ***Lender***)

and

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP

(as a ***Lender***)

TABLE OF CONTENTS

		Page
1	ACCOUNTING AND OTHER TERMS	1
2	LOANS AND TERMS OF PAYMENT	2
2.1	Promise to Pay	2
2.2	Term Loans	2
2.3	Payment of Interest on the Term Loans	5
2.4	Expenses	6
2.5	Requirements of Law; Increased Costs	7
2.6	Taxes; Withholding, Etc.	7
2.7	Additional Consideration	10
2.8	Note Register; Term Loan Notes	10
3	CONDITIONS OF TERM LOANS	11
3.1	Conditions Precedent to Tranche A Loan	11
3.2	Conditions Precedent to Tranche B Loan	12
3.3	RESERVED	13
3.4	RESERVED	13
3.5	Additional Conditions Precedent to Term Loans	13
3.6	Covenant to Deliver	13
3.7	Procedures for Borrowing	13
4	REPRESENTATIONS AND WARRANTIES	14
4.1	Due Organization, Existence, Power and Authority	14
4.2	Equity Interests	14
4.3	Authorization; No Conflict	14
4.4	Government Consents; Third Party Consents	14
4.5	Binding Obligation	15
4.6	Collateral	15
4.7	Adverse Proceedings, Compliance with Laws and Settlement Agreements	18
4.8	Exchange Act Documents; Financial Statements; Financial Condition; No Material Adverse Change; Books and Records	19
4.9	Solvency	19
4.10	Taxes	19
4.11	Environmental Matters	19
4.12	Material Contracts	20
4.13	Regulatory Compliance	20
4.14	Margin Stock	20
4.15	Subsidiaries; Capitalization	20
4.16	Employee Matters	21
4.17	Full Disclosure	21
4.18	FCPA; Patriot Act; OFAC; Export and Import Laws	21
4.19	Health Care Matters	22

4.20 Regulatory Approvals 25
4.21 Supply and Manufacturing 25
4.22 Cybersecurity and Data Protection 26
4.23 Additional Representations and Warranties 27

5 AFFIRMATIVE COVENANTS 27
5.1 Maintenance of Existence 27
5.2 Financial Statements, Notices, Reports 27
5.3 Taxes 29
5.4 Insurance 29
5.5 Operating Accounts 29
5.6 Compliance with Laws 29
5.7 Protection of Intellectual Property Rights 30
5.8 Books and Records 31
5.9 Access to Collateral; Audits 31
5.10 Use of Proceeds 31
5.11 Further Assurances 31
5.12 Additional Collateral; Guarantors 32
5.13 Formation or Acquisition of Subsidiaries 33
5.14 Post-Closing Requirements 34
5.15 Environmental 34
5.16 Inventory; Returns; Maintenance of Properties 35
5.17 Regulatory Obligations; Maintenance of FDA Approval; Manufacturing, Marketing and Distribution 35
5.18 Collateral Documents 36

6 NEGATIVE COVENANTS 36
6.1 Dispositions 36
6.2 Fundamental Changes; Location of Collateral 36
6.3 Mergers, Acquisitions, Liquidations or Dissolutions 37
6.4 Indebtedness 37
6.5 Encumbrances 37
6.6 No Further Negative Pledges; Negative Pledge 37
6.7 Maintenance of Collateral Accounts 38
6.8 Distributions; Investments 38
6.9 No Restrictions on Subsidiary Distributions 38
6.10 Subordinated Debt; Permitted Convertible Indebtedness 38
6.11 Amendments or Waivers of Organizational Documents 39
6.12 Compliance 39
6.13 Compliance with Sanctions and Anti-Money Laundering Laws 39
6.14 Amendments or Waivers of Company IP Agreements 40

7 EVENTS OF DEFAULT 40
7.1 Payment Default 40
7.2 Covenant Default 40
7.3 Material Adverse Change 40
7.4 Attachment; Levy; Restraint on Business 40
7.5 Insolvency 41
7.6 Other Agreements 41
7.7 Judgments 41
7.8 Misrepresentations 41
7.9 Loan Documents; Collateral 41
7.10 ERISA Event 42
7.11 Intercreditor Agreement 42

8 RIGHTS AND REMEDIES UPON AN EVENT OF DEFAULT 42
8.1 Rights and Remedies 42
8.2 Power of Attorney 43
8.3 Application of Payments and Proceeds Upon Default 44
8.4 Collateral Agent's Liability for Collateral 44
8.5 No Waiver; Remedies Cumulative 44
8.6 Demand Waiver; Makewhole Amount; Prepayment Premium 44

9 NOTICES 45

10 CHOICE OF LAW, VENUE, AND JURY TRIAL WAIVER 46

11 GENERAL PROVISIONS 47
11.1 Successors and Assigns 47
11.2 Indemnification 48
11.3 Severability of Provisions 49
11.4 Correction of Loan Documents 49
11.5 Amendments in Writing; Integration 49
11.6 Counterparts 49
11.7 Survival 49
11.8 Confidentiality 50
11.9 Attorneys' Fees, Costs and Expenses 50

11.10 Right of Set-Off 50
11.11 Marshalling; Payments Set Aside 51
11.12 Electronic Execution of Documents 51
11.13 Captions 51
11.14 Construction of Agreement 51
11.15 Third Parties 51
11.16 No Advisory or Fiduciary Duty 51
11.17 Credit Parties' Agent 52

12 COLLATERAL AGENT 52
12.1 Appointment and Authority 52
12.2 Rights as a Lender 52
12.3 Exculpatory Provisions 52
12.4 Reliance by Collateral Agent 53
12.5 Delegation of Duties 53
12.6 Resignation of Collateral Agent 53
12.7 Non-Reliance on Collateral Agent and Other Lenders 54
12.8 Collateral and Guaranty Matters 54
12.9 Reimbursement by Lenders 55
12.10 Notices and Items to Lenders 55

13 DEFINITIONS 55
13.1 Definitions 55

Exhibit A: Loan Advance Request Form

Exhibit B-1: Form of Tranche A Note

Exhibit B-2: Form of Tranche B Note

Exhibit C: Form of Security Agreement

Exhibit D: Commitments; Notice Addresses

Exhibit E: Form of Compliance Certificate

LOAN AGREEMENT

THIS LOAN AGREEMENT (this "**Agreement**"), dated as of March 7, 2022 (the "**Effective Date**") by and among UROGEN PHARMA, INC., a Delaware corporation (as "**Borrower**" and a Credit Party), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "**Parent**" and a Credit Party), the other Guarantors signatory hereto or otherwise party hereto from time to time, as additional Credit Parties, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales with company number 10443190 (as the "**Collateral Agent**"), BPCR LIMITED PARTNERSHIP, a limited partnership established under the laws of England and Wales with registration number LP020944 (as a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership acting by its general partner, BioPharma Credit Investments V GP LLC (as a "**Lender**"), provides the terms on which each Lender shall make, and Borrower shall repay, the Credit Extensions (as hereinafter defined). The parties hereto agree as follows:

1 ACCOUNTING AND OTHER TERMS

Except as otherwise expressly provided herein, all accounting terms not otherwise defined in this Agreement shall have the meanings assigned to them in conformity with Applicable Accounting Standards. Calculations and determinations must be made following Applicable Accounting Standards. If at any time any change in Applicable Accounting Standards would affect the computation of any financial requirement set forth in any Loan Document (including for purposes of measuring compliance with any provision of Section 6), and either Borrower or the Collateral Agent shall so request, the Collateral Agent and Borrower shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in Applicable Accounting Standards; provided, that, until so amended, (x) such requirement shall continue to be computed in accordance with Applicable Accounting Standards prior to such change therein and (y) all financial statements, Compliance Certificates and similar documents provided, delivered or submitted hereunder shall be provided, delivered or submitted together with a reconciliation between the calculations and amounts set forth therein before and after giving effect to such change in Applicable Accounting Standards. Notwithstanding any other provision contained herein, all terms of an accounting or financial nature used herein shall be construed, and all computations of amounts referred to herein, including in Section 5 and Section 6 shall be made, without giving effect to any (a) election under ASC 825-10 (or any other Financial Accounting Standards Board Accounting Standards Codification ("**ASC**") or Financial Accounting Standard or Applicable Accounting Standard (including IFRS 9) having a similar result or effect) to value any Indebtedness or other liabilities of any Credit Party or any Subsidiary of any Credit Party at "fair value" and (b) any treatment of Indebtedness in respect of convertible debt instruments under ASC 470-20 (or any other ASC or Financial Accounting Standard or Applicable Accounting Standard having a similar result or effect) to value any such Indebtedness in a reduced or bifurcated manner as described therein, and such Indebtedness shall at all times be valued at the full stated principal amount thereof. Notwithstanding anything to the contrary above or in the definition of "Capital Lease Obligations", all obligations of any Person that are or would have been treated as operating leases for purposes of Applicable Accounting Standards prior to the effectiveness of ASC 842 shall continue to be accounted for as operating leases for all purposes hereunder or under any other Loan Documents (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with ASC 842 (on a prospective or retroactive basis or otherwise) to be treated as Capital Leases. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "Dollars" or "$" are United States Dollars, unless otherwise noted.

For purposes of determining compliance with Section 5 and Section 6 with respect to the amount of any Indebtedness, Investment or other transaction in a currency other than Dollars, no Default or Event of Default shall be deemed to have occurred solely as a result of changes in rates of currency exchange occurring after the time such Indebtedness, Investment or other transaction is incurred, made or acquired (so long as such transaction, at the time incurred, made or acquired, was permitted hereunder).

2 LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay

.

Borrower hereby unconditionally promises to pay each Lender the outstanding principal amount of the Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans

.

(a) Availability. Subject to the terms and conditions of this Agreement (including Sections 3.1, 3.2, 3.5, 3.6 and 3.7):

(i) Borrower agrees to request in accordance with Section 3.7, and each Lender severally agrees to make, a term loan to Borrower on the Tranche A Closing Date in an original principal amount equal to such Lender's Tranche A Commitment (individually or collectively, as the context dictates, the "**Tranche A Loan**"); and

(ii) At Borrower's option, Borrower may request in accordance with Section 3.7, and each Lender severally agrees to make, a term loan to Borrower on the Tranche B Closing Date in an original principal amount equal to such Lender's Tranche B Commitment (collectively, the "**Tranche B Loan**").

After repayment or prepayment (in whole or in part), no Term Loan (or any portion thereof) may be re-borrowed.

(b) Repayment.

(i) With respect to any and all Term Loans, Borrower shall make four (4) equal quarterly payments of principal of each such Term Loan commencing on the first Payment Date that occurs during or immediately after the 17th calendar quarter following the Tranche A Closing Date and continuing through the Term Loan Maturity Date.

(ii) The Term Loans, including all unpaid principal thereunder (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any and all other outstanding amounts payable under the Loan Documents), is due and payable in full on the Term Loan Maturity Date.

(iii) The Term Loans may be prepaid only in accordance with Section 2.2(c), except as provided in Section 8.1.

(c) Prepayment of Term Loans.

(i) Borrower shall have the option, at any time after the Tranche A Closing Date, to prepay, in whole but not in part, outstanding principal amounts under the Term Loans advanced by Lenders under this Agreement; provided that (A) Borrower provides written notice to the Collateral Agent of its election (which shall be irrevocable unless the Collateral Agent otherwise consents in writing) to prepay all of the Term Loans at least three (3) Business Days prior to such prepayment, and (B) the prepayment of such principal amount shall be accompanied by any and all accrued and unpaid interest thereon through the date of prepayment, any and all amounts payable in connection with such prepayment pursuant to Section 2.2(e) and Section 2.2(f) (as applicable) and any and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4). The Collateral Agent will promptly notify each Lender of its receipt of such notice, and the amount of such Lender's Applicable Percentage of such prepayment. Notwithstanding anything in this Section 2.2(c)(i) to the contrary, Borrower may rescind any notice of prepayment under this Section 2.2(c)(i) if such prepayment would have resulted from a refinancing of the Term Loans or other contingent transaction, which refinancing or transaction shall not be consummated or shall otherwise be delayed (in which case, a new notice shall be required to be sent in connection with any subsequent prepayment).

(ii) Upon a Change in Control, Borrower shall promptly, and in any event no later than ten (10) days after the consummation of such Change in Control, notify the Collateral Agent in writing of the occurrence of a Change in Control, which notice shall include reasonable detail as to the nature, timing and other circumstances of such Change in Control (such notice, a "**Change in Control Notice**"). Borrower shall prepay in full all of the Term Loans advanced by Lenders under this Agreement, no later than three (3) Business Days after the delivery of such Change in Control Notice, in an amount equal to the sum of (A) all unpaid principal and any and all accrued and unpaid interest with respect to the Term Loans, and (B) any and all amounts payable with respect to the prepayment under this Section 2.2(c)(ii) pursuant to Section 2.2(e) and Section 2.2(f) (as applicable), together with any and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4). The Collateral Agent will promptly notify each Lender of its receipt of the Change in Control Notice, and the amount of such Lender's Applicable Percentage of such prepayment.

(iii) Prior to any prepayment, repurchase, redemption or similar action, of the Permitted Convertible Indebtedness in accordance with its terms (the "**Convertible Indebtedness Redemption**") (which occurs prior to the Term Loan Maturity Date), Borrower shall promptly, and in any event no later than fifteen (15) days prior to the consummation of such Convertible Indebtedness Redemption, notify the Collateral Agent in writing of the occurrence of such Convertible Indebtedness Redemption, which notice shall include reasonable detail as to the nature, timing and other circumstances of such Convertible Indebtedness Redemption (such notice, a "**Convertible Indebtedness Redemption Notice**"). Borrower shall prepay in full all of the Term Loans advanced by Lenders under this Agreement, no later than ten (10) days prior to the Convertible Indebtedness Redemption in an amount equal to the sum of (A) all unpaid principal and any and all accrued and unpaid interest with respect to the Term Loans (or such remaining outstanding portion thereof), and (B) any applicable amounts payable with respect to the prepayment under this Section 2.2(c)(iii) pursuant to Section 2.2(e) and Section 2.2(f) (as applicable) and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents. The Collateral Agent will promptly notify each Lender of its receipt of the Convertible Indebtedness Redemption Notice, and the amount of such Lender's Applicable Percentage of such prepayment. Notwithstanding the foregoing, none of the following shall be deemed to be a Convertible Indebtedness Redemption: (w) the conversion by holders of Permitted Convertible Indebtedness (including any cash payment upon conversion) or required payment of any interest with respect to any Permitted Convertible Indebtedness, in each case, in accordance with the terms of the indenture or other documentation governing such Permitted Convertible

Indebtedness, (x) cash payments to redeem any Permitted Convertible Indebtedness; provided, however, that the closing price per share of Parent's publicly-traded common stock on the Trading Day immediately prior to the day on which Borrower delivers the redemption notice pursuant to the terms of the indenture governing such Permitted Convertible Indebtedness is a least 1.2 times the conversion price of such Permitted Convertible Indebtedness, (y) the exchange of existing Permitted Convertible Indebtedness for (1) new Permitted Convertible Indebtedness (the "**Refinancing Convertible Debt**") (or the cash proceeds from the issuance of such Refinancing Convertible Debt) to the extent such Refinancing Convertible Debt is permitted to be issued under the terms of this Agreement and to the extent that such new Refinancing Convertible Debt bears interest at a rate per annum not to exceed five percent (5.0%), (2) Equity Interests, (3) the cash proceeds, if any, received pursuant to the exercise, early unwind or termination of any Permitted Equity Derivative entered into in connection with such existing Permitted Convertible Indebtedness, or (4) cash in respect of accrued and unpaid interest on such exchanged existing Permitted Convertible Indebtedness, or (z) delivery of Equity Interests and cash in lieu of fractional shares or in respect of accrued and unpaid interest to any holder of Permitted Convertible Indebtedness to induce such holder to convert Permitted Convertible Indebtedness in accordance with the terms of the indenture governing such Permitted Convertible Indebtedness (any such transaction described in clause (w), (x), (y) or (z) above, a "**Permitted Transaction**" and collectively, the "**Permitted Transactions**").

(d) Prepayment Application. Any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a) (together with the accompanying Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f) as applicable) shall be paid to Lenders in accordance with their respective Applicable Percentages for application to the Obligations in the following order: (i) first, to due and unpaid Lender Expenses; (ii) second, to due and unpaid Additional Consideration; (iii) third, to accrued and unpaid interest at the Default Rate incurred pursuant to Section 2.3(b), with respect to past due amounts, if any; (iv) fourth, without duplication of amounts paid pursuant to clause (iii) above, to accrued and unpaid interest at the Term Loan Rate; (v) fifth, to the Prepayment Premium; (vi) sixth, to the Makewhole Amount, if applicable; (vii) seventh, to the outstanding principal amount of the Term Loans being prepaid; and (viii) eighth, to any remaining amounts then due and payable under this Agreement and the other Loan Documents.

(e) Makewhole Amount.

(i) Any prepayment of the Tranche A Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in each case occurring prior to the 2nd-year anniversary of the Tranche A Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Makewhole Amount.

(ii) Any prepayment of the Tranche B Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in each case occurring prior to the 2nd-year anniversary of the Tranche B Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Makewhole Amount.

(f) Prepayment Premium.

(i) Any prepayment of the Tranche A Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Prepayment Premium.

(ii) Any prepayment of the Tranche B Loan by Borrower (A) pursuant to Section 2.2(c), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Prepayment Premium.

For the avoidance of doubt, no Prepayment Premium shall be due and owing for any payment of principal of the Term Loans made on the Term Loan Maturity Date.

(g) Any Makewhole Amount or Prepayment Premium payable as a result of any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall be presumed to be the liquidated damages sustained by each applicable Lender as the result of the early redemption and repayment of such Term Loan Notes and Borrower agrees that it is reasonable under the circumstances currently existing. BORROWER EXPRESSLY WAIVES (TO THE FULLEST EXTENT IT MAY LAWFULLY DO SO) THE PROVISIONS OF ANY PRESENT OR FUTURE REQUIREMENTS OF LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF ANY MAKEWHOLE AMOUNT OR PREPAYMENT PREMIUM IN CONNECTION WITH ANY SUCH PREPAYMENT OR ACCELERATION OR OTHERWISE. Borrower expressly agrees that (to the fullest extent it may lawfully do so) that: (i) each Makewhole Amount and Prepayment Premium is reasonable and is the product of an arm's-length transaction among sophisticated business people, ably represented by counsel; (ii) each Makewhole Amount and Prepayment Premium shall be payable notwithstanding the then-prevailing market rates at the time payment thereof is made; (iii) there has been a course of conduct among Lenders and Borrower giving specific consideration in this transaction for such agreement to pay each Makewhole Amount and Prepayment Premium; and (iv) Borrower shall be estopped hereafter from claiming differently than as agreed to in this Section 2.2(g). Borrower expressly acknowledges that its agreement to pay the Makewhole Amount and Prepayment Premium, as the case may be, to applicable Lenders as herein described is a material inducement to such Lenders to make any Credit Extension.

2.3 Payment of Interest on the Term Loans

.

(a) Interest Rate.

(i) Subject to Section 2.3(b), the principal amount outstanding under each Term Loan shall accrue interest at a fixed per annum rate equal to the LIBOR Rate plus eight and one quarter percent (8.25%) per annum (the "**Term Loan Rate**"), which interest shall be payable quarterly in arrears in accordance with this Section 2.3.

(ii) Interest shall accrue on each Term Loan commencing on, and including, the day on which such Term Loan is made, and shall accrue on such Term Loan, or any portion thereof, through and including the day on which such Term Loan or such portion is paid.

(iii) Interest is due and payable quarterly on each Interest Date, as calculated by the Collateral Agent (which calculations shall be deemed correct absent manifest error, provided that the Collateral Agent shall provide evidence of such calculation upon Borrower's written request), commencing on the Interest Date occurring in the calendar quarter immediately following the Tranche A Closing Date; provided,

however, that if any such date is not a Business Day, the applicable interest shall be due and payable on the first Business Day immediately after such date.

(b) Default Rate. In the event Borrower fails to pay any of the Obligations when due (after giving effect to any applicable grace or cure period), or upon the commencement and during the continuance of an Insolvency Proceeding of Borrower, or upon the occurrence and during the continuance of any other Event of Default, immediately (and without notice or demand by any Lender or the Collateral Agent for payment thereof) to Borrower, such past due Obligations shall accrue interest at a rate per annum which is three percentage points (3.00%) above the rate that is otherwise applicable thereto (the "**Default Rate**"), and such interest shall be payable entirely in cash on demand of any Lender or the Collateral Agent. Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment of any Obligations and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of the Collateral Agent or any Lender.

(c) 360-Day Year. Interest payable under each Term Loan shall be computed on the basis of a year of 360 days and the actual number of days elapsed.

(d) Payments. Except as otherwise expressly provided herein, all Term Loan payments and any other payments hereunder by (or on behalf of) Borrower shall be made on the date specified herein to such bank account of each applicable Lender as such Lender (or the Collateral Agent) shall have designated in a written notice to Borrower delivered on or before the Tranche A Closing Date (which such notice may be updated by such Lender (or the Collateral Agent) by written notice to the Borrower from time to time after the Tranche A Closing Date). Except as otherwise expressly provided herein, interest is payable quarterly on each Interest Date. Payments of principal or interest received after 11:00 a.m. on such date are considered received at the opening of business on the next Business Day. When any payment is due on a day that is not a Business Day, such payment is due on the next Business Day thereafter and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest made hereunder and pursuant to any other Loan Document, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

(e) Benchmark Replacement Setting. Notwithstanding anything to the contrary herein or in any other Loan Document:

(i) Replacing USD LIBOR. On March 5, 2021 the Financial Conduct Authority ("**FCA**"), the regulatory supervisor of USD LIBOR's administrator ("**IBA**"), announced in a public statement the future cessation or loss of representativeness of overnight/Spot Next, 1-month, 3-month, 6-month and 12- month USD LIBOR tenor settings. On the earlier of (A) the date that all Available Tenors of USD LIBOR have either permanently or indefinitely ceased to be provided by IBA or have been announced by or on behalf of the FCA pursuant to public statement or publication of information to be no longer representative and (B) the Early Opt-in Effective Date, if the then-current Benchmark is USD LIBOR, the Benchmark Replacement will replace such Benchmark for all purposes hereunder and under any Loan Document in respect of any setting of such Benchmark on such day and all subsequent settings without any amendment to, or further action or consent of any other party to, this Agreement or any other Loan Document. If the Benchmark Replacement is Daily Simple SOFR, all interest payments will be payable on a quarterly basis.

(ii) Replacing Future Benchmarks. Upon the occurrence of a Benchmark Transition Event, the Benchmark Replacement will replace the then-current Benchmark for all purposes hereunder and under any Loan Document in respect of any Benchmark setting at or after 5:00 p.m. on the fifth (5th) Business Day after the date notice of such Benchmark Replacement is provided to Borrower and the Lenders without any amendment to, or further action or consent of any other party to, this Agreement or any other Loan Document so long as the Collateral Agent has not received, by such time, written notice of objection to such Benchmark Replacement from Lenders comprising the Required Lenders. At any time that the administrator of the then-current Benchmark has permanently or indefinitely ceased to provide such Benchmark or such Benchmark has been announced by or on behalf of the regulatory supervisor for the administrator of such Benchmark pursuant to public statement or publication of information to be no longer representative of the underlying market and economic reality that such Benchmark is intended to measure and that representativeness will not be restored, Borrower, with respect to any request (pursuant to Section 3.7) for a borrowing of Term Loans to be made that would bear interest by reference to such Benchmark, will be deemed to have converted such request into a request for a borrowing of Term Loans to be made that will bear interest by reference to the Benchmark Replacement that has replaced such Benchmark.

(iii) Benchmark Replacement Conforming Changes. In connection with the implementation and administration of a Benchmark Replacement, the Collateral Agent will have the right to make Benchmark Replacement Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Benchmark Replacement Conforming Changes will become effective without any further action or consent of any other party to this Agreement.

(iv) Notices; Standards for Decisions and Determinations. The Collateral Agent will promptly notify Borrower and the Lenders of (A) the implementation of any Benchmark Replacement and (ii) the effectiveness of any Benchmark Replacement Conforming Changes. Any determination, decision or election that may be made by the Collateral Agent or, if applicable, any Lender (or group of Lenders) pursuant to this Section 2.3(e), including any determination with respect to a tenor, rate or adjustment or of the occurrence or non-occurrence of an event, circumstance or date and any decision to take or refrain from taking any action, will be conclusive and binding absent manifest error and may be made in its or their sole discretion and without consent from any other party to this Agreement.

(v) Unavailability of Tenor of Benchmark. At any time (including in connection with the implementation of a Benchmark Replacement), (i) if the then-current Benchmark is a term rate (including Term SOFR or USD LIBOR), then the Collateral Agent may remove any tenor of such Benchmark that is unavailable or non-representative tenor for Benchmark (including Benchmark Replacement) settings and (ii) the Collateral Agent may reinstate any such previously removed tenor for Benchmark (including Benchmark Replacement) settings.

2.4 Expenses

. Borrower shall pay to or reimburse (or pay directly on behalf of) the Collateral Agent and, as applicable, each Lender, all of such Person's reasonable and documented Lender Expenses incurred through and after the Effective Date, promptly after receipt of a written demand therefor by such Lender or the Collateral Agent (with, in the case of any Lender, a copy of such demand to the Collateral Agent), setting forth in reasonable detail such Person's Lender Expenses.

2.5 Requirements of Law; Increased Costs

. In the event that any applicable Change in Law:

(a) Does or shall subject any Lender to any Tax of any kind whatsoever with respect to this Agreement or the Term Loans (except, in each case, Indemnified Taxes, Taxes described in clause (b) through (d) of the definition of Excluded Taxes, and Connection Income Taxes);

(b) Does or shall impose, modify or hold applicable any reserve, capital requirement, special deposit, compulsory loan, insurance charge or similar requirements against assets held by, or deposits or other liabilities in or for the account of, advances or loans by, or other credit extended by, or any other acquisition of funds by, any Lender; or

(c) Does or shall impose on any Lender any other condition (other than Taxes); and the result of any of the foregoing is to increase the cost to such Lender (as determined by such Lender in good faith using calculation methods customary in the industry) of making, renewing or maintaining the Term Loans or to reduce any amount receivable in respect thereof or to reduce the rate of return on the capital of such Lender or any Person controlling such Lender,

then, in any such case, such Lender shall promptly notify Borrower in writing of the event by reason of which it has incurred additional costs or has reduced amounts receivable or rate of return, and submit to Borrower a certificate as to such additional costs or has reduced amounts receivable or rate of return containing the calculation thereof in reasonable detail, which shall be conclusive in the absence of manifest error. Such Lender shall first, prior to Borrower being required to take any action under this Section 2.5, take commercially reasonable actions to mitigate the additional costs or reduced amounts receivable or rate of return, including assigning all of its rights and delegating and transferring all of its obligations hereunder to an existing Affiliate of such Lender that would not be subject to such, or would be subject to less, additional costs or reduced amounts receivable or rate of return, if any. Borrower shall promptly, and no later than thirty (30) days of its receipt of the certificate described above, pay to such Lender, subject to the terms of this Section 2.5, any undisputed additional amounts necessary to compensate such Lender for such additional cost or reduced amounts receivable or rate of return as reasonably determined by such Lender with respect to this Agreement or the Term Loans made hereunder. The provisions hereof shall survive the termination of this Agreement and the payment of the outstanding Term Loans and all other Obligations. Failure or delay on the part of any such Lender to demand compensation for any increased costs or reduction in amounts received or receivable or reduction in return on capital under this Section 2.5 shall not constitute a waiver of such Lender's right to demand such compensation; provided that Borrower shall not be under any obligation to compensate such Lender under this Section 2.5 with respect to increased costs or reductions with respect to any period prior to the date that is 180 days prior to the date of the delivery of the notice required pursuant to the foregoing provisions of this paragraph; provided, further, that if the Change in Law giving rise to such increased costs or reductions is retroactive, then the 180-day period referred to above shall be extended to include the period of retroactive effect thereof.

2.6 Taxes; Withholding, Etc.

(a) All sums payable by any Credit Party hereunder and under the other Loan Documents shall (except to the extent required by Requirements of Law) be paid free and clear of, and without any deduction or withholding on account of, any Tax imposed, levied, collected, withheld or assessed by any Governmental Authority. In addition, Borrower agrees to pay, and shall indemnify and hold each Lender harmless from, Other Taxes, and as soon as practicable after the date of paying Other Taxes to a Governmental Authority, Borrower shall furnish to each Lender (as applicable, with a copy to the Collateral Agent) the original or a certified copy of a receipt evidencing payment thereof or other evidence reasonably satisfactory to such Lender.

(b) If any Credit Party or any other Person ("**Withholding Agent**") is required by Requirements of Law to make any deduction or withholding on account of any Tax (as determined in the good faith discretion of such Withholding Agent) from any sum paid or payable by any Credit Party to any Lender under any of the Loan Documents: (i) such Withholding Agent shall notify such Lender in writing (with a copy to the Collateral Agent) of any such requirement or any change in any such requirement promptly after such Withholding Agent becomes aware of it; (ii) such Withholding Agent shall make any such withholding or deduction; (iii) such Withholding Agent shall pay any such Tax before the date on which penalties attach thereto, such payment to be made (if the liability to pay is imposed on any Credit Party) for its own account or (if that liability is imposed on such Lender, as the case may be) on behalf of and in the name of such Lender in accordance with Requirements of Law; (iv) if the Tax is an Indemnified Tax, the sum payable by such Credit Party in respect of which the relevant deduction, withholding or payment of Indemnified Tax is required shall be increased to the extent necessary to ensure that, after the making of that deduction, withholding or payment (including any deductions for Indemnified Taxes applicable to additional sums payable under this Section 2.6(b)), such Lender receives on the due date a net sum equal to what it would have received had no such deduction, withholding or payment of Indemnified Tax been required or made; and (v) as soon as practicable after paying any sum from which it is required by Requirements of Law to make any deduction or withholding, Borrower shall (or shall cause such Withholding Agent, if not Borrower, to) deliver to such Lender (with a copy to the Collateral Agent) evidence reasonably satisfactory to such Lender of such deduction, withholding or payment and of the remittance thereof to the relevant taxing or other Governmental Authority.

(c) The Credit Parties shall jointly and severally indemnify each Lender for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 2.6(c)) paid by such Lender and any liability (including any reasonable expenses) arising therefrom or with respect thereto whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. Any indemnification payment pursuant to this Section 2.6(c) shall be made to the applicable Lender within twenty (20) days from written demand therefor.

(d) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to Borrower, at the time or times reasonably requested by Borrower, such properly completed and executed documentation reasonably requested by Borrower as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, such Lender, if reasonably requested by Borrower, shall deliver such other documentation prescribed by applicable law or reasonably requested by Borrower as will enable Borrower to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Section 2.6(d)(i), (ii) or (iv) below) shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender. For avoidance of doubt, for the purposes of this Section 2.6(d), the term "Lender" shall include each applicable assignee. Without limiting the generality of the foregoing:

(i) If any Lender is organized under the laws of the United States or any state thereof, such Lender shall deliver, and shall cause each applicable assignee thereof to deliver, to Borrower two (2) executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax.

(ii) If any Lender is a Foreign Lender, such Lender shall deliver, and shall cause each applicable assignee thereof to deliver, to Borrower, on or about the date on which such Foreign Lender becomes a Lender under this Agreement, and at such other times as may be necessary in the determination of Borrower (in the reasonable exercise of its discretion), whichever of the following is applicable:

(1) in the case that such Lender is a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document (including any original issue discount), a properly completed and duly executed copy of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, a properly completed and duly executed copy of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

(2) a completed and duly executed copy of IRS Form W-8ECI;

(3) in the case that such Foreign Lender is claiming an exemption from U.S. federal withholding Tax pursuant to the "portfolio interest exemption" under Section 881(c) of the IRC, it shall provide Borrower with the applicable executed IRS Form W-8BEN-E or IRS Form W-8BEN, as applicable, and a certificate reasonably satisfactory to Borrower to the effect that any interest received by such Foreign Lender is not received by a "bank" on "extension of credit made pursuant to a loan agreement entered into in the ordinary course of its trade or business" within the meaning of 881(c)(3)(A) of the IRC, a "10 percent shareholder" of Borrower within the meaning of Section 871(h)(3)(B) of the IRC, or a "controlled foreign corporation" related to Borrower as described in Section 881(c)(3)(C) of the IRC, or

(4) to the extent that such Foreign Lender is not the beneficial owner, an executed copy of IRS Form W-8IMY, accompanied by a withholding statement and IRS Form W-8ECI, IRS Form W-8BEN-E (or W-8BEN, as applicable), IRS Form W-9 or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a certificate referenced in Section 2.6(d)(ii)(3) above on behalf of each such direct or indirect partner.

(iii) If any Lender is a Foreign Lender it shall, to the extent it is legally entitled to do so, deliver to Borrower (in such number of copies as shall be requested by the recipient) on or about the date on which it becomes a party to this Agreement (and from time to time thereafter upon the reasonable request of Borrower), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower to determine the withholding or deduction required to be made.

(iv) If a payment made to any Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the IRC, as applicable), such Lender shall deliver to Borrower at the time or times prescribed by law and at such time or times reasonably requested by Borrower such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the IRC) and such additional documentation reasonably requested by Borrower as may be necessary for Borrower to comply with their obligations under FATCA and to determine that Lender has complied with its obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

(v) Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or notify the Borrower in writing of its legal inability to do so.

(e) If any party hereto determines, in its discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this Section 2.6 (including by the payment of additional amounts pursuant to this Section 2.6), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made, or additional amounts paid, under this Section 2.6 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this clause (e) in the event that such indemnified party is required to repay such refund to such Governmental Authority and the requirement to repay such refund to such Governmental Authority is not due to the indemnified party's failure to timely provide complete and accurate Internal Revenue Service forms and other documentation required pursuant to Section 2.6(d) or Section 2.8. Notwithstanding anything to the contrary in this clause (e), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this clause (e) if the payment of such amount would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the indemnification payments or additional amounts giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such tax had never been paid. This clause (e) shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

(f) Tax Status of Borrower. Borrower is currently treated as a corporation for U.S. federal income tax purposes.

(g) Tax Reporting Assistance. Borrower shall use reasonable efforts to assist any Lender (i) in the computation of accruals with respect to any "original issue discount" or "market discount" arising with respect to the Term Loans for U.S. federal income tax purposes, and (ii) with its compliance with any associated tax reporting or filing requirements of such Lender or its partners, members or beneficial owners.

2.7 Additional Consideration

. As additional consideration for the obligation of each Lender to fund its Applicable Percentage of the Term Loans and the funding of its Applicable Percentage of the Term Loans pursuant to Section 2.2(a) and Section 3.7, on the Tranche A Closing Date, Borrower shall pay to each Lender an amount equal to the product of (i) the sum of such Lender's Tranche A Commitment and Tranche B Commitment, *multiplied by* (ii) 0.0175 (such product, the "**Additional Consideration**"). Any and all Additional Consideration shall be fully earned when paid and shall not be refundable for any reason whatsoever and shall be treated as original issue discount with respect to the Tranche A Loan for U.S. federal income tax purposes. The Additional Consideration payable hereunder shall be due on the Tranche A Closing Date and shall be deducted from the proceeds of the Tranche A Loan to be advanced to Borrower pursuant to Section 2.2(a) and Section 3.7.

2.8 Note Register; Term Loan Notes

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(a) Note Register. Borrower will maintain at all times at its principal executive office a register that identifies each beneficial owner that is entitled to a payment of principal and stated interest on each Term Loan (the "**Note Register**") and provides for the registration and transfer of Term Loan Notes so that each Term Loan is at all times in "registered form" within the meaning of Section 163(f), 871(h)(2) and 881(c)(2) of the IRC and any related regulations (and any other relevant or successor provisions of the IRC or such regulations). Each Term Loan: (i) shall, pursuant to this clause (a), be registered as to both principal and any stated interest with Borrower or its agent, and (ii) may be transferred or exchanged by any Lender only by surrender of the old instrument at the principal executive office of Borrower (or at the place of payment named in the Term Loan Note, if any), accompanied, if so required by Borrower in the case of a Lender Transfer, by a written instrument of transfer in form reasonably satisfactory to Borrower duly executed by the holder thereof or by such holder's attorney duly authorized in writing, and Borrower will execute and deliver in exchange therefor a new Term Loan Note or Term Loan Notes, in such denomination(s) as may be requested by such holder, of like tenor and in the same aggregate outstanding principal amount as the aggregate outstanding principal amount of the Term Loan Note(s) so surrendered. Any Term Loan Note issued in exchange for any other Term Loan Note or upon transfer thereof shall carry the rights to unpaid interest and interest to accrue that were carried by the Term Loan Note so exchanged or transferred, and neither gain nor loss of interest shall result from any such transfer or exchange. The entries in the Note Register shall be conclusive and binding for all purposes, including as to the outstanding principal amount of the Term Loan Note and the payment of interest, principal and other sums due hereunder absent manifest error and Borrower, Lenders and any of their respective agents may treat the Person in whose name any Term Loan Note is registered as the sole and exclusive record and beneficial holder and owner of such Term Loan Note for all purposes whatsoever.

(b) Term Loan Notes. Each Lender shall issue to Borrower, and Borrower shall execute and deliver to each Lender to evidence such Lender's Term Loan, (i) on the Tranche A Closing Date, a Tranche A Note, and (ii) on the Tranche B Closing Date, a Tranche B Note. All amounts due under the Term Loan Notes shall be repayable as set forth in this Agreement and interest shall accrue on the principal amount of the Term Loans represented by the Term Loan Notes, in each case, in accordance with the terms of this Agreement. All Term Loan Notes shall rank for all purposes *pari passu* with each other.

3 CONDITIONS OF TERM LOANS

3.1 Conditions Precedent to Tranche A Loan

. Each Lender's obligation to advance its Applicable Percentage of the Tranche A Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt:

(i) on the Effective Date, of copies of the Loan Agreement, the Disclosure Letter, the Perfection Certificate for Parent and its Subsidiaries and the Advance Request Form, in each case (x) dated as of the Effective Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form and substance reasonably satisfactory to the Collateral Agent; and

(ii) on the Tranche A Closing Date, of copies of the other Loan Documents (including the schedules thereto), including the Tranche A Notes executed by Borrower and the Collateral Documents (but excluding any Control Agreements, Collateral Access Agreements and any other Loan Document described in Schedule 5.14 of the Disclosure Letter to be delivered after the Tranche A Closing Date) and, if and to the extent any update thereto is necessary between the Effective Date and the Tranche A Closing Date, an updated Disclosure Letter or Perfection Certificate (provided, that in no event may the Disclosure Letter or the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)), in each case (x) dated as of the Tranche A Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form and substance reasonably satisfactory to the Collateral Agent;

(b) the Collateral Agent's receipt of (i) true, correct and complete copies of the Operating Documents of each of Parent and the Credit Parties, and (ii) a Secretary's Certificate, dated the Tranche A Closing Date, certifying that the foregoing copies are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent);

(c) the Collateral Agent's receipt of a good standing certificate for each Credit Party (where applicable in the subject jurisdiction), certified (where available) by the Secretary of State (or the equivalent thereof) of the jurisdiction of incorporation, formation or organization of such Person as of a date no earlier than thirty (30) days prior to the Tranche A Closing Date;

(d) the Collateral Agent's receipt of a Secretary's Certificate in relation to each Credit Party, dated the Tranche A Closing Date, certifying that (i) attached as Exhibit A to such certificate is a true, correct, and complete copy of the Borrowing Resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Credit Party of the Loan Documents to which it is a party, (ii) the name(s) and title(s) of the officers of such Credit Party authorized to execute the Loan Documents to which such Credit Party is a party on behalf of such Credit Party together with a sample of the true signature(s) of such Credit Party(s), and (iii) that the Collateral Agent and each Lender may conclusively rely on such certificate with respect to the authority of such officers unless and until such Credit Party shall have delivered to the Collateral Agent a further certificate canceling or amending such prior certificate;

(e) each Credit Party shall have obtained all Governmental Approvals, if any, and all consents or approvals of other Persons, including the approval or consent of the equityholders of Borrower or Parent, if any, and the consent of RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2) required pursuant to Section 6.8 of the Pre-Paid Forward Contract, in each case that are necessary in connection with the transactions contemplated by the Loan Documents, and each of the foregoing shall be in full force and effect and in form and substance reasonably satisfactory to the Collateral Agent;

(f) the Collateral Agent's receipt on the Tranche A Closing Date of opinions of (i) Cooley LLP, counsel to Borrower and the other the Credit Parties, and (ii) Erdinast Ben Natan Toledano & Co. with Hamburger Evron, counsel to the Parent in each case in form and substance reasonably satisfactory to the Collateral Agent;

(g) (i) subject to Section 5.14, the Collateral Agent's receipt on the Tranche A Closing Date of (i) evidence that any products liability and general liability insurance policies maintained regarding any Collateral are in full force and effect and (ii) appropriate evidence showing the Collateral Agent, for the benefit of Lenders and the other Secured Parties, having been named as additional insured or loss payee, as applicable (such evidence to be

in form and substance reasonably satisfactory to the Collateral Agent) with respect to any products liability and general liability insurance policies maintained in the United States regarding any Collateral;

(h) the Collateral Agent's receipt prior to the Effective Date of all documentation and other information required by bank regulatory authorities under applicable "know-your-customer" and anti-money laundering rules and regulations, including the U.S.A. Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "**Patriot Act**");

(i) concurrent with the funding of the Tranche A Loan, payment of Lender Expenses then due as specified in Section 2.4 hereof for which Borrower has received an invoice at least one (1) Business Day prior, and payment of the Additional Consideration in accordance with Section 2.7, which such payments shall be deducted from the proceeds of the Tranche A Loan;

(j) the Collateral Agent's and each Lender's receipt of: (i) the RTW Intercreditor Agreement, executed and delivered by each of Parent and the RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2), (ii) subject to Section 5.14, a copy of the amendment to the Security Agreement/Debenture Unlimited in Amount, dated April 4, 2021, between Parent and RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2), acknowledging the creation of a first priority security interest in and Lien upon the Collateral in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties and providing that such security interest and Lien is senior in priority to any and all security interests and Liens in favor of RTW Investments ICAV thereunder, and (iii) subject to Section 5.14, evidence of the filing of such amended Security Agreement/Debenture Unlimited in Amount with the Israeli Registrar of Companies (such evidence to be in form and substance reasonably satisfactory to the Collateral Agent); and

(k) the Collateral Agent's receipt of a certificate, dated the Tranche A Closing Date and signed by a Responsible Officer of Parent, confirming: (i) there is no Adverse Proceeding pending or, to the Knowledge of Parent, threatened in writing, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter; (ii) satisfaction of the conditions precedent set forth in this Section 3.1 and in Section 3.5, Section 3.6 and Section 3.7 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent); and (iii) that the organizational structure and capital structure of Parent and each of its Subsidiaries is as described on Schedule 4.15 of the Disclosure Letter as at the Tranche A Closing Date.

3.2 Conditions Precedent to Tranche B Loan

. Each Lender's obligation to advance its Applicable Percentage of the Tranche B Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt, on the Tranche B Closing Date, of the Tranche B Note executed by Borrower, and, if and to the extent any update thereto is necessary between the Tranche A Closing Date and the Tranche B Closing Date, a Disclosure Letter or Perfection Certificate updated in reasonable detail (provided, that in no event may the Disclosure Letter or the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)), in each case (x) dated as of the Tranche B Closing Date, (y) executed (where applicable) and delivered by each applicable Credit Party, and (z) in form reasonably satisfactory to the Collateral Agent;

(b) the Collateral Agent's receipt of a Secretary's Certificate in relation to each Credit Party, dated the Tranche B Closing Date, certifying (i) that attached as Exhibit A to such certificate is a true, correct, and complete copy of the Borrowing Resolutions then in full force and effect authorizing the Tranche B Loan or, alternatively, (ii) that the Borrowing Resolutions adopted as of the Tranche A Closing Date authorizing the Term Loans and previously delivered to the Collateral Agent pursuant to Section 3.1(d) have not been modified and remain in full force and effect;

(c) [RESERVED];

(d) concurrent with the funding of the Tranche B Loan, payment of Lender Expenses then due as specified in Section 2.4 hereof and for which an invoice has been received by Borrower at least (1) Business Day prior, and such payment shall be deducted from the proceeds of the Tranche B Loan;

(e) no prepayment of the principal amount of any Term Loan has been made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a); and

(f) the Collateral Agent's receipt of a certificate, dated the Tranche B Closing Date and signed by a Responsible Officer of Parent, confirming: (i) there is no Adverse Proceeding pending or, to the Knowledge of Parent, threatened in writing, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter delivered in accordance with Section 3.1(a)(i) or Section 3.2(a)(i), as applicable; and (ii) satisfaction of the conditions precedent set forth in this Section 3.2 and in Section 3.5, Section 3.6 and Section 3.7 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent.

3.3 RESERVED

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3.4 RESERVED

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3.5 Additional Conditions Precedent to Term Loans

. The obligation of each Lender to advance its Applicable Percentage of each Term Loan is subject to the following additional conditions precedent:

(a) the representations and warranties made by the Credit Parties in Section 4 of this Agreement and in the other Loan Documents are true and correct in all material respects on the applicable Closing Date, unless any such representation or warranty is stated to relate to a specific earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (it being understood that any representation or warranty that is qualified as to "materiality," "Material Adverse Change," or similar language shall be true and correct in all respects (as

so qualified), in each case, on the applicable Closing Date (both with and without giving effect to the Term Loans) or as of such earlier date, as applicable); and

(b) there shall not have occurred (i) any Material Adverse Change or (ii) any Default or Event of Default.

3.6 Covenant to Deliver

. The Credit Parties agree to deliver to the Collateral Agent or each Lender, as applicable, each item required to be delivered to Collateral Agent or each Lender, as applicable, under this Agreement as a condition precedent to any Credit Extension; provided, however, that any such items set forth on Schedule 5.14 of the Disclosure Letter shall be delivered to the Collateral Agent within the time period prescribed therefor on such schedule. The Credit Parties expressly agree that a Credit Extension made prior to the receipt by the Collateral Agent or any Lender, as applicable, of any such item shall not constitute a waiver by the Collateral Agent or any Lender of the Credit Parties' obligation to deliver such item, and the making of any Credit Extension in the absence of any such item required to have been delivered by the date of such Credit Extension shall be in the applicable Lender's sole discretion.

3.7 Procedures for Borrowing

. Subject to the prior satisfaction of all other applicable conditions to the making of each Term Loan set forth in this Agreement, to obtain the Term Loans, Borrower shall deliver to the Collateral Agent and Lenders by electronic mail or facsimile a completed Advance Request Form for the Term Loans executed by a Responsible Officer of Borrower (which notice shall be irrevocable on and after the date on which such notice is given and Borrower shall be bound to make a borrowing in accordance therewith), in which case each Lender agrees, subject to the satisfaction of the applicable conditions precedent set forth in this Article 3, to advance an amount equal to its Applicable Percentage of the applicable Term Loan Amount to Borrower on the applicable Closing Date, by wire transfer of same day funds in Dollars, to such account(s) in the United States as may be designated in writing to the Collateral Agent by Borrower at least two (2) Business Days prior to such Closing Date; provided, however, that with respect to the Tranche B Loan, Borrower shall deliver to the Collateral Agent by electronic mail or facsimile such completed Advance Request Form no later than such date that is sixty (60) days prior to the Tranche B Closing Date.

4 REPRESENTATIONS AND WARRANTIES

In order to induce each Lender and the Collateral Agent to enter into this Agreement and for each Lender to make the Credit Extensions to be made on the applicable Closing Date, each Credit Party, jointly and severally with each other Credit Party, represents and warrants to each Lender and the Collateral Agent that the following statements are true and correct as of the Effective Date and on the applicable Closing Date on which each Term Loan is made (both with and without giving effect to the Term Loans) except as otherwise specified below:

4.1 Due Organization, Existence, Power and Authority

. Parent and each of its Subsidiaries (a) is duly incorporated, organized or formed, and validly existing and, where applicable, in good standing under the laws of its jurisdiction of incorporation, organization or formation identified on Schedule 4.15 of the Disclosure Letter, (b) has all requisite power and authority to (i) own, lease, license and operate its assets and properties and to carry on its business as currently conducted and (ii) execute and deliver the Loan Documents to which it is a party and to perform its obligations thereunder and otherwise carry out the transactions contemplated thereby, (c) is duly qualified and, where applicable, in good standing under the laws of each jurisdiction where its ownership, lease, license or operation of assets or properties or the conduct of its business requires such qualification, and (d) has all requisite Governmental Approvals to operate its business as currently conducted; except in each case referred to clauses (a) (other than with respect to Borrower and any other Credit Party), (b)(i), (c) or (d) above, to the extent that failure to do so could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.2 Equity Interests

. All of the outstanding Equity Interests in each Subsidiary of Parent, the Equity Interests in which are required to be pledged pursuant to the Collateral Documents, have been duly authorized and validly issued, are (where required by Requirements of Law to be) fully paid and, in the case of Equity Interests representing corporate interests, are non-assessable and, on the applicable Closing Date, all such Equity Interests owned directly by Parent or any other Credit Party are owned free and clear of all Liens except for Permitted Liens. Schedule 4.2 of the Disclosure Letter identifies each Person, the Equity Interests in which are required to be pledged on the Tranche A Closing Date (or the Tranche B Closing Date, if applicable) pursuant to the Collateral Documents.

4.3 Authorization; No Conflict

. Except as set forth on Schedule 4.3 of the Disclosure Letter, the execution, delivery and performance by each Credit Party of the Loan Documents to which it is a party, and the consummation of the transactions contemplated thereby, (a) have been duly authorized by all necessary corporate or other organizational action and (b) do not and will not (i) contravene the terms of any of such Credit Party's Operating Documents, (ii) conflict with or result in any breach or contravention of, or require any payment to be made under (A) any provision of any security issued by such Person or of any agreement, instrument or other undertaking to which such Credit Party is a party or affecting such Credit Party or the assets or properties of such Credit Party or any of its Subsidiaries or (B) any order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which such Credit Party or any of its properties or assets are subject, (iii) result in the creation of any Lien (other than under the Loan Documents) or (iv) violate any Requirements of Law, except, in the cases of clauses (b)(ii) and (b)(iv) above, to the extent that such conflict, breach, contravention, payment or violation could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.4 Government Consents; Third Party Consents

. Except as set forth on Schedule 4.4 of the Disclosure Letter, no Governmental Approval or other approval, consent, exemption or authorization, or other action by, or notice to, or filing with, any Governmental Authority or any other Person (including any counterparty to any Company IP Agreement or other Material Contract) is necessary or required in connection with (a) the execution, delivery or performance by, or enforcement against, any Credit Party of this Agreement or any other Loan Document, or for the consummation of the transactions contemplated hereby or thereby, (b) the grant by any Credit Party of the Liens granted by it pursuant to the Collateral Documents, (c) the perfection or maintenance of the Liens created under the Collateral Documents (including the priority thereof) or (d) the exercise by the Collateral Agent or any Lender of its rights under the Loan Documents or the remedies in respect of the Collateral pursuant to the Collateral Documents, except in each case of clause (a) through (d) above, for (i) filings necessary to perfect the Liens on the Collateral granted by the Credit Parties to the Collateral Agent for the benefit of Lenders and the other Secured Parties, (ii) the approvals, consents, exemptions, authorizations, actions, notices and filings which have been duly obtained, taken, given or made and are in full force and effect, (iii)

filings under state or federal securities laws and (iv) those approvals, consents, exemptions, authorizations or other actions, notices or filings, the failure of which to obtain or make could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.5 Binding Obligation

. This Agreement has been duly executed and delivered by Borrower and each other Credit Party that is a party hereto and each other Loan Document has been duly executed and delivered by each Credit Party that is a party thereto, and in each case constitutes a legal, valid and binding obligation of Borrower or such Credit Party (as applicable), enforceable against Borrower or such Credit Party (as applicable) in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by general principles of equity.

4.6 Collateral

. In connection with this Agreement, Parent has delivered to the Collateral Agent a completed certificate signed by a Responsible Officer of Parent (the "**Perfection Certificate**"). Each Credit Party, jointly and severally, represents and warrants to the Collateral Agent and each Lender that:

(a) (i) its exact legal name is that indicated on the Perfection Certificate and on the signature page thereof; (ii) it is an organization of the type and is organized in the jurisdiction set forth in the Perfection Certificate; (iii) the Perfection Certificate accurately sets forth its organizational identification number or accurately states that it has none; (iv) the Perfection Certificate accurately sets forth as of the applicable Closing Date its place of business, or, if more than one, its chief executive office as well as its mailing address (if different than its chief executive office); (v) except as set forth in the Perfection Certificate, it (and each of its predecessors) has not, in the five (5) years prior to the applicable Closing Date, changed its jurisdiction of formation, organizational structure or type, or any organizational number assigned by its jurisdiction; and (vi) all other information set forth on the Perfection Certificate pertaining to it and each of its Subsidiaries is accurate and complete in all material respects as of the applicable Closing Date (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificate after the Effective Date to the extent expressly permitted by one or more provisions in this Agreement and the other Loan Documents to reflect changes since the Effective Date, provided that in no event may the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)). If any Credit Party is not now a Registered Organization but later becomes one, it shall promptly notify the Collateral Agent of such occurrence and provide the Collateral Agent with such Credit Party's organizational identification number. The Collateral Agent and each Lender hereby agree that the Perfection Certificate shall be deemed to be updated to reflect information provided in any notice delivered by any Credit Party to the Collateral Agent pursuant to Section 6.2.

(b) (i) it has good and valid title to, has the rights it purports to have in, and subject to Permitted Subsidiary Distribution Restrictions, Permitted Negative Pledges and the occurrence of the applicable Closing Date, the power to transfer each item of the Collateral upon which it purports to grant a Lien under any Collateral Document, free and clear of any and all Liens except Permitted Liens and except for such minor irregularities or defects in title as could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change and (ii) it has no deposit accounts maintained at a bank or other depository or financial institution which are not Excluded Accounts other than the deposit accounts described in the Perfection Certificate delivered to the Collateral Agent in connection herewith.

(c) a true, correct and complete list of each pending, registered, issued or in-licensed Patent, Copyright and Trademark that relates to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory and that, individually or when taken together with any other such Patents, Copyrights or Trademarks, is material to the business of Parent and its Subsidiaries, taken as a whole, which is owned or co-owned by or exclusively or nonexclusively in-licensed to any Credit Party or any of its Subsidiaries as of the Effective Date and on the applicable Closing Date (collectively, the "**Current Company IP**"), including its name/title, current owner or co-owners (including ownership interest), registration, patent or application number, and registration or application date, in each jurisdiction where issued or filed in the Territory, is set forth on Schedule 4.6(c) of the Disclosure Letter. Except as set forth on Schedule 4.6(c) of the Disclosure Letter: (i)(A) each item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries is valid, subsisting and, to the Knowledge of such Credit Party, is enforceable (or will be enforceable upon issuance) and no item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries has in any respect lapsed or expired, been cancelled, held unpatentable or invalidated, or become abandoned or unenforceable (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment), and, to the Knowledge of such Credit Party, no circumstance or grounds exist that would invalidate or reduce, in whole or in part, the validity, enforceability, subsistence or scope of any such Current Company IP, or the ownership or use of such Current Company IP, by any Credit Party or any of its Subsidiaries, and (B) no written notice has been received challenging the validity, patentability, enforceability, inventorship or ownership (other than from patent and trademark offices through the normal prosecution practices), or relating to any lapse, expiration, invalidation, cancellation, abandonment or unenforceability, of any item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment); and (ii) to the Knowledge of such Credit Party, (A) each item of Current Company IP that is exclusively or nonexclusively in-licensed from another Person is valid, subsisting and enforceable and no item of Current Company IP that is exclusively or nonexclusively in-licensed by a Credit Party or any of its Subsidiaries has in any respect lapsed or expired, been cancelled, held unpatentable or invalidated, or become abandoned or unenforceable (other than through the lapse, expiration or abandonment of such Current Company IP in the exercise of normal prosecution practices and reasonable business judgment of licensor), and (B) no written notice has been received challenging the validity, patentability, enforceability, inventorship or ownership, or relating to any lapse, expiration, invalidation, cancellation, abandonment or unenforceability, of any item of Current Company IP that is exclusively or nonexclusively in-licensed by a Credit Party or any of its Subsidiaries (other than from patent and trademark offices through the licensor's normal prosecution practices). Each Credit Party or any of its Subsidiaries possesses valid title to the Current Company IP for which it is listed as the owner or co-owner, as applicable, on Schedule 4.6(c) of the Disclosure Letter. There are no Liens on any Current Company IP other than Permitted Liens. Except as set forth on Schedule 4.6(c) of the Disclosure Letter, (x) each Person who has or has had any rights in or to owned Current Company IP or any trade secrets owned by any Credit Party or any of its Subsidiaries, including each inventor named on the Patents within such owned Current Company IP filed by any Credit Party or any of its Subsidiaries has executed an agreement assigning his, her or its entire right, title and interest in and to such owned Current Company IP and such trade secrets, and the inventions, improvements, ideas, discoveries, writings, works of authorship, information and other intellectual property embodied, described or claimed therein, to the stated owner thereof, and (y) to the Knowledge of such Credit Party, no such Person has any contractual or other obligation that would preclude or conflict with such assignment or the exploitation of Product in the Territory or entitle such Person to ongoing payments. To the Knowledge of such Credit Party, there are no issued patents or pending patent applications, which, if issued, could reasonably be expected to materially adversely affect the exploitation of Product in the Territory.

(d) There are no maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is owned by or exclusively or nonexclusively licensed to any Credit Party or any of its Subsidiaries, nor have any applications or registrations therefor lapsed or become abandoned, been cancelled or expired (other than through the lapse, expiration or abandonment of such Current

Company IP in the exercise of normal prosecution practices and reasonable business judgment of the Credit Party, its Subsidiary and/or the licensor), in each case, except as would not reasonably be expected to result in a Material Adverse Change.

(e) There are no unpaid fees, royalties or indemnification payments under any Company IP Agreement that have become due, or are reasonably expected to become due or overdue except as would not reasonably be expected to result in a Material Adverse Change. Each Company IP Agreement is in full force and effect and, to the Knowledge of such Credit Party, is legal, valid, binding, and enforceable in accordance with its respective terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by equitable principles relating to enforceability. Neither Parent nor any of its Subsidiaries, as applicable, is in material breach of or material default under any Company IP Agreement to which it is a party or may otherwise be bound, and to the Knowledge of such Credit Party, no circumstances or grounds exist that would give rise to a claim of material breach or right of rescission, termination, non-renewal, revision, or amendment of any of the Company IP Agreements, including the execution, delivery and performance of this Agreement and the other Loan Documents.

(f) No payments by any Credit Party or any of its Subsidiaries are due to any other Person in respect of the Current Company IP, other than pursuant to the Company IP Agreements, the Pre-Paid Forward Contract, and those fees payable to patent offices in connection with the prosecution and maintenance of the Current Company IP and associated attorney fees.

(g) Except as noted on Schedule 4.6(g) of the Disclosure Letter, no Credit Party is a party to, nor is it bound by, any Excluded License or Restricted License.

(h) No Credit Party or any of its Subsidiaries has undertaken or omitted to undertake any acts, and, to the Knowledge of such Credit Party, no circumstance or grounds exist that would invalidate or reduce, in whole or in part, the enforceability or scope of (i) the Current Company IP in any manner that could reasonably be expected to materially adversely affect the exploitation of Product in the Territory, or (ii) any Credit Party's or Subsidiary's entitlement to own or license and exploit any Current Company IP in any manner other than with respect to Permitted Licenses and in-licenses and except as set forth on Schedule 4.6(h) of the Disclosure Letter.

(i) Except as set forth on Schedule 4.6(i) of the Disclosure Letter, to the Knowledge of such Credit Party, there is no product or other technology of any third party that could reasonably be expected to infringe a Patent within the Current Company IP.

(j) Except as set forth on Schedule 4.6(j) of the Disclosure Letter, in each case where an issued Patent within the Current Company IP that is material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory is owned or co-owned by any Credit Party or its Subsidiaries by assignment, the assignment has been duly recorded with the U.S. Patent and Trademark Office and foreign offices and agencies anywhere in the world in which foreign counterparts are registered, filed or issued.

(k) There are no pending or, to the Knowledge of such Credit Party, threatened (in writing) claims against Parent or any of its Subsidiaries alleging (i) that any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory infringes or violates (or in the past infringed or violated), or form a reasonable basis for a claim of infringement or violation of, any of the rights of any third parties in or to any Intellectual Property ("**Third Party IP**") or constitutes a misappropriation (or in the past constituted a misappropriation) of any Third Party IP, or (ii) that any Current Company IP is invalid, unpatentable or unenforceable (other than from patent and trademark offices through the normal prosecution practices).

(l) To the Knowledge of such Credit Party, the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory has not in the past and does not(i) infringed or infringe or violated or violate, or formed or form a reasonable basis for a claim of infringement or violation of, any of the rights of any third parties in or to any Third Party IP or (ii) constituted or constitute a misappropriation of any Third Party IP.

(m) Except as set forth on Schedule 4.6(m) of the Disclosure Letter, to the Knowledge of the Borrower, there are no settlements, covenants not to sue, consents, judgments, orders or similar obligations which: (i) restrict the rights of any Credit Party or any of its Subsidiaries to use any Intellectual Property relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory (in order to accommodate any Third Party IP or otherwise), or (ii) permit any third parties to use any Company IP existing as of the Effective Date and on the applicable Closing Date.

(n) Except as set forth on Schedule 4.6(n) of the Disclosure Letter, to the Knowledge of such Credit Party, (i) there is no, nor has there been any, infringement or violation by any Person of any of the Company IP existing as of the Effective Date and on the applicable Closing Date or any of the rights therein, and (ii) there is no, nor has there been any, misappropriation by any Person of any of the Company IP existing as of the Effective Date and on the applicable Closing Date or any of the subject matter thereof.

(o) Each Credit Party and each of its Subsidiaries has taken all commercially reasonable measures customary in the life sciences industry, to protect the confidentiality and value of all trade secrets owned by such Credit Party or any of its Subsidiaries or used or held for use by such Credit Party or any of its Subsidiaries, in each case relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory. Any disclosure by a Credit Party or any of its Subsidiaries of any such trade secrets to any third party has been pursuant to the terms of a written agreement (including appropriate confidentiality, access, use and non-disclosure provisions) with such third party, and no Credit Party or any of its Subsidiaries has suffered any material data breach or other incident that has resulted in any loss, unauthorized access, use, disclosure or modification of any such trade secrets.

(p) Except as set forth on Schedule 4.6(p) of the Disclosure Letter, to the Knowledge of such Credit Party, Product sold under the Patents in the U.S. within the Current Company IP has been marked with the proper patent notice.

(q) Except as set forth on Schedule 4.6(q) of the Disclosure Letter, to the Knowledge of such Credit Party, at the time of any shipment of Product occurring prior to the applicable Closing Date, the units thereof so shipped complied in all material respects with their relevant specifications and were developed and manufactured in accordance with current Good Manufacturing Practices and other applicable Requirements of Law.

(r) The Collateral Documents create in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a valid and continuing and, upon the making of the filings and the taking of the actions required under the terms of the Loan Documents (except to the extent not required to be perfected pursuant to the terms of the Loan Documents), perfected Lien on and security interest in the Collateral (in each case, solely to the

extent perfection is available under applicable Law through the making of such filings and taking of such actions), securing the payment of the Obligations, and having priority over all other Liens on and security interests in the Collateral (except Permitted Liens).

4.7 Adverse Proceedings, Compliance with Laws and Settlement Agreements

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(a) As of the Tranche A Closing Date: (i) except as set forth on Schedule 4.7 of the Disclosure Letter, there are no Adverse Proceedings pending or, to the Knowledge of such Credit Party, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against Parent or any of its Subsidiaries; and (ii) neither Borrower nor any of its Subsidiaries (A) is in violation of any Requirements of Law, excluding any Requirement of Law which is being contested in good faith by appropriate proceedings, or (B) is subject to or in default with respect to any final judgments, orders, writs, injunctions, settlement agreements, decrees, rules or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign.

(b) As of the Tranche B Closing Date: (i) except as set forth on Schedule 4.7 of the Disclosure Letter, there are no Adverse Proceedings pending or, to the Knowledge of such Credit Party, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against Parent or any of its Subsidiaries that either individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change; and (ii) neither Parent nor any of its Subsidiaries (A) is in violation of any Requirements of Law (including Environmental Laws), excluding any Requirement of Law which is being contested in good faith by appropriate proceedings, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, or (B) is subject to or in default with respect to any final judgments, orders, writs, injunctions, settlement agreements, decrees, rules or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change.

(c) Each of Parent and its Subsidiaries (and, to Parent's Knowledge, each other party thereto) is in compliance in all material respects with the terms of all settlement agreements (relating to any Adverse Proceeding) to which Parent or any Subsidiary is a party.

4.8 Exchange Act Documents; Financial Statements; Financial Condition; No Material Adverse Change; Books and Records

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(a) The Exchange Act Documents filed by Parent with the SEC since December 31, 2020, when they were filed with the SEC, conformed in all material respects to the requirements of the Exchange Act, and as of the time they were filed with the SEC, none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (excluding any projections and forward-looking statements, estimates, budgets and general economic or industry data of a general nature), in the light of the circumstances under which they were made, not misleading; provided, that, with respect to projected financial information, Parent represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projections are not a guarantee of financial performance and are subject to uncertainties and contingencies, many of which are beyond the control of Parent or any Subsidiary, and neither Parent nor any Subsidiary can give any assurance that such projections will be attained, that actual results may differ in a material manner from such projections and any failure to meet such projections shall not be deemed to be a breach of any representation or covenant herein).

(b) The financial statements (including the related notes thereto) of Parent and its Subsidiaries included in the Exchange Act Documents present fairly in all material respects the consolidated financial condition of Parent and such Subsidiaries and their consolidated results of operations as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified. Such financial statements have been prepared in conformity with Applicable Accounting Standards applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes, and any supporting schedules included in the Exchange Act Documents present fairly in all material respects the information required to be stated therein.

(c) Since December 31, 2020, there has not occurred any change or event that has had or could reasonably be expected to have, either alone or in conjunction with any other change(s), event(s) or failure(s), a Material Adverse Change.

(d) The Books of Parent and each of its Subsidiaries contain full, true and correct entries of all dealings and transactions in relation to its business and activities in conformity in all material respects with Applicable Accounting Standards and Requirements of Law.

4.9 Solvency

. Each Credit Party and its Subsidiaries, on a consolidated basis, are Solvent. Without limiting the generality of the foregoing, there has been no proposal made or resolution adopted by any competent corporate body for the dissolution or liquidation of any Credit Party, nor do any circumstances exist which may result in the dissolution or liquidation of any Credit Party (other than in respect of a dissolution or liquidation expressly permitted under Section 6.3(a)(iii)).

4.10 Taxes

. All U.S. federal, state, local and non-U.S. income and other material Tax returns of each Credit Party and each of its Subsidiaries required to be filed by any of them (or an extension has been obtained for the filing thereof) have been timely filed and are correct in all material respects, and all U.S. federal, state, local and non-U.S. Taxes which are due and payable by any Credit Party or any of its Subsidiaries have been paid when due and payable, except where the validity or amount thereof is being contested in good faith by appropriate proceedings; provided that no such Tax or any claim for Taxes that have become due and payable shall be required to be paid if, in each case, (a) the applicable Credit Party has set aside on its books adequate reserves therefor in conformity with Applicable Accounting Standards, or (b) the failure to timely file such Tax returns or the failure to pay such Taxes, could not reasonably be expected to result in a Material Adverse Change. There is no proposed Tax assessment against any Credit Party or any of its Subsidiaries that would, if made, result in a Material Adverse Change.

4.11 Environmental Matters

. Neither Parent nor any of its Subsidiaries nor any of their respective Facilities or operations is subject to any outstanding written order, consent decree or settlement agreement with any Person relating to any Environmental Law, any Environmental Claim, or any Hazardous Materials Activity that,

individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. There are and, to the Knowledge of such Credit Party, have been, no conditions, occurrences, or Hazardous Materials Activities that would reasonably be expected to form the basis of an Environmental Claim against Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. To the Knowledge of such Credit Party, no predecessor of Parent or any of its Subsidiaries has filed any notice under any Environmental Law indicating past or present treatment of Hazardous Materials at any Facility, which would reasonably be expected to form the basis of an Environmental Claim against Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change (but, for the avoidance of doubt, neither Parent nor Borrower has undertaken any investigation of or made any inquiries to, or relating to, any of its or its Subsidiaries' predecessors), and neither Parent's nor any of its Subsidiaries' operations involves the generation, transportation, treatment, storage or disposal of hazardous waste, as defined under 40 C.F.R. Parts 260 – 270 or any foreign or United States state equivalents, which would reasonably be expected to form the basis of an Environmental Claim against Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. No event or condition has occurred or is occurring with respect to any Credit Party relating to any Environmental Law, any Release of Hazardous Materials, or any Hazardous Materials Activity that, individually or in the aggregate, has resulted in, or could reasonably be expected to result in, a Material Adverse Change.

4.12 Material Contracts

. After giving effect to the consummation of the transactions contemplated by this Agreement, except as described on Schedule 4.12 of the Disclosure Letter, each Material Contract is a valid and binding obligation of the applicable Credit Party and, to the Knowledge of such Credit Party, each other party thereto, and is in full force and effect, and neither the applicable Credit Party nor, to the Knowledge of such Credit Party, any other party thereto is in material breach thereof or default thereunder, except where such breach or default (which default has not been cured or waived) could not reasonably be expected to give rise to any cancellation, termination or acceleration right of the applicable counterparty thereto or result in the invalidation thereof. No Credit Party or any of its Subsidiaries has received any written notice from any party to any Material Contract asserting or threatening to assert, circumstances that could reasonably be expected to result in the cancellation, termination or invalidation of any Material Contract (or any provision thereof) or the acceleration of such Credit Party's or Subsidiary's obligations thereunder.

4.13 Regulatory Compliance

. No Credit Party is or is required to be registered as, or is a company "controlled" by, an "investment company" as defined in, or is subject to regulation under, the Investment Company Act of 1940. Each Credit Party has complied in all material respects with the Federal Fair Labor Standards Act (and any foreign or United States state equivalent). Except as could not, either individually or in the aggregate, reasonably be expected to result in a Material Adverse Change, each Plan is in compliance with the applicable provisions of ERISA, the IRC and other U.S. federal or state or foreign Requirements of Law, respectively. (i) No ERISA Event has occurred or is reasonably expected to occur; (ii) neither any Credit Party nor any ERISA Affiliate has incurred, or reasonably expects to incur, any liability (and no event has occurred which, with the giving of notice under Section 4219 of ERISA, would result in such liability) under Section 4201 *et seq*. of ERISA with respect to a Multiemployer Plan; and (iii) neither any Credit Party nor any ERISA Affiliate has engaged in a transaction that would be subject to Section 4069 or 4212(c) of ERISA, except, with respect to each of clauses (i), (ii) and (iii) above, as could not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

4.14 Margin Stock

. No Credit Party is engaged principally, or as one of its important activities, in extending credit for the purpose of, whether immediate or ultimate, of purchasing or carrying Margin Stock. No Credit Party owns any Margin Stock. No Credit Party or any of its Subsidiaries has taken or permitted to be taken any action that might cause any Loan Document to violate Regulation T, U or X of the Federal Reserve Board.

4.15 Subsidiaries; Capitalization

. Schedule 4.15 of the Disclosure Letter includes a complete and accurate list as of the applicable Closing Date of Parent and each of its Subsidiaries, setting forth (a) its name and jurisdiction of incorporation, organization or formation, (b) in the case of each Credit Party (other than the Parent), the number of authorized and issued shares of each class of its Equity Interests outstanding, and (c) the percentage of its outstanding shares of each class owned (directly or indirectly) by Parent or any of its Subsidiaries and the certificate numbers(s) for the same (if any), and (d) the number and effect, if exercised, of all of its outstanding options, warrants, rights of conversion or purchase and all other similar rights with respect thereto. Except as set forth on Schedule 4.15 of the Disclosure Letter, no Credit Party is a Registered Organization.

4.16 Employee Matters

. Neither Parent nor any of its Subsidiaries is engaged in any unfair labor practice that could reasonably be expected to result in a Material Adverse Change. There is (a) no unfair labor practice complaint pending against Parent or any of its Subsidiaries or, to the Knowledge of Parent, threatened in writing against any of them before the National Labor Relations Board, and no grievance or arbitration proceeding arising out of or under any collective bargaining agreement that is pending against Parent or any of its Subsidiaries or, to the Knowledge of Parent, threatened in writing against any of them, (b) no strike or work stoppage in existence or, to the Knowledge of Parent, threatened in writing involving Parent or any of its Subsidiaries, and (c) to the Knowledge of Parent, no union representation question existing with respect to the employees of Parent or any of its Subsidiaries and, to the Knowledge of Parent, no union organization activity that is taking place that in each case specified in any of clauses (a), (b) and (c) above, individually or taken together with any other matter specified in clause (a), (b) or (c) above, could reasonably be expected to result in a Material Adverse Change.

4.17 Full Disclosure

. None of the documents, certificates or written statements (excluding any projections and forward-looking statements, estimates, budgets and general economic or industry data of a general nature) furnished or otherwise made available to the Collateral Agent or any Lender by or on behalf of any Credit Party for use in connection with the transactions contemplated hereby (in each case, taken as a whole and as modified or supplemented by other information so furnished promptly after the same becomes available, including the information in the Exchange Act Documents) contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein, as of the time when made or delivered, not misleading in light of the circumstances in which the same were made; provided, that, with respect to projected financial information, Parent represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projections are not a guarantee of financial performance and are subject to uncertainties and contingencies, many of which are beyond the control of Parent or any Subsidiary, and neither Parent nor any Subsidiary can give any assurance that such projections will be attained, that actual results may differ in a material manner from such projections and any failure to meet such projections shall not be deemed to be a breach of any representation or covenant herein). To the Knowledge of Parent, there are no facts (other than matters of a general economic or industry nature) that, individually or in the

aggregate, could reasonably be expected to result in a Material Adverse Change and that have not been disclosed herein or in such other documents, certificates and written statements furnished or made available to the Collateral Agent or any Lender for use in connection with the transactions contemplated hereby.

4.18 FCPA; Patriot Act; OFAC; Export and Import Laws

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(a) None of Parent, its Subsidiaries or, to the Knowledge of Parent, any director, officer, agent or employee of Parent or any Subsidiary of Parent has, at any time in the last five (5) years, (i) used any corporate funds of Parent or any Subsidiary of Parent (including Borrower) for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity, (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee or any Person acting in official capacity from corporate funds of Parent or any Subsidiary of Parent (including Borrower), (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "**FCPA**") or the U.K. Bribery Act 2010 ("**UKBA**") or (iv) made any bribe, improper rebate, payoff, influence payment, kickback or other unlawful payment, and no part of the proceeds of any Credit Extension will be used, directly or indirectly, for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else acting in official capacity, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other applicable anti-corruption laws.

(b) (i) The operations of Parent and its Subsidiaries are and have been conducted at all times in the last five (5) years in compliance with applicable financial recordkeeping and reporting requirements of the Bank Secrecy Act of 1970 (as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001) and the anti-money laundering laws, rules and regulations of each jurisdiction (foreign or domestic) in which Parent or any of its Subsidiaries is subject to such jurisdiction's Requirements of Law (collectively, the "**Anti-Money Laundering Laws**") and (ii) no action, suit or proceeding by or before any Governmental Authority or any arbitrator involving Parent or any of its Subsidiaries with respect to the Anti-Money Laundering Laws is pending or to the Knowledge of Parent, threatened in writing.

(c) None of Parent, its Subsidiaries or, to the Knowledge of Parent, any director, officer, agent or employee of Parent or any Subsidiary of Parent is, or is fifty percent (50.0%) or more owned or otherwise controlled by individuals or entities that are, the target or subject of any economic, trade or financial sanctions or restrictive measures administered and enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), the U.S. Department of State, the U.S. Department of Commerce, the United Nations Security Council, the European Union or the United Kingdom (collectively "**Sanctions**"). Borrower will not, directly or, to the Knowledge of Parent, indirectly through an agent, use the proceeds of any Credit Extension, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person, for (i) the purpose of financing the activities of any Person that is the target or subject of Sanctions or (ii) any purpose that could cause any Lender or the Collateral Agent to be in violation of Sanctions.

(d) Borrower will not, directly or, to the Knowledge of Parent, indirectly through an agent or any other Person, use any of the proceeds of any Credit Extension, or lend, contribute or otherwise make available such proceeds of any Credit Extension to any Subsidiary, joint venture partner or other Person, (i) for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other applicable anti-corruption laws, (ii) in violation of any Anti-Money Laundering Laws, or (iii) in violation of Sanctions;

(e) Parent, its Subsidiaries, and to the Knowledge of Parent, their respective directors, officers, agents and employees, are in compliance with all applicable Sanctions. Parent and its Subsidiaries have instituted and maintain appropriate policies reasonably designed to ensure compliance with applicable Sanctions and applicable anti-corruption laws, including the FCPA and UKBA.

(f) Parent and its Subsidiaries are in compliance in all material respects with applicable Export and Import Laws.

4.19 Health Care Matters

.

(a) *Compliance with Health Care Laws*. Except as set forth on Schedule 4.19(a) of the Disclosure Letter, each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries and each officer, Affiliate, and employee acting on behalf of such Credit Party or any of its Subsidiaries, is in compliance in all material respects with all Health Care Laws applicable to such Credit Party or Subsidiary.

(b) *Compliance with FDA Laws*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, are in compliance in all material respects with all applicable FDA Laws, including all applicable requirements of the Food Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) (the "**FDCA**") and the regulations promulgated thereunder and applicable FDA Guidance Documents, relating to research, development, testing, approval, post-approval monitoring, post-approval requirements, post-approval commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of Product in the Territory. Any Product distributed or sold in the Territory at all times during the past five (5) years has been (i) manufactured in all material respects in accordance with current Good Manufacturing Practices (as applicable), and (ii) if and to the extent such Product is required to be approved by the FDA pursuant to the FDCA in order to be legally marketed in the Territory for such Product's intended uses, such Product has been approved for such intended uses, meets in all material respects any additional conditions of approval or licensure by the FDA (as applicable), and no inquiries regarding material issues have been initiated by FDA, except in each case referred to in sub-clauses (i) or (ii) above, to the extent that any failure to ensure the foregoing could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

(c) *Applicability of Controlled Substances Act*. Product does not contain a controlled substance (as that term is defined under the Controlled Substances Act (21 U.S.C. § 801 et seq.)).

(d) *Material Statements*. Within the past four (4) years, neither any Credit Party, nor, to the Knowledge of such Credit Party, any Subsidiary or any officer, Affiliate or employee of any Credit Party or Subsidiary in its capacity as a Subsidiary or as an officer, Affiliate or employee of a Credit Party or Subsidiary (as applicable), nor, to the Knowledge of such Credit Party, any agent of any Credit Party or Subsidiary, (i) has made an untrue statement of a material fact or a fraudulent statement to any Governmental Authority, (ii) has failed to disclose a material fact to any Governmental Authority, or (iii) has otherwise committed an act, made a statement or failed to make a statement that, at the time such statement or disclosure was made

(or, in the case of such failure, should have been made) or such act was committed, could reasonably be expected to constitute a material violation of any Health Care Law.

(e) *Proceedings; Audits*. Without limiting the generality of Section 4.7, except as has been set forth on Schedule 4.19(e) of the Disclosure Letter: (i) to the Knowledge of such Credit Party, there is no Adverse Proceeding pending, or threatened in writing, against any Credit Party or any of its Subsidiaries relating to any allegations of non-compliance with any Health Care Laws, Data Protection Laws or FDA Laws; and (ii) to the Knowledge of such Credit Party, there are no facts, circumstances or conditions that, individually or in the aggregate, could reasonably be expected to form the basis for any allegations of non-compliance with any Health Care Laws, Data Protection Laws or FDA Laws.

(f) *Recalls, Safety Notices, Etc*. Neither any Credit Party nor any of its Subsidiaries has initiated or otherwise engaged in any recalls, field notifications, safety warnings, "dear doctor" letters, investigator notices, safety alerts or other notices of action, including as a result of any Risk Evaluation and Mitigation Strategy proposed or enforced by the FDA, relating to an alleged lack of safety or regulatory compliance of Product. Neither any Credit Party nor any of its Subsidiaries has a reasonable expectation that there are grounds for imposition of a clinical hold, as described in 21 C.F.R. § 312.42.

(g) *Preclinical Studies / Clinical Trials.* All pre-clinical and clinical studies relating to Product conducted by or on behalf of any Credit Party or any of its Subsidiaries have been, or are being, conducted in material compliance with all applicable Requirements of Law, including the requirements of Good Laboratory Practices and Good Clinical Practice, including regulations under the Common Rule, including regulations under 45 C.F.R. part 46, and guidance documents issued by the Office for Human Research Protection, the Animal Welfare Act and applicable experimental protocols, procedures and controls (and any applicable foreign or United States state equivalents), and, for the avoidance of doubt, all applicable foreign (and United States state) equivalents. No clinical trial conducted by or on behalf of any Credit Party or any of its Subsidiaries has been terminated or suspended by any Regulatory Authority and neither any Credit Party nor any of its Subsidiaries has received any notice that the FDA, any other Governmental Authority or any institutional review board, ethics committee or safety monitoring committee has recommended, initiated or threatened in writing to initiate any action to suspend or terminate any clinical trial conducted by or on behalf of any Credit Party or any of its Subsidiaries or to otherwise restrict the preclinical research on or clinical study of Product.

(h) *Advertising / Promotion*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, officers, employees and agents has advertised, promoted, marketed and distributed Product in compliance in all material respects with FDA Laws and other Requirements of Law. Except as set forth on Schedule 4.19(h) of the Disclosure Letter, neither any Credit Party nor, to the Knowledge of such Credit Party, any of its Subsidiaries, officers, employees or agents has received any notice (including any notice under 21 C.F.R. § 316.36) of or is subject to any civil, criminal or administrative action, suit, demand, claim, complaint, hearing, investigation, demand letter, warning letter, untitled letter, proceeding or request for information from the FDA or any other Governmental Authority concerning noncompliance with any FDA Laws or other Requirements of Law with regard to advertising, promoting, marketing or distributing Product.

(i) *Recordkeeping / Reporting*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, has maintained records relating to the research, development, testing, manufacture, recall, production, handling, labeling, packaging, storage, supply, promotion, distribution, marketing, commercialization, import, export and sale of Product in compliance in all material respects with FDA Laws, Health Care Laws and other applicable Requirements of Law, and each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, has submitted to the FDA and other Governmental Bodies in a timely manner all notices and annual or other reports required to be made by it, including adverse experience reports and annual reports (including annual reports specific to holders of Orphan Drug designations), for Product save to the extent that could not reasonably be expected to have a materially adverse impact on such Credit Party's or Subsidiary's rights in respect of Product.

(j) *Prohibited Transactions; No Whistleblowers*. Except as set forth on Schedule 4.19(j) of the Disclosure Letter, within the past six (6) years, to the Knowledge of such Credit Party, neither any Credit Party, any Subsidiary, any of officer, Affiliate or employee of a Credit Party or Subsidiary, nor any other Person acting on behalf of any Credit Party or any Subsidiary, directly or indirectly: (i) has offered or paid any remuneration, in cash or in kind, to, or made any financial arrangements with, any past, present or potential patient, supplier, physician or contractor, in order to illegally obtain business or payments from such Person in material violation of any Health Care Law; (ii) has given or made, or is party to any illegal agreement to give or make, any illegal gift or gratuitous payment of any kind, nature or description (whether in money, property or services) to any past, present or potential patient, supplier, physician or contractor, or any other Person in material violation of any Health Care Law; (iii) has given or made, or is party to any agreement to give or make on behalf of any Credit Party or any of its Subsidiaries, any contribution, payment or gift of funds or property to, or for the private use of, any governmental official, employee or agent where either the contribution, payment or gift or the purpose of such contribution, payment or gift is or was a material violation of the laws of any Governmental Authority having jurisdiction over such payment, contribution or gift; (iv) has established or maintained any unrecorded fund or asset for any purpose or made any materially misleading, false or artificial entries on any of its books or records for any reason; or (v) has made, or is party to any agreement to make, any payment to any Person with the intention or understanding that any part of such payment would be in material violation of any Health Care Law. To the Knowledge of such Credit Party, there are no actions pending or threatened (in writing) against any Credit Party or any of its Subsidiaries or any of their respective Affiliates under any foreign, federal or state whistleblower statute, including under the False Claims Act of 1863 (31 U.S.C. § 3729 et seq.).

(k) *Exclusion*. Except as set forth on Schedule 4.19(k) of the Disclosure Letter, neither any Credit Party nor, to the Knowledge of such Credit Party, any Subsidiary or any officer, Affiliate or employee having authority to act on behalf of any Credit Party or any Subsidiary, is or, to the Knowledge of such Credit Party, has been threatened in writing to be: (i) excluded from any Governmental Payor Program pursuant to 42 U.S.C. § 1320a-7b and related regulations, to the extent applicable; (ii) "suspended" or "debarred" from selling any products to the U.S. government or its agencies pursuant to the Federal Acquisition Regulation relating to debarment and suspension applicable to federal government agencies generally (42 C.F.R. Subpart 9.4), or other U.S. Requirements of Law; (iii) debarred, disqualified, suspended or excluded from participation in Medicare, Medicaid or any other Governmental Payor Program or is listed on the General Services Administration list of excluded parties, to the extent applicable; (iv) debarred by the FDA; or (v) a party to any other action or proceeding by any Governmental Authority that would prohibit the applicable Credit Party or Subsidiary from distributing or selling Product in the Territory or providing any services to any governmental or other purchaser pursuant to any Health Care Laws.

(l) *Health Information*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, to the extent applicable, is in material compliance with all applicable Data Protection Laws. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, to the extent applicable, has implemented adequate policies and procedures that comply with Data Protection Laws as well as training that is reasonable and customary in the pharmaceutical industry, designed to satisfy the requirements of all applicable Requirements of Law (including HIPAA, Section 5 of the FTC Act, Israeli Data Protection Law, GDPR and CCPA, as applicable) and is otherwise designed to assure continued compliance and to detect non-compliance. Neither any Credit Party nor, to the Knowledge of such Credit Party, any Subsidiary that is not a Credit Party, is a "covered entity" or "business associate" as defined in HIPAA (45 C.F.R. § 160.103).

(m) *Corporate Integrity Agreement*. Neither any Credit Party or Subsidiary or any of their respective Affiliates, nor any officer, director, managing employee or, to the Knowledge of such Credit Party, agent (as those terms are defined in 42 C.F.R. § 1001.1001) of any Credit Party or Subsidiary, is a party to or has any ongoing reporting or disclosure obligations under, or is otherwise subject to, any corporate integrity agreement, monitoring agreement, deferred prosecution agreement, consent decree, settlement order or other similar agreements, or any order, in each case imposed by any U.S. Governmental Authority, concerning compliance with any laws, rules or regulations, issued under or in connection with a Governmental Payor Program.

(n) *ESG Policies*. Each Credit Party and, to the Knowledge of such Credit Party, each of its Subsidiaries, to the extent applicable, is using best efforts to follow Nasdaq's global environmental, social and governance (ESG) reporting guide dated May 2019.

4.20 Regulatory Approvals

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(a) Except as set forth on Schedule 4.20(a) of the Disclosure Letter, each Credit Party and each Subsidiary involved in any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory has all Regulatory Approvals material to the conduct of its business and operations.

(b) Each Credit Party, each Subsidiary and, to the Knowledge of such Credit Party, each licensee of a Credit Party or a Subsidiary of any Intellectual Property relating to Product, is in compliance with, and at all times during the past five (5) years, has complied with all applicable foreign, federal, state and local laws, rules and regulations governing the research, development, testing, approval, designations, marketing, exclusivity, post-approval monitoring, post-approval requirements, post-approval commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of Product in the Territory, including all such regulations promulgated by each applicable Regulatory Agency (including the FDA and applicable foreign or United States state equivalents), except where any instance of failure to comply with any such laws, rules or regulations could not, whether individually or taken together with any other such failures, reasonably be expected to result in a Material Adverse Change. Except as set forth on Schedule 4.20(b) of the Disclosure Letter, no Credit Party or its Subsidiaries has received any written notice from any Regulatory Agency citing action or inaction by any Credit Party or any of its Subsidiaries that would constitute a violation of any applicable foreign, federal, state or local laws, rules or regulations, including a Warning Letter or Untitled Letter from FDA.

4.21 Supply and Manufacturing

.

(a) Except as set forth on Schedule 4.21(a) of the Disclosure Letter, to the Knowledge of such Credit Party, Product at all times has been manufactured in sufficient quantities and of a sufficient quality to satisfy demand of Product in the Specified Territory, without the occurrence of any event or any series of related events causing inventory of Product to have become exhausted prior to satisfying such demand. To the Knowledge of such Credit Party, no event or circumstance (or series of related events or circumstances) has occurred that has caused or could reasonably be expected to cause inventory of Product to become exhausted in any calendar year prior to satisfying the sales demand (if any) of Product in the Specified Territory in such calendar year.

(b) Except as set forth on Schedule 4.21(b) of the Disclosure Letter, to the Knowledge of such Credit Party, no event or circumstance (or series of related events or circumstances) has occurred or, in the reasonable business judgment of Parent, is reasonably likely to occur, that would cause or could reasonably be expected to cause JELMYTO® not to be manufactured in any calendar year in sufficient quantities to satisfy or exceed the greater of (i) the net sales amount for such calendar year set forth in the JELMYTO® Revenue Forecast and (ii) the expected needs of patients with the disease or condition for which JELMYTO® was designated as an Orphan Drug for such calendar year, as reasonably determined by Responsible Officers of the Credit Parties in good faith (provided such calendar year occurs during the full 7-year term of orphan drug exclusive approval granted under 21 C.F.R. §316.34 ending April 15, 2027).

(c) Except as set forth on Schedule 4.21(c) of the Disclosure Letter, to the Knowledge of such Credit Party, (i) no manufacturer (including a contract manufacturer) or producer of Product has been or is currently subject to a Regulatory Agency shutdown, restriction or import or export prohibition, (ii) no manufacturer (including a contract manufacturer) or producer of Product has received in the past five (5) years or is currently subject to (1) a FDA Form 483 or (2) other written Regulatory Agency notice of inspectional observations, Warning Letter, Untitled Letter or request to make changes to Product that could reasonably be expected to impact Product, in either case of sub-clause (1) or (2) with respect to any material facility manufacturing or producing Product for import, distribution or sale in the Territory, and (iii) with respect to each such FDA Form 483 received or other written Regulatory Agency notice (if any), all scientific and technical violations or other issues relating to good manufacturing practice requirements documented therein, and any disputes regarding any such violations or issues, have been corrected or otherwise resolved.

(d) Except as disclosed in Schedule 4.21(d) of the Disclosure Letter, no Credit Party or any of its Subsidiaries has received any notice from any party to any Manufacturing Agreement containing any indication by or intent or threat in writing of, such party to reduce or cease, in any material respect, the supply of Product or the active pharmaceutical ingredient incorporated therein in the Territory or any other raw materials needed to fulfill its contractual obligations related to Product in any Manufacturing Agreement through calendar year 2027 (or such earlier date in accordance with the terms and conditions of such Manufacturing Agreement, as applicable).

4.22 Cybersecurity and Data Protection

.

(a) Except as set forth in Schedule 4.22(a) of the Disclosure Letter, the information technology systems used in the business of each of Parent and its Subsidiaries ("**Systems**") operate and perform in all material respects as required to permit each of Parent and its Subsidiaries to conduct their respective businesses as presently conducted in their respective Specified Territory.

(b) Except as set forth on Schedule 4.22(b) of the Disclosure Letter, Parent and each of its Subsidiaries has implemented and maintains a commercially reasonable privacy and information security program ("**Security Program**") that addresses privacy, physical and cyber security, disaster recovery, business continuity and incident response, and that includes reasonable and appropriate administrative, technical and physical safeguards that are designed to protect the integrity and availability of the Systems and to protect against (i) any unauthorized, accidental, or unlawful access to or acquisition,

use, disclosure, processing, loss, destruction, or modification of Personal Data that would require notification to affected individuals or any Governmental Authority under any applicable Data Protection Law (each, a "**Personal Data Breach**"), (ii) any unauthorized or unlawful access to or acquisition, use, disclosure, or loss of Sensitive Information that is not Personal Data, and (iii) material security incidents that would result in unauthorized or unlawful access to or acquisition, use, control, disruption, destruction, or modification of any of the Systems (each, a "**Security Incident**").

(c) Parent and each of its Subsidiaries has conducted commercially reasonable privacy and security audits and penetration tests at reasonable intervals on all Systems that maintain, store, or process Sensitive Information. Parent and each of its Subsidiaries has addressed all material privacy or data security issues identified as "critical," "high risk," or similar level of risk rating that are raised in any such audits or penetration tests (including any third party audits of the Systems).

(d) [Reserved]

(e) Except as set forth on Schedule 4.22(e) of the Disclosure Letter, and except as would not reasonably be expected to result in a Material Adverse Change, to the Knowledge of Parent neither Parent nor any of its Subsidiaries, has, in the past three (3) years, suffered any Security Incidents.

(f) Parent and each of its Subsidiaries is in material compliance with the requirements of (i) their respective Security Programs, (ii) applicable Data Protection Laws, (iii) their respective contractual obligations regarding the privacy, security, and notification of breaches of customer, consumer, patient, clinical trial participant, employee, and other Personal Data, (iv) their respective contractual non-disclosure obligations, and (v) their respective publicly available privacy notices and policies.

(g) Except as set forth on Schedule 4.22(g) of the Disclosure Letter, in the past six (6) years: (i) neither Parent nor any of its Subsidiaries has received any written third party claims or, to the Knowledge of Parent, any threat (in writing) of a third party claim, related to any Personal Data Breaches; and (ii) neither Parent nor any of its Subsidiaries has received any written notice of any claims, investigations (including investigations by any Governmental Authority), or alleged violations relating to any Personal Data Breaches.

(h) Parent and each of its Subsidiaries has maintained all database registrations required under applicable Data Protection Laws.

4.23 Additional Representations and Warranties

.

(a) After giving effect to consummation of the transactions contemplated by this Agreement, (i) there is no Indebtedness other than Permitted Indebtedness described in clauses (a) and (b) of the definition of Permitted Indebtedness, and (ii) all amounts due and owing by Parent under the Pre-Paid Forward Contract, if any, have been paid in full.

(b) There are no Hedging Agreements.

(c) Any and all payments required to be made to the Israeli Innovation Authority on account of any grants received by Parent or any of its Subsidiaries from the Israeli Innovation Authority for research and development funding or otherwise have been paid in full, and Parent and its Subsidiaries have full freedom to Transfer technology funded with any such grants and manufacture products developed with any such technology anywhere in the Territory.

5 AFFIRMATIVE COVENANTS

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), each Credit Party shall, and shall cause each of its Subsidiaries to:

5.1 Maintenance of Existence

. (a) Preserve, renew and maintain in full force and effect its and all its Subsidiaries' legal existence under the Requirements of Law in their respective jurisdictions of organization, incorporation or formation; (b) take all commercially reasonable action to maintain all rights, privileges (including its good standing), permits, licenses and franchises necessary or desirable for it and all of its Subsidiaries in the ordinary course of its business, except in the case of clause (a) (other than with respect to Parent or Borrower) and clause (b) above, (i) to the extent that failure to do so could not reasonably be expected to result in a Material Adverse Change or (ii) pursuant to a transaction permitted by this Agreement; and (c) comply with all Requirements of Law of any Governmental Authority to which it is subject, except where the failure to do so could not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change.

5.2 Financial Statements, Notices, Reports

. Deliver to the Collateral Agent:

(a) Financial Statements.

(i) Annual Financial Statements. As soon as available, but in any event within ninety (90) days after the end of each fiscal year of Parent (or such earlier date on which Parent is required to file a Form 10-K under the Exchange Act, as applicable), beginning with the fiscal year ending December 31, 2021, a consolidated balance sheet of Parent and its Subsidiaries as of the end of such fiscal year, and the related consolidated statements of income, cash flows and stockholders' equity for such fiscal year, all prepared in accordance with Applicable Accounting Standards, with such consolidated financial statements to be audited and accompanied by (i) a report and opinion of Parent's independent certified public accounting firm of recognized national standing (which report and opinion shall be prepared in accordance with Applicable Accounting Standards and shall not be subject to any qualification as to "going concern" or scope of audit), stating that such financial statements fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of the dates and for the periods specified in accordance with Applicable Accounting Standards, and (ii) if and only if Parent is required to comply with the internal control provisions pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 requiring an attestation report of such independent certified public accounting firm, an attestation report of such independent certified public accounting firm as to Parent's internal controls pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 attesting to management's assessment that such internal controls meet

the requirements of the Sarbanes-Oxley Act of 2002; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC);

(ii) Quarterly Financial Statements. As soon as available, but in any event within forty-five (45) days after the end of each of the first three (3) fiscal quarters of each fiscal year of Parent (or such earlier date on which Parent is required to file a Form 10-Q under the Exchange Act, if applicable), beginning with the fiscal quarter ending March 31, 2022, a consolidated balance sheet of Parent and its Subsidiaries as of the end of such fiscal quarter, and the related consolidated statements of income and cash flows and for such fiscal quarter and (in respect of the second and third fiscal quarters of such fiscal year) for the then-elapsed portion of Parent's fiscal year, all prepared in accordance with Applicable Accounting Standards, subject to normal year-end audit adjustments and the absence of disclosures normally made in footnotes; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC). Such consolidated financial statements shall be certified by a Responsible Officer of Parent as, to his or her knowledge, fairly presenting, in all material respects, the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of the dates and for the periods specified in accordance with Applicable Accounting Standards consistently applied, and on a basis consistent with the audited consolidated financial statements referred to under Section 5.2(a)(i), subject to normal year-end audit adjustments and the absence of footnotes; provided, however, that such certification by a Responsible Officer of Parent shall be deemed to have made if a similar certification is required under the Sarbanes-Oxley Act of 2002 and such certification shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC);

(iii) Quarterly Compliance Certificate. Upon delivery (or within five (5) Business Days following any deemed delivery) of financial statements pursuant to Section 5.2(a)(i) or Section 5.2(a)(ii), a duly completed Compliance Certificate signed by a Responsible Officer of Parent, certifying, among other things, that (A) such financial statements fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of the applicable dates and for the applicable periods in accordance with Applicable Accounting Standards consistently applied, and are not subject to any qualification as to "going concern" or scope of audit, and (B) no Event of Default or Default has occurred or, if such an Event of Default or Default has occurred, specifying the nature and extent thereof and any corrective action taken or proposed to be taken with respect thereto; and

(iv) Information During Event of Default. As promptly as practicable (and in any event within five (5) Business Days of the request therefor), such additional information regarding the business or financial affairs of Parent or any of its Subsidiaries, or compliance with the terms of this Agreement or any other Loan Documents, as the Collateral Agent may from time to time reasonably request during the existence of any Event of Default (subject to reasonable requirements of confidentiality, including requirements imposed by Requirements of Law or contract, in each case in a form reasonably acceptable to the Collateral Agent; provided that Borrower shall not be obligated to disclose any information that is reasonably subject to the assertion of attorney-client privilege or attorney work-product).

(b) Notice of Defaults or Events of Default, ERISA Events and Material Adverse Changes. Written notice as promptly as practicable (and in any event within five (5) Business Days) after a Responsible Officer of any Credit Party shall have obtained knowledge thereof, of the occurrence of any (i) Default or Event of Default, (ii) ERISA Event or (iii) Material Adverse Change.

(c) Legal Action Notice. Prompt written notice (which shall be deemed given to the extent timely reported in a Form 8-K under the Exchange Act and available on the SEC's EDGAR system (or any successor system adopted by the SEC)) of any legal action, litigation, investigation or proceeding pending or threatened in writing against Parent or any of its Subsidiaries (i) that could reasonably be expected to result in uninsured damages or costs to Parent or any of its Subsidiaries in an amount in excess of the materiality thresholds applied by Borrower in accordance with the Exchange Act and related regulations and standards for purposes of its Exchange Act reporting, or (ii) that alleges violations of any Health Care Laws, FDA Laws, Data Protection Laws or any other applicable statutes, rules, regulations, standards, guidelines, policies and order administered or issued by any U.S. or foreign Governmental Authority which, individually or together with any other such allegations, could reasonably be expected to result in a Material Adverse Change; and in each case of sub-clause (i) or (ii) above, provide such additional information (including a description in reasonable detail regarding any material development) as the Collateral Agent may reasonably request in relation thereto; provided that Borrower shall not be obligated to disclose any information that is reasonably subject to the assertion of attorney-client privilege or attorney work-product.

5.3 Taxes

. Timely file all U.S. federal, state, local and non-U.S. income and other material Tax returns required to be filed by any of them (or an extension has been obtained for the filing thereof) and pay all U.S. federal, state, local and non-U.S. Taxes before any penalty or fine accrue thereon; provided, however, that no such Tax or any claim for Taxes that have become due and payable shall be required to be paid if, in each case, (a) it is being contested in good faith by appropriate proceedings and with respect to which adequate reserves have been set aside on its books and maintained in conformity with Applicable Accounting Standards, or (b) to the extent that the failure to do so could not reasonably be expected to result in a Material Adverse Change.

5.4 Insurance

. Maintain with financially sound and reputable independent insurance companies or underwriters, insurance with respect to its properties and business against loss or damage of the kinds customarily insured against by Persons of comparable size engaged in the same or similar business, of such types and in such amounts (after giving effect to any self-insurance reasonable and customary for similarly situated Persons of comparable size engaged in the same or similar businesses as Parent and its Subsidiaries) as are customarily carried under similar circumstances by such other Persons. Subject to the timing requirements of Section 5.14 (solely with respect to any such policies in effect as of the Tranche A Closing Date), any products liability or general liability insurance maintained in the United States regarding Collateral shall name the Collateral Agent, on behalf of the Lenders and the other Secured Parties, as additional insured or loss payee, as applicable (the additional insured clauses or endorsements for which, in form and substance reasonably satisfactory to the Collateral Agent). So long as no Event of Default shall have occurred and be continuing, Parent and its Subsidiaries may retain all or any portion of the proceeds of any insurance of Parent and its Subsidiaries (and each Lender shall promptly remit to Borrower any proceeds received by it with respect to any such insurance).

5.5 Operating Accounts

. In the case of any Credit Party, promptly following the establishment of any new Collateral Account (but prior to the movement of any cash or other funds into such Collateral Account), at or with any bank or other depository or financial institution located in the United States, subject such account to a Control Agreement or other appropriate instrument that is reasonably acceptable to the Collateral Agent. For each Collateral Account that each Credit

Party at any time maintains in the United States, such Credit Party shall cause the applicable bank or other depository or financial institution located in the United States or Israel at or with which any Collateral Account is maintained to execute and deliver, and such Credit Party shall execute and deliver, to the Collateral Agent, a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect the Collateral Agent's Lien, for the benefit of Lenders and the other Secured Parties, in such Collateral Account in accordance with the terms hereunder, which Control Agreement may not be terminated without the prior written consent of the Collateral Agent. The provisions of the previous two (2) sentences shall not apply to (1) accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of any Credit Party's employees, (2) zero balance accounts, (3) accounts (including trust accounts) used exclusively for escrow, customs, insurance or fiduciary purposes, (4) merchant accounts, (5) accounts used exclusively for compliance with any Requirements of Law to the extent such Requirements of Law prohibit the granting of a Lien thereon, (6) accounts which constitute cash collateral in respect of a Permitted Lien and (7) any other accounts designated as an Excluded Account by a Responsible Officer of Borrower or Parent in writing delivered to the Collateral Agent, the cash balance of which such accounts do not exceed $5,000,000 in the aggregate at any time (all such accounts in sub-clauses (1) through (7) above, collectively, the "**Excluded Accounts**"). Notwithstanding the foregoing, the Credit Parties shall have until the date that is ninety (90) days (or such longer period as the Collateral Agent may agree in its sole discretion) following (i) the Tranche A Closing Date to comply with the provisions of this Section 5.5 with regards to Collateral Accounts (other than Excluded Accounts) of the Credit Parties in existence on the Tranche A Closing Date (or opened during such 90-day period (or such longer period as the Collateral Agent may agree in its sole discretion)) and (ii) the closing date of any Acquisition or other Investment to comply with the provisions of this Section 5.5 with regards to Collateral Accounts (other than Excluded Accounts) of the Credit Parties acquired in connection with such Acquisition or other Investment.

5.6 Compliance with Laws

. Comply in all respects with the Requirements of Law and all orders, writs, injunctions, decrees and judgments applicable to it or to its business or its assets or properties (including Environmental Laws, ERISA, Anti-Money Laundering Laws, OFAC, FCPA, Health Care Laws, FDA Laws, Data Protection Laws and the Federal Fair Labor Standards Act (and any foreign or United States state equivalents), including in connection with governing the research, development, testing, approval, post-approval monitoring, post-approval requirements, post-approval commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of Product in the Territory, except, in each case, if the failure to comply therewith could not, individually or taken together with any other such failures, reasonably be expected to result in a Material Adverse Change.

5.7 Protection of Intellectual Property Rights

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(a) Except as could not reasonably be expected to result in a Material Adverse Change or as expressly permitted under clause (b) below, use best efforts to: (i) protect, defend and maintain the validity and enforceability of the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory, including defending any future or current oppositions, interference proceedings, reissue proceedings, reexamination proceedings, *inter partes* review proceedings, derivation proceedings, post grant review proceedings, cancellation proceedings, injunctions, lawsuits, hearings, investigations, complaints, arbitrations, mediations, demands, International Trade Commission investigations, decrees, or any other disputes, disagreements, or claims, challenging the legality, validity, patentability, enforceability, inventorship or ownership of such Company IP; (ii) maintain the confidential nature of any trade secrets and trade secret rights which are used in the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory; and (iii) not allow any Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory to be abandoned, disclaimed, forfeited or dedicated to the public by Parent or any of its Subsidiaries (other than through the abandonment of Current Company IP in the exercise of the Borrower's normal prosecution practices and reasonable business judgment, e.g., the abandonment of a continuation application that is no longer needed to maintain the pendency of another patent application) or any Company IP Agreement to be terminated, as applicable, without the Collateral Agent's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed); provided, however, that with respect to any such Company IP that is not owned by Parent or any of its Subsidiaries, the obligations in clauses (i) and (iii) above shall apply only to the extent Parent or any of its Subsidiaries have the right to take such actions or to cause any licensee or other third party to take such actions pursuant to applicable agreements or contractual rights.

(b) (i) Except as Parent may otherwise determine in its reasonable business judgment, use all commercially reasonable efforts, either directly or indirectly, with respect to any licensee or licensor under the terms of any Credit Party's (or any of its Subsidiary's) agreement with the respective licensee or licensor, as applicable, to take commercially reasonable actions (including taking legal action to specifically enforce the applicable terms of any license agreement) and prepare, execute, deliver and file agreements, documents or instruments which are necessary to (A) prosecute and maintain the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory and (B) diligently defend or assert the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory against material infringement, misappropriation, violation or interference by any other Persons and, in the case of Copyrights, Trademarks and Patents within such material Company IP, against any claims of invalidity, unpatentability or unenforceability (including by bringing any legal action for infringement, dilution, violation, derivation or defending any counterclaim of invalidity or action of a non-Affiliate third party for declaratory judgment of non-infringement or non-interference); and (ii) use all commercially reasonable efforts to cause any licensee or licensor of any material Company IP not to, and such Credit Party shall not, disclaim, forfeit, dedicate to the public or abandon, or fail to take any action necessary to prevent the disclaimer, forfeiture or abandonment of such Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory (other than through the lapse, expiration or abandonment of Current Company IP in the exercise of the Borrower's normal prosecution practices and reasonable business judgment, *e.g.*, the abandonment of a continuation application that is no longer needed to maintain the pendency of another patent application), except clauses (i) and (ii) above shall apply only to the extent Parent or any of its Subsidiaries have the right to take such actions or to cause any licensor, licensee or other third party to take such actions pursuant to applicable agreements or contractual rights, and taking such actions would not otherwise breach, terminate or otherwise violate the terms of the applicable agreements.

(c) Save as contemplated by any Permitted License, use all commercially reasonable efforts to protect, defend and maintain market and data exclusivity for the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory through the Term Loan Maturity Date, and use all commercially reasonable efforts to not allow for the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of a bioequivalent version of Product in the Territory before the Term Loan Maturity Date, in each case if such bioequivalent version infringes or violates, or could reasonably be expected to infringe or violate, any of the rights of any Credit Party or its Subsidiary in or to any material Company IP, without the Collateral Agent's prior written consent. Parent agrees to (i) notify the Collateral Agent in writing of, and (ii) keep the Collateral Agent reasonably informed regarding, and (iii) at the reasonable request of the Collateral Agent in writing, consult with and consider in good faith any comments of the Collateral Agent regarding, the commencement of and any material filings in any opposition, interference proceeding, reissue proceeding, reexamination proceeding, *inter partes* review proceeding, post-grant

review proceeding, derivation proceeding, cancellation proceeding, injunction, lawsuit, hearing, investigation, complaint, arbitration, mediation, demand, International Trade Commission investigation, decree, or any other dispute, disagreement, or claim, in each case challenging the legality, validity, patentability, enforceability, inventorship or ownership of any material Company IP (including any claim in any Patent within the Company IP that is material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory).

(d) Provide written notice to the Collateral Agent within thirty (30) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Each Credit Party shall take such commercially reasonable steps as the Collateral Agent reasonably requests to obtain the consent of, or waiver by, any Person whose consent or waiver is necessary for (i) any Restricted License to, without giving effect to Section 9-408 of the Code, be deemed "Collateral" and for the Collateral Agent to have a security interest in it that might otherwise be restricted or prohibited by Requirements of Law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (ii) the Collateral Agent to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with the Collateral Agent's rights and remedies under this Agreement and the other Loan Documents.

5.8 Books and Records

. Maintain proper Books, in which entries that are full, true and correct in all material respects and are in conformity with Applicable Accounting Standards consistently applied shall be made of all material financial transactions and matters involving the assets, properties and business of such Credit Party (or such Subsidiary).

5.9 Access to Collateral; Audits

. Allow the Collateral Agent, or its agents or representatives, at any time after the occurrence and during the continuance of an Event of Default, during normal business hours and upon reasonable advance notice, to visit and inspect any of the Collateral or to inspect and copy and (at the sole discretion of the Collateral Agent) audit any Credit Party's Books. The foregoing inspections and audits, if any, shall be at the relevant Credit Party's expense.

5.10 Use of Proceeds

. (a) Use the proceeds of the Term Loans solely to fund its general corporate and working capital requirements; and (b) not use the proceeds of the Term Loans, directly or indirectly, for the purpose of purchasing or carrying any Margin Stock, for the purpose of reducing or retiring any Indebtedness that was originally incurred to purchase or carry any Margin Stock, for the purpose of extending credit to any other Person for the purpose of purchasing or carrying any Margin Stock or for any other purpose that might cause any Term Loan to be considered a "purpose credit" within the meaning of Regulation T, U or X of the Federal Reserve Board. If requested by the Collateral Agent, Borrower shall complete and sign Part I of a copy of Federal Reserve Form G-3 referred to in Regulation U and deliver such copy to the Collateral Agent.

5.11 Further Assurances

. Subject to the limitations in Section 5.12(d), promptly upon the reasonable written request of the Collateral Agent, execute, acknowledge and deliver such further documents and do such other acts and things in order to effectuate or carry out more effectively the purposes of this Agreement and the other Loan Documents at its expense, including after the Tranche A Closing Date taking such steps as are reasonably deemed necessary or desirable by the Collateral Agent to maintain, protect and enforce its Lien, for the benefit of Lenders and the other Secured Parties, on Collateral securing the Obligations created under the Collateral Documents and the other Loan Documents in accordance with the terms of the Collateral Documents and the other Loan Documents, subject to Permitted Liens.

5.12 Additional Collateral; Guarantors

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(a) From and after the Tranche A Closing Date, except as otherwise approved in writing by the Collateral Agent, each Credit Party (other than Borrower) shall, and each Credit Party shall cause each of its Subsidiaries (other than Excluded Subsidiaries), and Parent may at its election cause any Excluded Subsidiaries (and the Collateral Agent and Lenders shall cooperate with any such election) to guarantee the Obligations (and to execute and deliver to the Collateral Agent a joinder to the Security Agreement (in the form attached thereto)), and each Credit Party (other than Borrower) shall, and each Credit Party shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of such Credit Party's or Subsidiary's properties and assets constituting Collateral, whether now existing or hereafter acquired or existing (including in connection with an Asset Acquisition), to secure such guaranty (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the form(s) attached thereto), as applicable); provided, that such Credit Party's obligations to take the foregoing actions with respect to any assets acquired as part of an Asset Acquisition and to cause any Subsidiaries incorporated, organized, formed or acquired (including by Stock Acquisition) after the Tranche A Closing Date, including all such Subsidiary's properties and assets (including in connection with an Asset Acquisition), to take the foregoing actions shall, in each case, be subject to the timing requirements of Section 5.13 or Section 5.14, as applicable. Additionally, from and after the Tranche A Closing Date, each Credit Party shall, and shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens, the limitations set forth herein and the limitations set forth in the other Loan Documents), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of such Credit Party's or Subsidiary's properties and assets constituting Collateral, whether now existing or hereafter acquired or existing (including in connection with an Asset Acquisition), to secure the payment and performance in full of all of the Obligations (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the form(s) attached thereto), as applicable); provided, that such Credit Party's obligations to take the foregoing actions with respect to any assets acquired as part of an Asset Acquisition and to cause any Subsidiaries incorporated, organized, formed or acquired (including by Stock Acquisition) after the Tranche A Closing Date, including all such Subsidiary's properties and assets (including in connection with an Asset Acquisition), to take the foregoing actions shall, in each case, be subject to the timing requirements of Section 5.13 or Section 5.14, as applicable. Furthermore, except as otherwise approved in writing by the Collateral Agent, from and after the Tranche A Closing Date, each Credit Party shall, and shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to, grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon (subject to Permitted Liens, the limitations set forth herein and the limitations set forth in the other Loan Documents), and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, all of the Equity Interests (other than Excluded Equity Interests) in each of its Subsidiaries (other than Excluded Subsidiaries) (and to execute and deliver to the Collateral Agent a joinder or pledge amendment to the Security Agreement (in the

form(s) attached thereto), as applicable). In connection with each pledge of certificated Equity Interests required under the Loan Documents, the Credit Parties shall deliver, or cause to be delivered, to the Collateral Agent, in addition to a pledge amendment to the Security Agreement (in the form attached thereto), such certificate(s) together with stock powers or assignments, as applicable, properly endorsed for transfer to the Collateral Agent or duly executed in blank, in each case reasonably satisfactory to the Collateral Agent. In connection with each pledge of uncertificated Equity Interests required under the Loan Documents, the Credit Parties shall deliver, or cause to be delivered, to the Collateral Agent, in addition to a pledge amendment to the Security Agreement (in the form attached thereto), an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent, substantially in the form attached to the Security Agreement.

(b) In the event any Credit Party acquires any fee title to real estate in the U.S. with a fair market value (reasonably determined in good faith by a Responsible Officer of such Credit Party) in excess of $5,000,000, unless otherwise agreed by the Collateral Agent, such Person shall execute or deliver, or cause to be executed or delivered, to the Collateral Agent, (i) within sixty (60) days after such acquisition, an appraisal complying with the Financial Institutions Reform, Recovery and Enforcement Act of 1989, (ii) within forty-five (45) days after receipt of notice from the Collateral Agent that such real estate is located in a Special Flood Hazard Area, Federal Flood Insurance, (iii) within sixty (60) days after such acquisition, a fully executed Mortgage, in form and substance reasonably satisfactory to the Collateral Agent, together with an A.L.T.A. lender's title insurance policy issued by a title insurer reasonably satisfactory to the Collateral Agent, in form and substance (including any endorsements) and in an amount reasonably satisfactory to the Collateral Agent insuring that the Mortgage is a valid and enforceable first priority Lien on the respective property, free and clear of all defects, encumbrances and Liens (other than Permitted Liens), (iv) simultaneously with such acquisition, then-current A.L.T.A. surveys, certified to the Collateral Agent by a licensed surveyor sufficient to allow the issuer of the lender's title insurance policy to issue such policy without a survey exception and (v) within sixty (60) days after such acquisition, an environmental site assessment prepared by a qualified firm reasonably acceptable to the Collateral Agent, in form and substance reasonably satisfactory to the Collateral Agent.

(c) If any Credit Party becomes (or any New Subsidiary is) a Registered Organization, Borrower or such Credit Party shall (or shall cause such New Subsidiary to) promptly notify the Collateral Agent of such occurrence and provide the Collateral Agent with such Credit Party's (or New Subsidiary's) organizational identification number.

(d) If, as a result of a change in law including any change to a provision of the IRC or future guidance from the IRS or United States Department of Treasury, either: (i) a Credit Party's pledge of the stock of a Foreign Subsidiary or Foreign Subsidiary Holdco or (ii) a Foreign Subsidiary (in the event Borrower elected pursuant to Section 5.12(a) to cause such Foreign Subsidiary to be a Guarantor hereunder) or Foreign Subsidiary Holdco being a Guarantor hereunder would reasonably be expected to result in an income inclusion for any Credit Party under Section 956 of the IRC (or a successor or similar provision), or the United States Treasury Regulations promulgated thereunder which causes a material adverse tax consequence for a Credit Party, the parties hereto shall cooperate in good faith to amend this Agreement, the Security Agreement and any other applicable Loan Document to eliminate (or, if it is not possible to eliminate, mitigate) such material adverse tax consequence for such Credit Party. Further, if any Credit Party or any of its Subsidiaries at any time after the Tranche A Closing Date forms or acquires a Foreign Subsidiary or Foreign Subsidiary Holdco, the parties hereto shall cooperate in good faith to determine if either (x) a Credit Party's pledge of the stock of such Foreign Subsidiary or Foreign Subsidiary Holdco or (y) such Foreign Subsidiary Holdco being a Guarantor hereunder would result in an income inclusion for any Credit Party under Section 956 of the IRC (or a successor or similar provision), or the United States Treasury Regulations promulgated thereunder which causes a material adverse tax consequence for a Credit Party. If such material adverse tax consequence for a Credit Party exists, the parties hereto shall cooperate in good faith to structure such pledge or guarantee in a manner that eliminates (or, if it is not possible to eliminate, mitigates to the point that it is not material) such material adverse tax consequence for such Credit Party. If it is not possible to eliminate (or mitigate) the material adverse tax consequence, then, as applicable, and solely if, at each instance, such pledge or guaranty, as applicable, is the cause of such material adverse tax consequence (A) a pledge of up to sixty-five percent (65.0%) of the issued and outstanding voting Equity Interests and one hundred percent (100%) the issued and outstanding non-voting Equity Interests of the Foreign Subsidiary or Foreign Subsidiary Holdco directly owned by a Credit Party shall be permitted and (B) a guarantee by a Foreign Subsidiary Holdco will not be required.

(e) Notwithstanding anything to the contrary herein, in no event shall any Credit Party or any Subsidiary be required to enter into or deliver any foreign law-governed documents, file or record any documents or agreements (including any agreements relating to Intellectual Property) with any foreign Governmental Authority or take any other actions under foreign law with respect to Collateral held in any jurisdiction other than the United States, Israel or the jurisdiction of such Credit Party or Subsidiary, or, solely upon the occurrence and during the continuance of an Event of Default and by written notice to the Credit Parties, as the Collateral Agent may in its sole discretion otherwise require.

5.13 Formation or Acquisition of Subsidiaries

. If any Credit Party or any of its Subsidiaries at any time after the Tranche A Closing Date incorporates, organizes, forms or acquires (including by a Stock Acquisition) a Subsidiary (including by division) other than an Excluded Subsidiary (a "**New Subsidiary**") or if any Credit Party makes an Asset Acquisition (other than an Asset Acquisition in the ordinary course of business), as promptly as practicable but in no event later than thirty (30) days after such incorporation, organization, formation or acquisition or Asset Acquisition: (a) without limiting the generality of clause (c) below, such Credit Party will cause such New Subsidiary or Credit Party, as applicable, to the extent required or applicable to execute and deliver to the Collateral Agent a joinder to the Security Agreement (in the form attached thereto) and any relevant IP Agreement or other Collateral Documents, as applicable; (b) such Credit Party will deliver (or cause to be delivered) to the Collateral Agent (i) true, correct and complete copies of the Operating Documents of such New Subsidiary, (ii) a Secretary's Certificate, certifying that the copies of the Operating Documents of such New Subsidiary are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent) and (iii) a good standing certificate for such New Subsidiary certified by the Secretary of State (or the equivalent thereof) of its jurisdiction of organization, incorporation or formation (where applicable in the subject jurisdiction); and (c) such Credit Party will cause such New Subsidiary to satisfy all requirements contained in this Agreement (including Section 5.12) and each other Loan Document if and to the extent applicable to such New Subsidiary. The parties hereto agree that any New Subsidiary shall constitute a Credit Party for all purposes hereunder as of the date of the execution and delivery of any joinder contemplated by clause (a) above or the date such New Subsidiary provides any guarantee of the Obligations as contemplated by Section 5.12. Any document, agreement or instrument executed or issued pursuant to this Section 5.13 shall be a Loan Document.

5.14 Post-Closing Requirements

. Parent will, and will cause each of its Subsidiaries, as applicable, to take each of the actions set forth on Schedule 5.14 of the Disclosure Letter within the time period prescribed therefor on such schedule (or such longer period as the Collateral Agent may agree in its sole discretion), which shall include, among other things, that: (a) notwithstanding anything to the contrary in Section 3.1(g) or Section 5.4, the Credit Parties shall have until the date that is thirty (30) days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to comply with the provisions of Section 5.4 with regards to naming the Collateral Agent, on behalf of the Lenders and the other Secured Parties, as additional insured or loss payee, on any products liability or general liability insurance in the United States regarding Collateral in effect on the Tranche A Closing Date; (b) notwithstanding anything to the contrary in Section 5.5, the Credit Parties shall have until the date that is ninety (90) days following the Tranche A Closing

Date (or such longer period as the Collateral Agent may agree in its sole discretion) to comply with the provisions of Section 5.5 with regards to Collateral Accounts of the Credit Parties in existence on the Tranche A Closing Date or opened during such 90-day period; (c) notwithstanding anything to the contrary in Section 6.2(b), the Credit Parties shall have until the date that is thirty (30) days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to comply with the provisions of Section 6.2(b)(ii) with regards to the location of the primary Books of any Credit Party or any of its Subsidiaries or the location of any material portion of the Collateral on the Tranche A Closing Date or during such 30-day period; and (d) notwithstanding anything to the contrary in Section 3.1(j), the Credit Parties shall have until the date that is 21 days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to deliver (x) a copy of the amendment to the Security Agreement/Debenture Unlimited in Amount, dated April 4, 2021, between Parent and RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2), acknowledging the creation of a first priority security interest in and Lien upon the Collateral in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties and providing that such security interest and Lien is senior in priority to any and all security interests and Liens in favor of RTW Investments ICAV thereunder, and (y) evidence of the filing of such amended Security Agreement/Debenture Unlimited in Amount with the Israeli Registrar of Companies (such evidence to be in form and substance reasonably satisfactory to the Collateral Agent). All representations and warranties and covenants contained in this Agreement and the other Loan Documents shall be deemed modified to the extent necessary to take the actions set forth on Schedule 5.14 of the Disclosure Letter within the time periods set forth therein, rather than elsewhere provided in the Loan Documents, such that to the extent any such action set forth in Schedule 5.14 of the Disclosure Letter is not overdue, the applicable Credit Party shall not be in breach of any representation or warranty or covenant contained in this Agreement or any other Loan Document applicable to such action for the period from the Tranche A Closing Date until the date on which such action is required to be fulfilled as set forth on Schedule 5.14 of the Disclosure Letter.

5.15 Environmental

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(a) Deliver to the Collateral Agent:

(i) as soon as practicable following receipt thereof, copies of all environmental audits, investigations, analyses and reports of any kind or character, whether prepared by personnel of Parent or any of its Subsidiaries or by independent consultants, governmental authorities or any other Persons, with respect to significant environmental matters at any Facility or with respect to any material Environmental Claims;

(ii) promptly upon a Responsible Officer of any Credit Party or any of its Subsidiaries obtaining knowledge of the occurrence thereof, written notice describing in reasonable detail (A) any Release required to be reported to any federal, state, local or foreign governmental or regulatory agency under any applicable Environmental Laws, (B) any remedial action taken by any Credit Party or any other Person in response to (x) any Hazardous Materials Activities, the existence of which, individually or in the aggregate, could reasonably be expected to result in one or more Environmental Claims resulting in a Material Adverse Change, or (y) any Environmental Claims that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, and (C) any Credit Party's discovery of any occurrence or condition on any real property adjoining or in the vicinity of any Facility that could cause such Facility or any part thereof to be subject to any material restrictions on the ownership, occupancy, transferability or use thereof under any Environmental Laws, provided, that with respect to real property adjoining or in the vicinity of any Facility, Borrower shall have no duty to affirmatively investigate or make any efforts to become or stay informed regarding any such adjoining or nearby properties;

(iii) as soon as practicable following the sending or receipt thereof by any Credit Party, a copy of any and all written communications with respect to (A) any Environmental Claims that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, (B) any Release required to be reported to any federal, state, local or foreign governmental or regulatory agency, and (C) any request for information from any Governmental Authority that suggests such Governmental Authority is investigating whether any Credit Party or any of its Subsidiaries may be potentially responsible for any Hazardous Materials Activity that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change;

(iv) prompt written notice describing in reasonable detail (A) any proposed acquisition of stock, assets, or property by Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to (x) expose Parent or any of its Subsidiaries to, or result in, Environmental Claims that could reasonably be expected to result in a Material Adverse Change or (y) affect the ability of Parent or any of its Subsidiaries to maintain in full force and effect all material Governmental Approvals required under any Environmental Laws for their respective operations and (B) any proposed action to be taken by Parent or any of its Subsidiaries to modify current operations in a manner that, individually or taken together with any other such proposed actions, could reasonably be expected to subject Parent or any of its Subsidiaries to any additional material obligations or requirements under any Environmental Laws; and

(v) with reasonable promptness, such other documents and information as from time to time may be reasonably requested by the Collateral Agent in relation to any matters disclosed pursuant to this Section 5.15(a).

(b) Each Credit Party shall, and shall cause each of its Subsidiaries to, promptly take any and all actions reasonably necessary to (i) cure any violation of applicable Environmental Laws by Parent or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, and (ii) make an appropriate response to any Environmental Claim against Parent or any of its Subsidiaries and discharge any obligations it may have to any Person thereunder where failure to do so, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change.

5.16 Inventory; Returns; Maintenance of Properties

. Keep all Inventory which constitutes Product in good and marketable condition, free from material defects and otherwise keep all Inventory which constitutes Product in material compliance with all applicable FDA Laws (including, for the avoidance of doubt, all foreign or United States state equivalents), as applicable. Returns and allowances between a Credit Party and its Account Debtors shall follow such Credit Party's customary practices. Each Credit Party will, and will cause each of its Subsidiaries to, maintain or cause to be maintained in good repair, working order and condition, ordinary wear and tear, casualty and condemnation excepted, all material tangible properties used or useful in its respective business, and from time to time will make or cause to be made all commercially reasonable repairs, renewals and replacements thereof except where failure to do so could not reasonably be expected to result in a Material Adverse Change.

5.17 Regulatory Obligations; Maintenance of FDA Approval; Manufacturing, Marketing and Distribution

- . (a)(i) Comply in all material respects with FDA post-approval requirements (and applicable foreign or United States state equivalents) for Product in the Territory, (ii) maintain all Regulatory Approvals required or otherwise material to manufacture, market and distribute Product in the Territory, (iii) with respect to each calendar year commencing with calendar year 2022, maintain manufacturing capacity to sell JELMYTO® in the Territory in sufficient quantities to satisfy or exceed either (x) the net sales amount for such calendar year set forth in the JELMYTO® Revenue Forecast or (y) the expected needs of patients with the disease or condition for which JELMYTO® was designated as an Orphan Drug for such calendar year, as reasonably determined by Responsible Officers of the Credit Parties in good faith; unless, however, that, with respect to any such calendar year, if the net sales amount for such calendar year set forth in the JELMYTO® Revenue Forecast would not be sufficient to meet reasonably anticipated demand for such calendar year, in which case, maintain manufacturing capacity to sell JELMYTO® in the Territory in sufficient quantities to satisfy or exceed the needs of patients with the disease or condition for which JELMYTO® was designated as an Orphan Drug for such calendar year.

(b) Deliver to the Collateral Agent, as promptly as practicable after a Responsible Officer of any Credit Party shall have obtained knowledge thereof, written notice describing in reasonable detail any instance where the Credit Party or any of its Subsidiaries has a reasonable expectation that there are grounds for imposition of a clinical hold, as described in 21 C.F.R. § 312.42.

5.18 Collateral Documents

. Comply in all respects with all of its covenants, agreements, undertakings and obligations arising under each Collateral Document to which it is a party.

6 NEGATIVE COVENANTS

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), such Credit Party shall not, and shall cause each of its Subsidiaries not to:

6.1 Dispositions

. Convey, sell, lease, transfer, exchange, assign, covenant not to sue, enter into a coexistence agreement, exclusively or nonexclusively license out, or otherwise dispose of (including any sale-leaseback or any transfer of assets pursuant to a plan of division), directly or indirectly and whether in one or a series of transactions (collectively, "**Transfer**"), all or any part of its properties or assets constituting Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party) or any Company IP that does not constitute Collateral under the Loan Documents but is related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory; except, in each case of this Section 6.1, for Permitted Transfers not otherwise expressly prohibited under Section 6.6(b).

6.2 Fundamental Changes; Location of Collateral

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(a) Without at least ten (10) days prior written notice to the Collateral Agent, solely in the case of a Credit Party: (i) change its jurisdiction of organization, incorporation or formation, (ii) change its organizational structure or type, (iii) change its legal name, or (iv) change any organizational number (if any) assigned by its jurisdiction of organization, incorporation or formation.

(b) Maintain its primary Books at or deliver any Collateral with a fair market value (reasonably determined in good faith by a Responsible Officer of Borrower), individually or together with any other Collateral, in excess of $1,000,000 to, one or more mortgaged or leased locations or one or more warehouses, processors or bailees, as applicable, unless, subject to the timing requirements of Section 5.14 (solely with respect to such locations, warehouses, processors or bailees where such Books or Collateral is located on the Tranche A Closing Date or during the 60-day period following the Tranche A Closing Date), such Credit Party uses commercially reasonable efforts to deliver to the Collateral Agent a Collateral Access Agreement for such mortgaged or leased location or such warehouse, processor or bailee governing such Books or such Collateral (as applicable) and the location at which such Books are maintained or to which such Collateral has been delivered (as applicable), in each case in form and substance reasonably satisfactory to the Collateral Agent, as promptly as practicable (and in no event later than sixty (60) days after) such Books are maintained or such Collateral is delivered to such mortgaged or leased location or warehouse, processor or bailee (as applicable). Notwithstanding anything to the contrary herein, such obligation to deliver Collateral Access Agreements will not apply to any inventory or assets while in transit.

6.3 Mergers, Acquisitions, Liquidations or Dissolutions

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(a) Merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve, or permit any of its Subsidiaries to merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve with or into any other Person, except that:

(i) any Subsidiary of Parent may merge or consolidate with or into a Credit Party, provided that the Credit Party is the surviving entity,

(ii) any Subsidiary of Parent may merge or consolidate with any other Subsidiary of Parent, provided that if any party to such merger or consolidation is a Credit Party then either (x) such Credit Party is the surviving entity or (y) the surviving or resulting entity executes and delivers to the Collateral Agent a joinder to the Security Agreement in the form attached thereto and any relevant IP Agreement or other Collateral Documents, as applicable, and otherwise satisfies the requirements of Section 5.13 substantially contemporaneously with completion of such merger or consolidation;

(iii) any Subsidiary of Parent may divide itself into two (2) or more entities or be dissolved or liquidated, provided that if such Subsidiary is a Credit Party, the properties and assets of such Subsidiary are allocated or distributed to an existing or newly-formed Credit Party; and

(iv) any Permitted Acquisition or Permitted Investment may be structured as a merger or consolidation.

(b) make, or permit any of its Subsidiaries to make, Acquisitions outside the ordinary course of business, including any purchase of the assets of any division or line of business of any other Person, other than Permitted Acquisitions or Permitted Investments. For the avoidance of doubt, nothing herein shall prohibit any Credit Party or its Subsidiaries from entering into in-licensing agreements; provided that, in each case, no Indebtedness not otherwise permitted hereunder is incurred or assumed in connection therewith.

6.4 Indebtedness

. Directly or indirectly, create, incur, assume or guaranty, or otherwise become or remain directly or indirectly liable with respect to, any Indebtedness (including any Indebtedness consisting of obligations evidenced by a bond, debenture, note or other similar instrument) that is not Permitted Indebtedness; provided, however, that the accrual of interest, the accretion of accreted value and the payment of interest in the form of additional Indebtedness shall not be deemed to be an incurrence of Indebtedness for purposes of this Section 6.4.

6.5 Encumbrances

. Except for Permitted Liens, (i) create, incur, allow, or suffer to exist any Lien on any Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party), or (ii) permit (other than pursuant to the terms of the Loan Documents) any material portion of the Collateral (including, for the avoidance of doubt, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party) not to be subject to the first priority security interest granted in the Loan Documents or otherwise pursuant to the Collateral Documents, in each case of this clause (ii), other than as a direct result of any action by the Collateral Agent or any Lender or failure of the Collateral Agent or any Lender to perform an obligation thereof under the Loan Documents.

6.6 No Further Negative Pledges; Negative Pledge

.

(a) No Credit Party nor any of its Subsidiaries shall enter into any agreement, document or instrument directly or indirectly prohibiting (or having the effect of prohibiting) or limiting the ability of such Credit Party or Subsidiary to create, incur, assume or suffer to exist any Lien upon any Collateral, whether now owned or hereafter acquired, in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, with respect to the Obligations or under the Loan Documents, in each case of this Section 6.6, other than Permitted Negative Pledges.

(b) Notwithstanding Section 6.1, no Credit Party will Transfer, or create, incur, allow or suffer to exist any Lien on, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party, except for: (i) Permitted Liens; (ii) transfers between or among Credit Parties, provided that any and all steps as may be reasonably required to be taken in order to create and maintain a first priority security interest in and Lien upon such Equity Interests in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, are taken contemporaneously with the completion of any such transfer; and (iii) sales, assignments, transfers, exchanges or other dispositions to qualify directors if required by Requirements of Law or otherwise permitted under this Agreement, provided that such sale, assignment, transfer, exchange or other disposition shall be for the minimum number of Equity Interests as are necessary for such qualification under Requirements of Law.

6.7 Maintenance of Collateral Accounts

. Maintain any Collateral Account except in accordance with the terms of Section 5.5 hereof.

6.8 Distributions; Investments

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(a) Pay any dividends or make any distribution or payment on, or redeem, retire or repurchase any of its Equity Interests, except, in each case of this Section 6.8, for Permitted Distributions, Permitted Transactions and Permitted Equity Derivatives.

(b) Directly or indirectly make any Investment other than Permitted Acquisitions and Permitted Investments.

For the avoidance of doubt, nothing in this Section 6.8 shall prohibit any Credit Party or its Subsidiaries from entering into in-licensing agreements; provided, however, that, in each case, no Indebtedness that is not Permitted Indebtedness is incurred or assumed in connection therewith.

6.9 No Restrictions on Subsidiary Distributions

. No Credit Party nor any of its Subsidiaries shall enter into any agreement, document or instrument directly or indirectly prohibiting (or having the effect of prohibiting) or limiting the ability of any Subsidiary of Parent to (a) pay dividends or make any other distributions on any of such Subsidiary's Equity Interests owned by Parent or any other Subsidiary of Parent, (b) repay or prepay any Indebtedness owed by such Subsidiary to Parent or any other Subsidiary of Parent, (c) make loans or advances to Borrower or any other Subsidiary of Parent, or (d) transfer, lease or license any Collateral to Borrower or any other Subsidiary of Parent, except, in each case of this Section 6.9, for Permitted Subsidiary Distribution Restrictions.

6.10 Subordinated Debt; Permitted Convertible Indebtedness

. Notwithstanding anything to the contrary in this Agreement:

(a) Make or permit any voluntary or optional prepayment or repayment of the outstanding principal amount of any Subordinated Debt other than in accordance with the express terms of a subordination, intercreditor or other similar agreement relating to such Subordinated Debt, if any, that is in form and substance reasonably satisfactory to the Collateral Agent;

(b) Make or permit any payment of interest (including accrued and unpaid interest) in cash on or in respect of any Subordinated Debt at any time that a Default or Event of Default shall have occurred and be continuing other than in accordance with the express terms of a subordination, intercreditor or other similar agreement relating to such Subordinated Debt, if any, that is in form and substance reasonably satisfactory to the Collateral Agent; or

(c) Amend, restate, supplement or otherwise modify any terms, conditions or other provisions of any Subordinated Debt, or any agreement, instrument or other document relating thereto, in any manner which would contravene in any respect any of the foregoing or adversely affect the payment or priority subordination thereof (as applicable) to Obligations owed to Lenders, in each case except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt, if any, is subject, without the prior written consent of the Collateral Agent (in its sole discretion).

(d) For the avoidance of doubt, no Credit Party shall, and shall cause each of its Subsidiaries not to, directly or indirectly, create, incur, assume or guaranty, or otherwise become directly or indirectly liable with respect to, any Subordinated Debt except as otherwise expressly permitted hereunder.

(e) Make or permit any voluntary or optional prepayment or repayment of the outstanding amount of any Indebtedness under the Pre-Paid Forward Contract or other PPFC Documents (including any principal or interest), or amend, restate, supplement or otherwise modify any terms, conditions or other provisions of such Indebtedness or the Pre-Paid Forward Contract or other PPFC Documents in any manner which would contravene in any respect any of the foregoing or adversely affect the payment or priority subordination thereof (as applicable) to Obligations owed to Lenders, in each case other than in accordance with the express terms of the RTW Intercreditor Agreement.

(f) No Credit Party shall, and shall cause each of its Subsidiaries not to, directly or indirectly, make (or exercise any option with respect thereto) any payment, prepayment, repurchase or redemption for cash of any Permitted Convertible Indebtedness unless and until all of the Obligations are paid in full, other than to the extent made solely with the proceeds of any issuance of Equity Interests or Permitted Convertible Indebtedness, provided, that nothing in this Section 6.10(e) shall prohibit or otherwise restrict (v) scheduled cash interest payments, (w) required cash payments of accrued but unpaid interest upon repurchase or redemption thereof, (x) cash payments in lieu of any fractional share issuable upon conversion thereof, (y) required cash payments of any amounts due upon the scheduled maturity thereof or (z) any ordinary course fees or other expenses in connection therewith.

6.11 Amendments or Waivers of Organizational Documents

. Amend, restate, supplement or otherwise modify, or waive, any provision of its Operating Documents in a manner that would reasonably be expected to result in a Material Adverse Change.

6.12 Compliance

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(a) Become an "investment company" under the Investment Company Act of 1940, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose;

(b) No ERISA Affiliate shall cause or suffer to exist (i) any event that would result in the imposition of a Lien on any assets or properties of any Credit Party or a Subsidiary of a Credit Party with respect to any Plan or Multiemployer Plan or (ii) any other ERISA Event that, in the case of clauses (i) and (ii), could reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change; or

(c) Permit the occurrence of any other event with respect to any present pension, profit sharing or deferred compensation plan which could reasonably be expected to result in a Material Adverse Change.

6.13 Compliance with Sanctions and Anti-Money Laundering Laws

. The Collateral Agent and each Lender hereby notifies each Credit Party that pursuant to the requirements of Sanctions and Anti-Money Laundering Laws, and such Person's policies and practices, the Collateral Agent and each Lender is required to obtain, verify and record certain information and documentation that identifies each Credit Party and its principals, which information includes the name and address of each Credit Party and its principals and such other information that will allow the Collateral Agent and each Lender to identify such party in accordance with Sanctions and Anti-Money Laundering Laws. No Credit Party will, nor will any Credit Party permit any of its Subsidiaries or controlled Affiliates to, directly or indirectly, knowingly enter into any documents or contracts with any Sanctioned Person to the extent such action is prohibited under Sanctions or Anti-Money Laundering Laws. Each Credit Party shall notify the Collateral Agent and each Lender in writing promptly (but in any event within five (5) Business Days after) a Responsible Officer of any Credit Party becomes aware that any Credit Party or any Subsidiary or Affiliate of any Credit Party is a Sanctioned Person or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. No Credit Party will, nor will any Credit Party permit any of its Subsidiaries or Affiliates to, directly or indirectly, (i) conduct any prohibited business or engage in any prohibited transaction or deal with any Sanctioned Person, including the making or receiving of any contribution of funds, goods or services to or for the benefit of any Sanctioned Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Sanctions, or (iii) engage in or conspire to engage in any transaction that evades or avoids or violates, or has the purpose of evading or avoiding, or attempts to violate, any of prohibitions under applicable Sanctions or Anti-Money Laundering Laws.

6.14 Amendments or Waivers of Company IP Agreements

. (a) Waive, amend, cancel or terminate, exercise or fail to exercise, any material rights constituting or relating to any of the Company IP Agreements or (b) breach, default under, or take any action or fail to take any action that, with the passage of time or the giving of notice or both, would constitute a default or event of default under any of the Company IP Agreements, in each case of this Section 6.14, which, individually or taken together with any other such waivers, amendments, cancellations, terminations, exercises or failures, could reasonably be expected to materially and adversely impact the ability to develop, commercialize or exploit JELMYTO® in the Specified Territory or any Credit Party's or Subsidiary's rights in respect of JELMYTO®.

7 EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

7.1 Payment Default

. Any Credit Party fails to (a) make any payment of any principal of the Term Loans when and as the same shall become due and payable, whether at the due date thereof (including pursuant to Section 2.2(c)) or at a date fixed for prepayment (whether voluntary or mandatory) thereof or by acceleration thereof or otherwise, or (b) within five (5) Business Days after the same becomes due and payable, any payment of interest or premium pursuant to Section 2.2, including any applicable Additional Consideration, Makewhole Amount or Prepayment Premium, or any other Obligations (which such five (5) Business Day cure period shall not apply to any such payments due on the Term Loan Maturity Date or such earlier date pursuant to Section 2.2(c)(ii) or Section 2.2(c)(iii) hereof or the date of acceleration pursuant to Section 8.1(a) hereof). A failure to pay any such interest, premium or Obligations pursuant to the foregoing clause (b) prior to the end of such five (5) Business Day-period shall not constitute an Event of Default (unless such payment is due on the Term Loan Maturity Date or such earlier date pursuant to Section 2.2(c)(ii) or Section 2.2(c)(iii) hereof or the date of acceleration pursuant to Section 8.1(a) hereof).

7.2 Covenant Default

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(a) The Credit Parties: (i) fail or neglect to perform any obligation in Sections 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.10, 5.12, 5.13, 5.14 5.16 or 5.17 or (ii) violate or breach any covenant or agreement in Section 6; or

(b) The Credit Parties fail or neglect to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents on its part to be performed, kept or observed and such failure or neglect continues for twenty (20) days, after the earlier of the date on which (i) a Responsible Officer of any Credit Party becomes aware of such failure or neglect and (ii) written notice thereof shall have been given to Borrower by the Collateral Agent or any Lender. Cure periods provided under this Section 7.2(b) shall not apply, among other things, to any of the covenants referenced in clause (a) above.

7.3 Material Adverse Change

. A Material Adverse Change occurs.

7.4 Attachment; Levy; Restraint on Business

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(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of any Credit Party or of any entity under the control of any Credit Party (including a Subsidiary) in excess of $10,000,000 on deposit or otherwise maintained with the Collateral Agent, or (ii) a notice of lien or levy is filed against any of material portion of Collateral by any Governmental Authority, and the same under sub-clauses (i) and (ii) hereof are not, within thirty (30) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, that no Credit Extensions shall be made during any thirty (30) day cure period; or

(b) (i) Any material portion of Collateral is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Parent and its Subsidiaries from conducting any material part of their business, taken as a whole.

7.5 Insolvency

.

(a) An involuntary proceeding shall be commenced or an involuntary petition shall be filed in a court of competent jurisdiction seeking: (i) relief in respect of any Credit Party, or of a substantial part of the property of any Credit Party, under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law; (ii) the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for any Credit Party or for a substantial part of the property or assets of any Credit Party; or (iii) the winding-up or liquidation of any Credit Party, and such proceeding or petition shall continue undismissed or unstayed for sixty (60) days or an order or decree approving or ordering any of the foregoing shall be entered; or

(b) Any Credit Party shall: (i) voluntarily commence any proceeding or file any petition seeking relief under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law; (ii) consent to the institution of, or fail to contest in a timely and appropriate manner, any proceeding or the filing of any petition described in clause (a) above; (iii) apply for or consent to the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for any Credit Party or for a substantial part of the property or assets of any Credit Party; (iv) file an answer admitting the material allegations of a petition filed against it in any such proceeding; (v) make a general assignment for the benefit of creditors; (vi) become unable, admit in writing its inability or fail generally to pay its debts as they become due; (vii) take any action for the purpose of effecting any of the foregoing; or (viii) wind up or liquidate (except as otherwise expressly permitted hereunder).

7.6 Other Agreements

.

(a) Any Credit Party fails to pay any Indebtedness (other than the Indebtedness represented by this Agreement and the other Loan Documents) within any applicable grace period after such payment is due and payable (including at final maturity) or after the acceleration of any such Indebtedness by the holder(s) thereof because of a default, in each case, if the total amount of such Indebtedness unpaid or accelerated exceeds $10,000,000.

(b) Parent fails to make any payments under the terms of the Pre-Paid Forward Contract when due or payable (after expiration of any applicable grace period) or an insolvency event or similar event occurs under the terms of the Pre-Paid Forward Contract.

7.7 Judgments

. One or more final, non-appealable judgments, orders, or decrees for the payment of money in an amount in excess of $10,000,000 (but excluding any final judgments, orders, or decrees for the payment of money that are covered by independent third-party insurance as to which liability has not been

denied by such insurance carrier or by an indemnification claim against a solvent and unaffiliated Person that is not a Credit Party as to which such Person has not denied liability for such claim), shall be rendered against one or more Credit Parties and the same are not, within thirty (30) days after the entry thereof, discharged or execution thereof stayed or bonded pending appeal, or such judgments are not discharged prior to the expiration of any such stay.

7.8 Misrepresentations

. Any Credit Party or any Person acting for any Credit Party makes or is deemed to make any representation, warranty, or other statement now or later in this Agreement, any other Loan Document or in any writing delivered to the Collateral Agent or any Lender or to induce the Collateral Agent or any Lender to enter this Agreement or any other Loan Document, and such representation, warranty, or other statement is incorrect in any material respect (or, to the extent any such representation, warranty or other statement is qualified by materiality or Material Adverse Change, in any respect) when made or deemed to be made.

7.9 Loan Documents; Collateral

. Any material provision of any Loan Document shall for any reason cease to be valid and binding on or enforceable against any Credit Party, or any Credit Party shall so state in writing or bring an action to limit its obligations or liabilities thereunder; or any Collateral Document shall for any reason (other than pursuant to the terms thereof) cease to create a valid security interest in any material portion of the Collateral purported to be covered thereby or such security interest shall for any reason (other than pursuant to the terms of the Loan Documents) cease to be a perfected and first priority security interest in any material portion of the Collateral subject thereto, subject only to Permitted Liens, in each case, other than as a direct result of any action by the Collateral Agent or any Lender or failure of the Collateral Agent or any Lender to perform an obligation thereof under the Loan Documents.

7.10 ERISA Event

. An ERISA Event occurs that, individually or taken together with any other ERISA Events, results or could reasonably be expected to result in a Material Adverse Change, or the imposition of a Lien under Section 303(k) of ERISA on any Collateral that could reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change.

7.11 Intercreditor Agreement

. A material default or breach occurs under the RTW Intercreditor Agreement or any other subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt or Permitted Convertible Indebtedness, or any creditor party to such an agreement with the Collateral Agent (or Lenders) and any Credit Party breaches the terms of such agreement in any material respect; provided, that material defaults or breaches for the purposes of this Section 7.11 shall include breaches of payment, enforcement and subordination provisions or restrictions. For the avoidance of doubt, default or breaches by any Secured Party shall not constitute an Event of Default hereunder.

8 RIGHTS AND REMEDIES UPON AN EVENT OF DEFAULT

8.1 Rights and Remedies

. While an Event of Default occurs and continues, the Collateral Agent may, or at the request of the Required Lenders, will, without notice or demand:

(a) declare all Obligations (including, for the avoidance of doubt, any and all amounts payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable) immediately due and payable (but if an Event of Default described in Section 7.5 occurs, all Obligations, including any and all amounts payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, are automatically and immediately due and payable without any notice, demand or other action by the Collateral Agent or any Lender), whereupon all Obligations for principal, interest, premium or otherwise (including, for the avoidance of doubt, any and all amounts payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable) shall become due and payable by Borrower without presentment for payment, demand, notice of protest or other demand or notice of any kind, which are all expressly waived by the Credit Parties hereby;

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement;

(c) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that the Collateral Agent considers advisable, notify any Person owing Borrower money of the Collateral Agent's security interest, for the benefit of the Lenders and the other Secured Parties, in such funds, and verify the amount of the Collateral Accounts;

(d) make any payments and do any acts it considers necessary or reasonable to protect the Collateral or the Collateral Agent's security interest, for the benefit of Lenders and the other Secured Parties, in the Collateral. Parent or Borrower, as applicable, shall assemble the Collateral if the Collateral Agent or the Required Lenders requests and make it available as the Collateral Agent designates or the Required Lenders designate. The Collateral Agent or its agents or representatives may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien that appears to be prior or superior to its security interest, for the benefit of Lenders and the other Secured Parties, and pay all expenses incurred. Each of Parent and Borrower grants the Collateral Agent an irrevocable, royalty-free license or other right to enter, use, operate and occupy (and for its agents or representatives to enter, use, operate and occupy), without charge, any such premises to exercise any of the Collateral Agent's or any Lender's rights or remedies under this Section 8.1 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral);

(e) apply to the Obligations (i) any balances and deposits of Borrower it holds, (ii) any amount held by the Collateral Agent owing to or for the credit or the account of Borrower or (iii) any balance from any Collateral Account of any Credit Party or instruct the bank at which any such Collateral Account is maintained to pay the balance of any such Collateral Account to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct;

(f) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. With respect to any and all Intellectual Property owned or held by any Credit Party and included in Collateral, each Credit Party hereby grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, as of the Tranche A Closing Date: (i) an irrevocable, non-exclusive, assignable, royalty-free license or other right to use (and for its agents or representatives to use), without charge, including the right to sublicense, use and practice, any and all such

Intellectual Property in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral, and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; and (ii) in connection with the Collateral Agent's exercise of its rights or remedies under this Section 8.1 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral), each Credit Party's rights under all licenses and all franchise Contracts inure to the benefit of all Secured Parties. Each Credit Party shall retain the right to control the Collateral Agent's use of its trade names and Trademarks and such trade names and Trademarks, together with the goodwill associated therewith, are and remain the exclusive property of the Credit Parties, and any and all use of the same by the Collateral Agent shall inure to the benefit of the Credit Parties;

(g) place a "hold" on any account maintained with the Collateral Agent or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(h) demand and receive possession of the Books of any Credit Party regarding Collateral; and

(i) exercise all rights and remedies available to the Collateral Agent or any Lender under the Collateral Documents or any other Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Each of the Collateral Agent and Lender agrees that in connection with any foreclosure or other exercise of rights under this Agreement or any other Loan Document with respect to any Intellectual Property included in the Collateral, the rights of the licensees under any license of such Intellectual Property will not be terminated, limited or otherwise adversely affected so long as no default exists thereunder in a way that would permit the licensor to terminate such license (commonly termed a non-disturbance). Without limitation to any other provision herein or in any other Loan Document, while an Event of Default occurs and continues, at the Collateral Agent's or the Required Lenders' request, representatives from Borrower and the Collateral Agent shall promptly meet (in person or telephonically) to discuss in good faith how to collect, receive, appropriate and realize upon Borrower's rights and interests in, to and under any Company IP Agreement, including in connection with any foreclosure or other exercise of the Collateral Agent's or any Lender's rights with respect thereto. If Borrower and the Collateral Agent do not mutually agree with respect thereto within ten (10) Business Days after such request by the Collateral Agent (or such later date as agreed by the Collateral Agent), then the Collateral Agent may request Borrower to, and Borrower (promptly following the receipt of such request) shall, use reasonable best efforts to obtain the written consent of any counterparty to the exercise by the Collateral Agent or any Lender of any and all rights and remedies under this Agreement or any other Loan Document with respect to any Company IP Agreement, in form and substance reasonably satisfactory to the Collateral Agent.

8.2 Power of Attorney

. Borrower hereby irrevocably appoints the Collateral Agent and any Related Party thereof as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's name on any checks or other forms of payment or security; (b) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Collateral Accounts directly with depository banks where the Collateral Accounts are maintained, for amounts and on terms the Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's products liability or general liability insurance policies maintained in any jurisdiction regarding Collateral; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of the Collateral Agent or a third party as the Code permits. Borrower hereby appoints the Collateral Agent and any Related Party thereof as its lawful attorney-in-fact to file or record any documents necessary to perfect or continue the perfection of the Collateral Agent's security interest, for the benefit of Lenders and the other Secured Parties, in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) have been satisfied in full and no Lender is under any further obligation to make Credit Extensions hereunder. The foregoing appointment of the Collateral Agent and any Related Party thereof as Borrower's attorney in fact, and all of the Collateral Agent's (or such Related Party's) rights and powers, coupled with an interest, are irrevocable until all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) have been fully repaid and performed and each Lender's obligation to provide Credit Extensions terminates.

8.3 Application of Payments and Proceeds Upon Default

. If an Event of Default has occurred and is continuing, the Collateral Agent shall apply any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Collateral Accounts or disposition of any other Collateral, or otherwise, to the Obligations in such order as the Collateral Agent shall determine in its sole discretion. Any surplus shall be paid to Borrower or other Persons legally entitled thereto; Borrower shall remain liable to Lenders for any deficiency. If the Collateral Agent or any Lender directly or indirectly enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, the Collateral Agent or such Lender, as applicable, shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by the applicable Lender(s) of cash therefor.

8.4 Collateral Agent's Liability for Collateral

. So long as the Collateral Agent complies with Requirements of Law regarding the safekeeping of the Collateral in the possession or under the control of the Collateral Agent and absent bad faith, gross negligence or willful misconduct of the Collateral Agent, the Collateral Agent shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; or (c) any act or default of any other Person. In no event shall the Collateral Agent or any Lender have any liability for any diminution in the value of the Collateral for any reason except as a result of Collateral Agent's bad faith, gross negligence or willful misconduct. Borrower bears all risk of loss, damage or destruction of the Collateral.

8.5 No Waiver; Remedies Cumulative

. The Collateral Agent's or any Lender's failure, at any time or times, to require strict performance by Borrower or any other Person of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of the Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Each of the Collateral Agent's and Lender's rights and remedies under this Agreement and the other Loan Documents are cumulative. Each of the Collateral Agent and Lenders has all rights and remedies provided under the Code, by law, or in equity. The exercise by the Collateral Agent or any Lender of one right or remedy is not an election and shall not preclude the Collateral Agent or any Lender from exercising any other remedy under this Agreement or other remedy available at law or in equity, and the waiver by the Collateral

Agent or any Lender of any Event of Default is not a continuing waiver. The Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

8.6 Demand Waiver; Makewhole Amount; Prepayment Premium

. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by the Collateral Agent on which Borrower is liable. Borrower acknowledges and agrees that if the maturity of all Obligations shall be accelerated pursuant to Section 8.1(a) by reason of the occurrence of an Event of Default, the applicable Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, shall become due and payable by Borrower upon such acceleration, whether such acceleration is automatic or is effected by the Collateral Agent's or any Lender's declaration thereof, as provided in Section 8.1(a), and Borrower shall pay the applicable Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, as compensation to Lenders for the loss of its investment opportunity and not as a penalty, and Borrower waives any right to object thereto in any voluntary or involuntary bankruptcy, insolvency or similar proceeding or otherwise.

9 NOTICES

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; (d) when delivered, if hand-delivered by messenger; or (e) if sent by electronic mail, when received in readable form, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address (if any) indicated below. Any party to this Agreement may change its mailing or electronic mail address or facsimile number by giving all other parties hereto written notice thereof in accordance with the terms of this Section 9.

If to Borrower or any other Credit Party:

c/o UroGen Pharma Ltd.
400 Alexander Park Drive
Princeton, New Jersey 08540
Attn: Chief Financial Officer
Email: molly.henderson@urogen.com and legal@urogen.com

with copies to (which shall not constitute notice) to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121-1909
Attn: Charles J. Bair
Facsimile: 858 550 6420
Email: cbair@cooley.com

If to Collateral Agent: BioPharma Credit PLC
c/o Beaufort House
51 New North Road
Exeter EX4 4EP
United Kingdom
Attn: Company Secretary
Tel: +44 01 392 477 500
Fax: +44 01 392 498 288
Email: biopharmacreditplc@linkgroup.co.uk

with copies (which shall not constitute notice) to:

Pharmakon Advisors LP
110 East 59th Street, #3300
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Fax: +1 (917) 210-4048
Email: Pharmakon@Pharmakonadvisors.com

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: (212) 872-8081
Fax: (212) 872-1002
Email: gsecol@akingump.com

If to any Lender: To the address of such Lender set forth on Exhibit D attached hereto

with copies (which shall not constitute notice) to:

Pharmakon Advisors LP
110 East 59th Street, #3300
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Fax: +1 (917) 210-4048
Email: Pharmakon@Pharmakonadvisors.com

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: (212) 872-8081
Fax: (212) 872-1002
Email: gsecol@akingump.com

10 CHOICE OF LAW, VENUE, AND JURY TRIAL WAIVER

THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT. Except as contemplated by the immediately succeeding paragraph, each party hereto submits to the exclusive jurisdiction of the courts of the State of New York sitting in New York County, and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, and agrees that all claims in respect of any such action, litigation or proceeding may be heard and determined in such New York State court or, to the fullest extent permitted by Requirements of Law, in such Federal court; provided, however, that nothing in this Agreement shall be deemed to operate to preclude the Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of the Collateral Agent or any Lender. Each Credit Party expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and each Credit Party hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or *forum non conveniens* and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Each Credit Party hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to such party at the address set forth in (or otherwise provided in accordance with the terms of) Section 9 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of such party's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

The preceding paragraph notwithstanding, each of the Collateral Agent or Lenders may, in its sole discretion and election, initiate and file legal proceedings in any matter related to this Agreement in the State of Israel. In any such event, the competent courts in Tel-Aviv-Jaffa, Israel, shall have sole and exclusive jurisdiction in relation to any such proceeding.

TO THE FULLEST EXTENT PERMITTED BY REQUIREMENTS OF LAW, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ITS RIGHT TO A JURY TRIAL IN ANY CLAIM, SUIT, ACTION OR PROCEEDING WITH RESPECT TO, OR DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH, THIS AGREEMENT, ANY OTHER LOAN DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREIN AND THEREIN OR RELATED HERETO OR THERETO (WHETHER FOUNDED IN CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO OTHER PARTY AND NO RELATED PARTY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10 AND (C) HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

11 GENERAL PROVISIONS

11.1 Successors and Assigns

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(a) This Agreement binds and is for the benefit of the parties hereto and their respective successors and permitted assigns.

(b) No Credit Party may transfer, pledge or assign this Agreement or any other Loan Document or any rights or obligations hereunder or thereunder without the prior written consent of each Lender. Subject to Section 11.1(d), any Lender may at any time sell, transfer, assign or pledge this Agreement or any other Loan Document or any of its rights or obligations hereunder or thereunder, or grant a participation in all or any part of, or any interest in, such Lender's obligations, rights or benefits under this Agreement and the other Loan Documents, including with respect to any Term Loan (or any portion thereof), to any other Lender, any Affiliate of any Lender or any third Person without Borrower's consent (any such sale, transfer, assignment, pledge or grant of a participation, a "**Lender Transfer**"); provided, however, that no Lender may make a Lender Transfer to a Disqualified Assignee without Borrower's prior written consent except after the occurrence and during the continuance of an Event of Default (in which case such consent is not required); provided, further, that no Lender may make a Lender Transfer to any third Person if such Lender Transfer would result in material adverse tax consequences to Borrower or Parent, in the reasonable judgment of the Collateral Agent after consultation with Borrower, without Borrower's prior written consent except after the occurrence and during the continuance of an Event of Default (in which case such consent is not required).

(c) In the case of a Lender Transfer in the form of a participation granted by any Lender to any third party, (i) such Lender's obligations under this Agreement shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of its obligations hereunder, (iii) Borrower shall continue to deal solely and directly with such Lender in connection with such Lender's rights and obligations

under this Agreement and (iv) any agreement or instrument pursuant to which such Lender sells such participation shall provide that such Lender shall retain the sole right to enforce this Agreement and to approve any amendment, restatement, supplement or other modification hereto, in each case subject to the terms and conditions of this Agreement. Borrower agrees that each participant shall be entitled to the benefits of Sections 2.5 and 2.6 (subject to the requirements and limitations therein, including the requirements under Section 2.6(d) (it being understood that the documentation required under Section 2.6(d) shall be delivered to the applicable Lender)) to the same extent as if it were a Person that had acquired its interest by assignment pursuant to clause (b) above; provided that, with respect to any participation, such participant shall not be entitled to receive any greater payment under Sections 2.5 or 2.6 than the applicable Lender (i.e., the party that participated the interest) would have been entitled to receive, except to the extent of any entitlement to receive a greater payment resulting from a Change in Law that occurs after such participant acquired the applicable participation.

(d) The Collateral Agent (as a non-fiduciary agent on behalf of Borrower) shall record any Lender Transfer in the Note Register. Each Lender shall provide Borrower and the Collateral Agent with written notice of a Lender Transfer delivered no later than five (5) Business Days prior to the date on which such Lender Transfer is consummated. If any Lender sells a participation, such Lender shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and principal amounts (and stated interest) of each participant's interest in the Term Loans or other obligations under the Loan Documents (the "**Participant Register**"); provided, however, that such Lender shall have no obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan, letter of credit or other obligation is in "registered form" within the meaning of Section 163(f), 871(h)(2) and 881(c)(2) of the IRC and any related regulations (and any other relevant or successor provisions of the IRC or such regulations). The entries in the Participant Register shall be conclusive absent manifest error, and the Collateral Agent and each Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary.

(e) Any attempted transfer, pledge or assignment of this Agreement or any other Loan Document or any rights or obligations hereunder or thereunder in violation of this Section 11.1 shall be null and void and neither Borrower nor any transfer agent shall give any effect in the Note Register to such attempted transfer.

11.2 Indemnification

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(a) Borrower agrees to indemnify and hold harmless each of the Collateral Agent, Lenders and its and their respective Affiliates (and its or their respective successors and assigns) and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof (each such Person, an "**Indemnified Person**") from and against any and all Indemnified Liabilities; provided, however, that (i) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities to the extent such Indemnified Liabilities arise from the bad faith, gross negligence or willful misconduct of that Indemnified Person (or its Affiliates or controlling Persons or their respective directors, officers, managers, partners, members, agents, sub-agents or advisors), in each case, as determined by a final, non-appealable judgment of a court of competent jurisdiction, (ii) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities if and to the extent such Indemnified Liabilities arise from a material breach of any obligation of such Indemnified Person hereunder, and (iii) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities if and to the extent such Indemnified Liabilities arise from any claim by one Indemnified Person against another Indemnified Person that does not relate to any act or omission of Borrower or any other Credit Party, and (iv) no Credit Party shall be liable for any settlement of any claim or proceeding effected by any Indemnified Person without the prior written consent of such Credit Party (which consent shall not be unreasonably withheld, conditioned or delayed), but if settled with such consent or if there shall be a final judgment against an Indemnified Person, each of the Credit Parties shall, jointly and severally with each other Credit Parties, indemnify and hold harmless such Indemnified Person from and against any loss or liability by reason of such settlement or judgment in the manner set forth in this Agreement. This Section 11.2(a) shall not apply with respect to Taxes other than any Taxes that represent liabilities, obligations, losses, damages, penalties, claims, costs, expenses and disbursements arising from any non-Tax claim.

(b) To the extent permitted by Requirements of Law, no party to this Agreement shall assert, and each party to this Agreement hereby waives, any claim against any other party hereto (and its or their successors and assigns), and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) (whether or not the claim therefor is based on contract, tort or duty imposed by any applicable legal requirement) arising out of, in connection with, arising out of, as a result of, or in any way related to, this Agreement or any Loan Document or any agreement or instrument contemplated hereby or thereby or referred to herein or therein, the transactions contemplated hereby or thereby, any Credit Extension or the use of the proceeds thereof or any act or omission or event occurring in connection therewith, and each party to this Agreement hereby waives, releases and agrees not to sue upon any such claim or any such damages, whether or not accrued and whether or not known or suspected to exist in its favor.

(c) Any action taken by any Credit Party under or with respect to any Loan Document, even if required under any Loan Document or at the request of the Collateral Agent or any Lender, shall be at the expense of such Credit Party, and neither the Collateral Agent nor any Secured Party shall be required under any Loan Document to reimburse any Credit Party or any Subsidiary of any Credit Party therefor except as expressly provided therein. In addition, and without limiting the generality of Section 2.4, Borrower agrees to pay or reimburse upon demand each of the Collateral Agent and Lenders (and their respective successors and assigns) and each of their respective Related Parties, if applicable, for any and all fees, expenses and disbursements of the kind or nature described in clause (b) of the definition of "Lender Expenses" incurred by it.

11.3 Severability of Provisions

. In case any provision in or obligation hereunder or under any other Loan Document shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

11.4 Correction of Loan Documents

. The Collateral Agent or Required Lenders may correct patent errors and fill in any blanks in the Loan Documents consistent with the agreement of the parties hereto so long as the Collateral Agent or Required Lenders, as applicable, provides the Credit Parties and the other parties hereto with written notice of such correction and allows the Credit Parties at least ten (10) days to object to such correction in writing delivered to the Collateral Agent and each Lender. In the event of such objection, such correction shall not be made except by an amendment to this Agreement in accordance with Section 11.5.

11.5 Amendments in Writing; Integration

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(a) No amendment, restatement or modification of or supplement to any provision of this Agreement or any other Loan Document, or waiver, discharge or termination of any obligation hereunder or thereunder, no approval or consent hereunder or thereunder (including any consent to any departure by Borrower or any other Credit Party herefrom or therefrom), shall in any event be effective unless the same shall be in writing and signed by Borrower (on its own behalf and on behalf of each other Credit Party) and the Required Lenders; provided, however, that no such amendment, restatement, modification, supplement, waiver, discharge, termination, approval or consent shall, unless in writing and signed by the Collateral Agent and the Required Lenders, affect the rights or duties of, or any amounts payable to, the Collateral Agent under this Agreement or any other Loan Document. Any such waiver, approval or consent granted shall be limited to the specific circumstance expressly described in it, and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver, approval or consent.

(b) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations among the parties hereto about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

11.6 Counterparts

. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

11.7 Survival

. **Termination Prior to Term Loan Maturity Date**. All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to this Section 11.7 and all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted and any other obligations which, by their terms, are to survive the termination of this Agreement) have been paid in full and satisfied in accordance with the terms of this Agreement. The obligation of Borrower or any other the Credit Parties in Section 11.2 to indemnify Indemnified Persons shall survive until the statute of limitations with respect to such claim or cause of action shall have run. So long all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted and any other obligations which, by their terms, are to survive the termination of this Agreement and for which no claim has been made) have been paid in full and satisfied in accordance with the terms of this Agreement, this Agreement shall be terminated (a) prior to the Term Loan Maturity Date by Borrower, effective five (5) Business Days (or such shorter period as the Collateral Agent may agree in its sole discretion) after written notice of termination is delivered to the Collateral Agent and the Lenders, or (b) if no such notice is delivered, automatically on the Term Loan Maturity Date.

11.8 Confidentiality

. Any information regarding the Credit Parties and their Subsidiaries and their businesses provided to the Collateral Agent or any Lender by or on behalf of any Credit Party pursuant to the Loan Documents shall be deemed "Confidential Information"; provided, however, that Confidential Information does not include information that is either: (i) in the public domain or in the possession of the Collateral Agent, any Lender or any of their respective Affiliates or when disclosed to the Collateral Agent, any Lender or any of their respective Affiliates, or becomes part of the public domain after disclosure to the Collateral Agent, any Lender or any of their respective Affiliates, in each case, other than as a result of a breach by the Collateral Agent, any Lender or any of their respective Affiliates of the obligations under this Section 11.8; or (ii) disclosed to the Collateral Agent, any Lender or any of their respective Affiliates by a third party if the Collateral Agent, such Lender or such Affiliate, as applicable, does not know (following due and careful enquiry) that the third party is prohibited from disclosing the information. Neither the Collateral Agent nor any Lender shall disclose any Confidential Information to a third party or use Confidential Information for any purpose other than the exercise of its rights and the performance of its duties or obligations under the Loan Documents. The foregoing in this Section 11.8 notwithstanding, the Collateral Agent and each Lender may disclose Confidential Information: (a) to any of its Subsidiaries or Affiliates; (b) to prospective transferees, purchasers or participants of any interest in the Term Loans (including, for the avoidance of doubt, in connection with any proposed Lender Transfer), provided that no such disclosure to any Competitors shall be permitted hereunder without Borrower's prior written consent (which consent shall not be required after the occurrence and during the continuance of an Event of Default); (c) as required by law, regulation, subpoena, or other order, provided, that (x) prior to any disclosure under this clause (c), the Collateral Agent or such Lender, as applicable, agrees to endeavor to provide Borrower with prior written notice thereof and with respect to any law, regulation, subpoena or other order, to the extent that the Collateral Agent or such Lender is permitted to provide such prior notice to Borrower pursuant to the terms hereof, and (y) any disclosure under this clause (c) shall be limited solely to that portion of the Confidential Information as may be specifically compelled by such law, regulation, subpoena or other order; (d) to the extent requested by regulators having jurisdiction over the Collateral Agent or such Lender or as otherwise required in connection with the Collateral Agent's or such Lender's examination or audit by such regulators; (e) as the Collateral Agent or such Lender considers reasonably necessary in exercising remedies under the Loan Documents; (f) to third-party service providers of the Collateral Agent or such Lender; and (g) to any of the Collateral Agent's or such Lender's Related Parties; provided, however, that the third parties to which Confidential Information is disclosed pursuant to clauses (a), (b), (f) and (g) are bound by obligations of confidentiality and non-use that are no less restrictive than those contained herein.

The provisions of this Section 11.8 shall survive the termination of this Agreement.

11.9 Attorneys' Fees, Costs and Expenses

. In any action or proceeding between any Credit Party and the Collateral Agent or any Lender arising out of or relating to the Loan Documents, the prevailing party shall be entitled to recover its reasonable attorneys' fees and other costs and expenses incurred, in addition to any other relief to which it may be entitled.

11.10 Right of Set-Off

. In addition to any rights now or hereafter granted under Requirements of Law and not by way of limitation of any such rights, upon the occurrence of an Event of Default and at any time thereafter during the continuance of any Event of Default, each Lender is hereby authorized by each Credit Party at any time or from time to time, without prior notice to any Credit Party, any such notice being hereby expressly waived by Borrower (on its own behalf and on behalf of each other Credit Party), to set off and to appropriate and to apply any and all deposits (general or special, including Indebtedness evidenced by certificates of deposit, whether matured or unmatured, but not including trust accounts) and any other Indebtedness at any time held or owing by such Lender to or for the credit or the account of any Credit Party against and on account of the obligations and liabilities of any Credit Party to such Lender hereunder and under the other Loan Documents, including all claims of any nature or description arising out of or connected hereto or

with any other Loan Document, irrespective of whether or not (a) the Collateral Agent or such Lender shall have made any demand hereunder or (b) the principal of or the interest on the Term Loans or any other amounts due hereunder shall have become due and payable pursuant to Section 2 and although such obligations and liabilities, or any of them, may be contingent or unmatured. Each Lender agrees promptly to notify Borrower and the Collateral Agent after any such set off and application made by such Lender; provided, that the failure to give such notice shall not affect the validity of such set off and application.

11.11 Marshalling; Payments Set Aside

. Neither the Collateral Agent nor any Lender shall be under any obligation to marshal any assets in favor of any Credit Party or any other Person or against or in payment of any or all of the Obligations. To the extent that any Credit Party makes a payment or payments to any Lender, or the Collateral Agent or any Lender enforces any Liens or exercises its rights of setoff, and such payment or payments or the proceeds of such enforcement or setoff or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside or required to be repaid to a trustee, receiver or any other party under any bankruptcy law, any other state or federal law, common law or any equitable cause, then, to the extent of such recovery, the obligation or part thereof originally intended to be satisfied, and all Liens, rights and remedies therefor or related thereto, shall be revived and continued in full force and effect as if such payment or payments had not been made or such enforcement or setoff had not occurred.

11.12 Electronic Execution of Documents

. The words "execution," "signed," "signature" and words of like import in any Loan Document shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any Requirements of Law, including any state law based on the Uniform Electronic Transactions Act.

11.13 Captions

. Section headings herein are included herein for convenience of reference only and shall not constitute a part hereof for any other purpose or be given any substantive effect.

11.14 Construction of Agreement

. The parties hereto mutually acknowledge that they and their respective attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty, this Agreement shall be construed without regard to which of the parties hereto caused the uncertainty to exist.

11.15 Third Parties

. Nothing in this Agreement, whether express or implied, is intended to: (a) except as expressly provided in Section 11.2(a), confer any benefits, rights or remedies under or by reason of this Agreement on any Persons other than the express parties to it and their respective successors and permitted assigns; (b) relieve or discharge the obligation or liability of any Person not an express party to this Agreement; or (c) give any Person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

11.16 No Advisory or Fiduciary Duty

. The Collateral Agent and each Lender may have economic interests that conflict with those of the Credit Parties. Each Credit Party agrees that nothing in the Loan Documents or otherwise will be deemed to create an advisory, fiduciary or agency relationship or fiduciary or other implied duty between any Lender or the Collateral Agent, on the one hand, and such Credit Party, its Subsidiaries, and any of their respective stockholders or affiliates, on the other hand. Each Credit Party acknowledges and agrees that (i) the transactions contemplated by the Loan Documents are arm's-length commercial transactions between each Lender and the Collateral Agent, on the one hand, and such Credit Party, its Subsidiaries and their respective affiliates, on the other hand, (ii) in connection therewith and with the process leading to such transaction, the Collateral Agent and each Lender is acting solely as a principal and not the advisor, agent or fiduciary of such Credit Party, its Subsidiaries or their respective affiliates, management, stockholders, creditors or any other Person, (iii) neither the Collateral Agent nor any Lender has assumed an advisory or fiduciary responsibility in favor of any Credit Party, its Subsidiaries or their respective affiliates with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Collateral Agent or any Lender or any of their respective affiliates has advised or is currently advising such Credit Party, its Subsidiaries or their respective affiliates on other matters) or any other obligation to such Credit Party, its Subsidiaries or their respective affiliates except the obligations expressly set forth in the Loan Documents, and (iv) each Credit Party, its Subsidiaries and their respective affiliates have consulted their own legal and financial advisors to the extent each deemed appropriate. Each Credit Party further acknowledges and agrees that it is responsible for making its own independent judgment with respect to such transactions and the process leading thereto. Each Credit Party agrees that it will not claim that the Collateral Agent or any Lender has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to such Credit Party, its Subsidiaries or their respective affiliates in connection with such transaction or the process leading thereto.

11.17 Credit Parties' Agent

. Each of the Credit Parties hereby irrevocably appoints Borrower, as its agent, attorney-in-fact and legal representative for all purposes, including requesting disbursement of the Term Loans and receiving account statements and other notices and communications to Credit Parties (or any of them) from the Collateral Agent or the Lenders, executing amendments, waivers or other modifications of or supplements to Loan Documents and executing or designating new Loan Documents. The Collateral Agent or the Lenders may rely, and shall be fully protected in relying, on any request for the Term Loans, disbursement instruction, report, information or any other notice or communication made or given by Borrower and any amendment, waiver or other modification of or supplement to a Loan Document or the execution or designation of new Loan Documents executed or made by Borrower, whether in its own name or on behalf of one or more of the other Credit Parties, and the Collateral Agent or the Lenders shall not have any obligation to make any inquiry or request any confirmation from or on behalf of any other Credit Party as to the binding effect on it of any such request, instruction, report, information, other notice, communication, amendment, supplement, waiver, other modification, execution or designation, nor shall the joint and several character of the Credit Parties' obligations hereunder be affected thereby.

12 COLLATERAL AGENT

12.1 Appointment and Authority

. Each Lender hereby irrevocably appoints BioPharma Credit PLC to act on its behalf as the Collateral Agent hereunder and under the other Loan Documents and authorizes the Collateral Agent to take such actions on its behalf and to exercise such powers as are delegated to the Collateral Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto. Except for the first two (2) sentences of Section 12.6 and the first sentence and penultimate paragraph of Section 12.8, the provisions of this Section 12 are solely for the benefit of the Collateral Agent and Lenders, and neither Borrower nor any other Credit Party shall have rights as a third party beneficiary of any of such provisions. Subject to Section 12.8 and Section 11.5, any action required or permitted to be taken by the Collateral Agent hereunder shall be taken with the prior approval of the Required Lenders.

12.2 Rights as a Lender

. The Person serving as the Collateral Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Collateral Agent and the term "Lender" or "Lenders" shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Collateral Agent hereunder in its individual capacity. Such Person and its Affiliates may lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with Borrower or any Subsidiary or other Affiliate thereof as if such Person were not the Collateral Agent hereunder and without any duty to account therefor to any Lender.

12.3 Exculpatory Provisions

.

(a) The Collateral Agent shall not have any duties or obligations to the Lenders except those expressly set forth herein and in the other Loan Documents to which it is a party. Without limiting the generality of the foregoing, with respect to the Lenders, the Collateral Agent:

(i) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default or Event of Default has occurred and is continuing;

(ii) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents to which it is a party that the Collateral Agent is required to exercise as directed in writing by the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in such other Loan Documents), provided that the Collateral Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Collateral Agent to liability or that is contrary to any Loan Document or Requirements of Law; and

(iii) shall not, except as expressly set forth herein and in the other Loan Documents to which it is a party, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to Borrower or any of its Affiliates that is communicated to or obtained by the Person serving as the Collateral Agent or any of its Affiliates in any capacity.

(b) The Collateral Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Lenders (or such other number or percentage of the Lenders as shall be necessary, or as the Collateral Agent shall believe in good faith shall be necessary, under the circumstances as provided in Section 11.5) or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and nonappealable judgment. The Collateral Agent shall be deemed not to have knowledge of any Default or Event of Default unless and until notice describing such Default or Event of Default is given to the Collateral Agent in writing by Borrower or a Lender.

(c) The Collateral Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Section 3 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Collateral Agent.

12.4 Reliance by Collateral Agent

. The Collateral Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Collateral Agent also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. The Collateral Agent may consult with legal counsel (who may be counsel for Borrower), independent accountants, manufacturing consultants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants, consultants or experts.

12.5 Delegation of Duties

. The Collateral Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Loan Document by or through any one or more sub-agents appointed by the Collateral Agent. The Collateral Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The exculpatory provisions of this Section 12 shall apply to any such sub-agent and to the Related Parties of the Collateral Agent and any such sub-agent. The Collateral Agent shall not be responsible for the negligence or misconduct of any sub-agent except to the extent that a court of competent jurisdiction determines in a final and nonappealable judgment that the Collateral Agent acted with gross negligence or willful misconduct in the selection of such sub-agent.

12.6 Resignation of Collateral Agent

. The Collateral Agent may at any time give notice of its resignation to the Lenders and Borrower. Upon the receipt of any such notice of resignation, the Required Lenders shall have the right, in consultation with Borrower so long as no Default or Event of Default has occurred and is continuing, to appoint a successor (which shall not be a Competitor except after the occurrence and during the continuance of an Event of Default). If no successor shall have been so appointed by the Required Lenders and shall have accepted such appointment within thirty (30) days after the retiring Collateral Agent gives notice of its resignation, then the retiring Collateral Agent may, on behalf of the Lenders, appoint a successor Collateral Agent that is a Related Party of the Collateral Agent or any Lender; provided that, whether or not a successor has been appointed or has accepted such appointment,

such resignation shall become effective upon delivery of the notice thereof. Upon the acceptance of a successor's appointment as Collateral Agent hereunder, such successor shall succeed to and become vested with all of the rights, powers, privileges and duties of the retiring (or retired) Collateral Agent, and the retiring Collateral Agent shall be discharged from all of its duties and obligations under the Loan Documents (if not already discharged therefrom as provided above in this Section 12.6). After the retiring Collateral Agent's resignation, the provisions of this Section 12 and Section 10 shall continue in effect for the benefit of such retiring Collateral Agent, its sub-agents and their respective Related Parties in respect of any actions taken or omitted to be taken by any of them while the retiring Collateral Agent was acting as Collateral Agent. Upon any resignation by the Collateral Agent, all payments, communications and determinations provided to be made by, to or through the Collateral Agent shall instead be made by, to or through each Lender directly, until such time as a Person accepts an appointment as Collateral Agent in accordance with this Section 12.6.

12.7 Non-Reliance on Collateral Agent and Other Lenders

. Each Lender acknowledges that it has, independently and without reliance upon the Collateral Agent or any other Lender or any of their respective Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement and make Credit Extensions hereunder. Each Lender also acknowledges that it will, independently and without reliance upon the Collateral Agent or any other Lender or any of their respective Related Parties and based on such documents and information as it shall from time to time deem appropriate, continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Loan Document or any related agreement or any document furnished hereunder or thereunder.

12.8 Collateral and Guaranty Matters

. Each Lender agrees that any action taken by the Collateral Agent or the Required Lenders in accordance with the provisions of this Agreement or of the other Loan Documents, and the exercise by the Collateral Agent or Required Lenders of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Lenders. Without limiting the generality of the foregoing, the Lenders irrevocably authorize and instruct the Collateral Agent, and the Collateral Agent agrees:

(a) to release any Lien on any property granted to or held by the Collateral Agent under any Collateral Document (i) upon payment and satisfaction in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with the terms of this Agreement, (ii) that is sold, transferred, disposed or to be sold, transferred, disposed as part of or in connection with any sale, transfer or other disposition (other than any sale to a Credit Party) permitted hereunder, (iii) subject to Section 11.5, if approved, authorized or ratified in writing by the Required Lenders, or (iv) to the extent such property is owned by a Guarantor, upon the release of such Guarantor from its obligations under the Loan Documents pursuant to clause (c) below;

(b) to subordinate any Lien on any property granted to or held by the Collateral Agent under any Loan Document to the holder of any Lien on such property that is permitted by clause (d), (i), (j), (m), (n) and (r) of the definition of "Permitted Liens" (solely with respect to modifications, replacements, extensions or renewals of Liens permitted under clause (d), (i), (j), (m) and (n) of the definition of "Permitted Liens");

(c) to release any Guarantor (other than Parent or Borrower) from its obligations under each Collateral Document if such Person ceases to be a Subsidiary as a result of a transaction permitted hereunder or upon payment and satisfaction in full of all Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with this Agreement;

(d) to enter into non-disturbance and similar agreements in connection with the licensing of Intellectual Property permitted pursuant to the terms of this Agreement; and

(e) to enter into any subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt.

Without prejudice to the obligation to fulfill the foregoing, upon request by the Collateral Agent at any time the Required Lenders will confirm in writing the Collateral Agent's authority to release or subordinate its interest in particular types or items of property, or to release any Guarantor (other than Parent or Borrower) from its obligations under each Collateral Document pursuant to this Section 12.8.

In each case as specified in this Section 12.8, the Collateral Agent will (and each Lender irrevocably authorizes and instructs the Collateral Agent to), at Borrower's expense, execute and deliver to the applicable Credit Party such documents as such Credit Party may reasonably request (i) to evidence the release or subordination of such item of Collateral from the Liens and security interests granted under the Collateral Documents, (ii) to enter into non-disturbance or similar agreements in connection with the licensing of Intellectual Property, (iii) to enter into any subordination, intercreditor or other similar agreement with respect to any Permitted Indebtedness that constitutes Subordinated Debt or (iv) to evidence the release of any Guarantor (as applicable) from its obligations under each Collateral Document, in each case in accordance with the terms of the Loan Documents and this Section 12.8 and in form and substance reasonably acceptable to the Collateral Agent.

Without limiting the generality of Section 12.10 below, the Collateral Agent shall deliver to the Lenders notice of any action taken by it under this Section 12.8 promptly after the taking thereof; provided that delivery of or failure to deliver any such notice shall not affect the Collateral Agent's rights, powers, privileges and protections under this Section 12.

12.9 Reimbursement by Lenders

. To the extent that Borrower for any reason fails to indefeasibly pay any amount required under Section 2.4 to be paid by it to the Collateral Agent (or any sub-agent thereof) or any Related Party of any of the foregoing, each Lender severally agrees to pay to the Collateral Agent (or any such sub-agent) or such Related Party, as the case may be, such Lender's *pro rata* share (based upon the percentages as used in determining the Required Lenders as of the time that the applicable unreimbursed expense or indemnity payment is sought) of such unpaid amount; provided that the unreimbursed expense or indemnified loss, damage, liability or related expense, as the case may be, was incurred by or asserted against the Collateral Agent (or any such sub-agent) in its capacity as such or against any Related Party of any of the foregoing acting for the Collateral Agent (or any sub-agent) in connection with such capacity.

12.10 Notices and Items to Lenders

. The Collateral Agent shall deliver to the Lenders each notice, report, statement, approval, direction, consent, exemption, authorization, waiver, certificate, filing or other item received by it pursuant to this Agreement or any other Loan Document (including any item received by it pursuant to Section

3 or set forth on Schedule 5.14 of the Disclosure Letter); provided, that any delivery of or failure to deliver any such notice, report, statement, approval, direction, consent, exemption, authorization, waiver, certificate, filing or item shall not otherwise alter or effect the rights of the Lenders or the Collateral Agent under this Agreement or any other Loan Document or the validity of such item. In addition, to the extent the Collateral Agent or the Required Lenders deliver any notices, approvals, authorizations, directions, consents or waivers to Borrower pursuant to this Agreement or any other Loan Document, the Collateral Agent or the Required Lenders, as applicable, will also deliver such notice, approval, authorization, direction, consent or waiver to the other Lenders on or about the same time such notice, approval, authorization, direction, consent or waiver is provided to Borrower; provided, that the delivery of or failure to deliver such notice, approval, authorization, direction, consent or waiver to the other Lenders shall not in any way effect the obligations of Borrower, or the rights of the Collateral Agent or the Required Lenders, in respect of such notice, approval, authorization, direction, consent or waiver or the validity thereof.

13 DEFINITIONS

13.1 Definitions

. For the purposes of and as used in the Loan Documents: (a) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (b) except as the context otherwise requires (including to the extent otherwise expressly provided in any Loan Document), (i) references to any law, statute, treaty, order, policy, rule or regulation include any amendments, supplements and successors thereto and (ii) references to any contract, agreement, instrument or other document include any amendments, restatements, supplements or modifications thereto or thereof from time to time to the extent permitted by the provisions thereof; (c) the word "shall" is mandatory; (d) the word "may" is permissive; (e) the word "or" has the inclusive meaning represented by the phrase "and/or"; (f) the words "include", "includes" and "including" are not limiting; (g) the singular includes the plural and the plural includes the singular; (h) numbers denoting amounts that are set off in parentheses are negative unless the context dictates otherwise; (i) each authorization herein shall be deemed irrevocable and coupled with an interest; (j) all accounting terms shall be interpreted, and all determinations relating thereto shall be made, in accordance with Applicable Accounting Standards; (k) references to any time of day shall be to New York time; (l) the words "herein", "hereof", "hereby", "hereto" and "hereunder" refer to this Agreement as a whole; and (m) unless otherwise expressly provided, references to specific sections, articles, clauses, sub-clauses, annexes and exhibits are to this Agreement and references to specific schedules are to the Disclosure Letter. As used in this Agreement, the following capitalized terms have the following meanings:

"Account" means any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes all accounts receivable, book debts, and other sums owing to Credit Parties.

"Account Debtor" means any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"Acquisition" means (a) any Stock Acquisition, or (b) any Asset Acquisition.

"Additional Consideration" is defined in Section 2.7.

"Advance Request Form" means a Loan Advance Request Form in substantially the form attached hereto as Exhibit A.

"Adverse Proceeding" means any action, suit, proceeding, hearing (whether administrative, judicial or otherwise), governmental investigation or arbitration (whether or not purportedly on behalf of any Credit Party or any of its Subsidiaries) at law or in equity, or before or by any Governmental Authority, domestic or foreign (including any Environmental Claims), whether pending or, to the Knowledge of such Credit Party, threatened in writing against or adversely affecting any Credit Party or any of its Subsidiaries or any property of any Credit Party or any of its Subsidiaries.

"Affiliate" means, with respect to any Person, each other Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company or limited liability partnership, that Person's managers and members. As used in this definition, "control" means (a) direct or indirect beneficial ownership of at least fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in a Person or (b) the power to direct or cause the direction of the management of such Person by contract or otherwise. In no event shall the Collateral Agent or any Lender be deemed to be an Affiliate of Parent or any of its Subsidiaries.

"Agreement" is defined in the preamble hereof.

"Anti-Money Laundering Laws" is defined in Section 4.18(b).

"Applicable Accounting Standards" means with respect to Parent and its Subsidiaries, generally accepted accounting principles in the United States as set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination, consistently applied.

"Applicable Percentage" means, at any time: (a) with respect to the Tranche A Loan or the Tranche A Loan Amount, the percentage equal to a fraction, the numerator of which is (i) on or prior to the Tranche A Closing Date, the amount of such Lender's Tranche A Commitment at such time and the denominator of which is the Tranche A Loan Amount at such time or (ii) thereafter, the outstanding principal amount of such Lender's portion of the Tranche A Loan at such time, and the denominator of which is the aggregate outstanding principal amount of the Tranche A Term Loan at such time; (b) with respect to the Tranche B Loan or the Tranche B Loan Amount, the percentage equal to a fraction, the numerator of which is (i) on or prior to the Tranche B Closing Date, the amount of such Lender's Tranche B Commitment at such time and the denominator of which is the Tranche B Loan Amount at such time or (ii) thereafter, the outstanding principal amount of such Lender's portion of the Tranche B Loan at such time, and the denominator of which is the aggregate outstanding principal amount of the Tranche B Term Loan at such time; and (c) with respect to the Term Loans and the Term Loan Commitments, the percentage equal to a fraction, the numerator of which is, the sum of the amount of such Lender's outstanding Term Loan Commitments and the amount of such Lender's portion of the outstanding principal amount of the Term Loans at such time, and the denominator of which is the sum of the amount of all outstanding Term Loan Commitments and the aggregate outstanding principal amount of the Term Loans at such time.

"ASC" is defined in Section 1.

"Asset Acquisition" means, with respect to Parent or any of its Subsidiaries, any purchase, exclusive or nonexclusive in-license or other acquisition of any properties or assets of any other Person (including any purchase or other acquisition of any business unit, line of business or division of such Person). Notwithstanding the foregoing, "Asset Acquisition" does not include any in-license or any collaboration, co-promotion or co-marketing arrangement pursuant to which Parent or any Subsidiary acquires rights to research, develop, use, make, promote, sell or market the products of another Person.

"Available Tenor" means, as of any date of determination and with respect to the then-current Benchmark, as applicable, (a) if the then-current Benchmark is a term rate, any tenor for such Benchmark or that is or may be used for determining the length of an Interest Period or (b) otherwise, any payment period for interest calculated with reference to such Benchmark, as applicable, pursuant to this Agreement as of such date.

"Bankruptcy Code" means Title 11 of the United States Code entitled "Bankruptcy," as now and hereafter in effect, or any successor statute (and any foreign equivalent).

"Benchmark" means, initially, USD LIBOR; provided, that if a replacement of the Benchmark has occurred pursuant to Section 2.3(e), then "Benchmark" means the applicable Benchmark Replacement to the extent that such Benchmark Replacement has replaced such prior benchmark rate. Any reference to "Benchmark" shall include, as applicable, the published component used in the calculation thereof.

"Benchmark Replacement" means, for any Available Tenor:

(a) For purposes of Section 2.3(e)(i), the first alternative below that can be determined by the Collateral Agent:

(i) the sum of: (i) Term SOFR and (ii) 0.11448% (11.448 basis points) for an Available Tenor of one-month's duration, 0.26161% (26.161 basis points) for an Available Tenor of three-months' duration, and 0.42826% (42.826 basis points) for an Available Tenor of six-months' duration, or

(ii) the sum of: (i) Daily Simple SOFR and (ii) the spread adjustment selected or recommended by the Relevant Governmental Body for the replacement of the tenor of USD LIBOR with a SOFR-based rate having approximately the same length as the interest payment period specified in Section 2.3(e)(i); and

(b) For purposes of Section 2.3(e)(ii), the sum of: (i) the alternate benchmark rate and (ii) an adjustment (which may be a positive or negative value or zero), in each case, that has been selected by the Collateral Agent as the replacement for such Available Tenor of such Benchmark giving due consideration to any evolving or then-prevailing market convention, including any applicable recommendations made by the Relevant Governmental Body, for U.S. dollar-denominated syndicated or bilateral credit facilities at such time;

provided that, if the Benchmark Replacement as determined pursuant to clause (a) or (b) above would be less than the Floor, the Benchmark Replacement will be deemed to be the Floor for the purposes of this Agreement and the other Loan Documents.

"Benchmark Replacement Conforming Changes" means, with respect to any Benchmark Replacement, any technical, administrative or operational changes (including changes to the definition of the definition of "Business Day," the definition of "Interest Period," timing and frequency of determining rates and making payments of interest, timing of borrowing requests or prepayment notices and other technical, administrative or operational matters) that the Collateral Agent decides may be appropriate to reflect the adoption and implementation of such Benchmark Replacement and to permit the administration thereof by the Collateral Agent in a manner substantially consistent with market practice (or, if the Collateral Agent decides that adoption of any portion of such market practice is not administratively feasible or if the Collateral Agent determines that no market practice for the administration of such Benchmark Replacement exists, in such other manner of administration as the Collateral Agent decides is reasonably necessary in connection with the administration of this Agreement and the other Loan Documents).

"Benchmark Transition Event" means, with respect to any then-current Benchmark other than USD LIBOR, the occurrence of a public statement or publication of information by or on behalf of the administrator of the then-current Benchmark, the regulatory supervisor for the administrator of such Benchmark, the Board of Governors of the Federal Reserve System, the Federal Reserve Bank of New York, an insolvency official with jurisdiction over the administrator for such Benchmark, a resolution authority with jurisdiction over the administrator for such Benchmark or a court or an entity with similar insolvency or resolution authority over the administrator for such Benchmark, announcing or stating that (a) such administrator has ceased or will cease on a specified date to provide all Available Tenors of such Benchmark, permanently or indefinitely, provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark or (b) all Available Tenors of such Benchmark are or will no longer be representative of the underlying market and economic reality that such Benchmark is intended to measure and that representativeness will not be restored.

"Board of Directors" means, with respect to any Person, (i) in the case of any corporation, the board of directors of such Person, (ii) in the case of any limited liability company, the board of managers of such Person, or if there is none, the Board of Directors of the managing member of such Person, (iii) in the case of any partnership or exempted limited partnership, the Board of Directors of the general partner of such Person and (iv) in any other case, the functional equivalent of the foregoing.

"Board of Governors" means the Board of Governors of the United States Federal Reserve System, or any successor thereto.

"Books" means all books and records including ledgers, records regarding a Credit Party's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Borrower" is defined in the preamble hereof.

"Borrowing Resolutions" means, with respect to any Credit Party, those resolutions adopted by such Credit Party's Board of Directors and delivered by such Credit Party to the Collateral Agent pursuant to Section 3.1(d) or Section 3.2(b), as applicable, approving the Loan Documents to which such Credit Party is a party and the transactions contemplated thereby (including the Term Loans).

"Business Day" means any day that is not a Saturday or a Sunday or a day on which banks are authorized or required to be closed in New York, New York, London, England or Tel Aviv, Israel.

"Capital Lease" means, as applied to any Person, any lease of, or other arrangement conveying the right to use, any property by that Person as lessee that has been or should be accounted for as a capital lease on a balance sheet of such Person prepared in accordance with Applicable Accounting Standards (subject to Section 1 hereof).

"Capital Lease Obligations" means, at any time, with respect to any Capital Lease, any lease entered into as part of any sale leaseback transaction of any Person or any synthetic lease, the amount of all obligations of such Person that is (or that would be, if such synthetic lease or other lease were accounted for as a Capital Lease) capitalized on a balance sheet of such Person prepared in accordance with Applicable Accounting Standards.

"Cash Equivalents" means

(a) securities issued or directly and fully guaranteed or insured by the United States government or any agency or instrumentality of the United States government or by the government of Israel or any other member country of the Organisation for Economic Co-operation and Development ("OECD") (provided that the full faith and credit of the United States or such other member country of OECD, as applicable, is pledged in support of those securities) or any agency or instrumentality of Israel or the OECD, in each case, having maturities of not more than two (2) years from the date of acquisition;

(b) certificates of deposit, time deposits with maturities of one year or less from the date of acquisition, bankers' acceptances with maturities not exceeding one year and overnight bank deposits and demand deposits, in each case, with any commercial bank having (i) capital and surplus in excess of $500,000,000 in the case of U.S. banks or (ii) capital and surplus in excess of $100,000,000 (or the U.S. dollar equivalent as of the date of determination) in the case of non-U.S. banks or a rating for its long-term unsecured and noncredit enhanced debt obligations of "A" or higher by Standard & Poor's Rating Services or Fitch Ratings Ltd or "A2" or higher by Moody's Investors Service Limited;

(c) commercial paper or marketable short-term money market or readily marketable direct obligations and similar securities having a credit rating of either A-1 or higher by Standard & Poor's Rating Service or F1 or higher by Fitch Ratings Ltd or P-1 or higher Moody's Investors Service Limited, and, in each case, maturing within two (2) years after the date of acquisition;

(d) repurchase obligations with a term of not more than seven (7) days for underlying securities of the types described in clauses (a) and (c) above entered into with any financial institution meeting the qualifications specified in clause (b) above;

(e) investment funds investing ninety-five percent (95.0%) of their assets in securities of the types described in clauses (a) through (d) above and clause (f) below;

(f) investments in money market funds which have a credit rating of either A-1 or higher by Standard & Poor's Rating Service or F1 or higher by Fitch Ratings Ltd or P-1 or higher by Moody's Investors Service Limited (or, if at any time none of Fitch Ratings Ltd, Moody's Investors Service Limited or Standard & Poor's Rating Service shall be rating such obligations, an equivalent rating from another rating agency) and that have portfolio assets of at least $1,000,000,000; and

(g) other investments in accordance with the Borrower's investment policy as of the Tranche A Closing Date or otherwise approved in writing by the Collateral Agent.

"CCPA" means the provisions and implementing regulations of the California Consumer Privacy Act, as amended and codified at Cal. Civ. Code § 1798.100 *et seq*.

"Change in Control" means: (a) a transaction or series of transactions (including any merger or consolidation involving Borrower or Parent) whereby any "person" or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act, but excluding any employee benefit plan of such Person or its Subsidiaries, and any Person acting in its capacity as trustee, agent or other fiduciary or administrator of any such plan) (i) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of fifty percent (50.0%) or more of any class of outstanding Equity Interests of Parent ordinarily entitled to vote in the election of directors (or compatible voting Equity Interests), or (ii) obtains the power (whether or not exercised) to elect a majority of directors of Parent; (b) a sale, directly or indirectly, of all or substantially all of the consolidated assets of Parent and its Subsidiaries or of Borrower and its Subsidiaries, as the case may be, in one transaction or a series of transactions (whether by way of merger, stock purchase, asset purchase or otherwise); (c) a merger or consolidation involving Borrower or Parent, as the case may be, in which Borrower or Parent (as applicable) is not the surviving Person; or (d) Parent ceasing to own, directly or indirectly, 100% of the outstanding Equity Interests of Borrower in one transaction or a series of transactions.

"Change in Law" means the occurrence, after the date of this Agreement, of any of the following: (a) the adoption or taking into effect of any law, treaty, order, policy, rule or regulation, (b) any change in any law, treaty, order, policy, rule or regulation or in the administration, published interpretation or application thereof by any Governmental Authority or (c) the making or issuance of any request, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided that notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"Closing Date" means the Tranche A Closing Date or the Tranche B Closing Date, as applicable.

"Code" means the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 of the Code shall govern; provided, further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, the Collateral Agent's Lien, for the benefit of Lenders and the other Secured Parties, on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"Collateral" means, collectively, "Collateral", as such term is defined in the Security Agreement, "Charged Assets", as such term is defined in the Israeli Security Agreement, and any and all other assets and properties of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Collateral Document, but in any event excluding all Excluded Property.

"Collateral Access Agreement" means an agreement, in form and substance reasonably satisfactory to the Collateral Agent and to which the Collateral Agent is a party, pursuant to which a mortgagee or lessor of real property on which Collateral is stored or otherwise located, or a warehouseman, processor or other bailee of Inventory or other property owned by any Credit Party, acknowledges the Liens and security interests of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, and waives (or, if approved by the Collateral Agent in its sole discretion, subordinates) any Liens or security interests held by such Person on any such Collateral, and, in the case of any such agreement with a mortgagee or lessor, permits the Collateral Agent and any Lender (and its representatives and designees) reasonable access to any Collateral stored or otherwise located thereon.

"Collateral Account" means any Deposit Account of a Credit Party maintained with a bank or other depository or financial institution located in the United States, any Securities Account of a Credit Party maintained with a securities intermediary located in the United States, or any Commodity Account of a Credit Party maintained with a commodity intermediary located in the United States, in each case, other than an Excluded Account.

"Collateral Agent" is defined in the preamble hereof.

"Collateral Documents" means the Security Agreement, the Israeli Security Agreement, the Control Agreements, the IP Agreements, any Mortgages and all other instruments, documents and agreements delivered by any Credit Party pursuant or incidental to this Agreement or any of the other Loan Documents, in each case, in order to grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, or perfect a Lien on any Collateral as security for the Obligations, and all amendments, restatements, modifications or supplements thereof or thereto.

"Commodity Account" means any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"Common Rule" means the U.S. Federal Policy for the Protection of Human Subjects, codified at 45 C.F.R. part 46, and any foreign (or United States state) equivalents.

"Company IP" means any and all of the following, as they exist in and throughout the Territory: (a) Current Company IP; (b) improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications with respect to any Current Company IP, any patent issued with respect to any of the Current Company IP, including any patent right claiming the apparatus, system, component or composition of matter of, or the method of making or using, Product in the Territory, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent and all foreign and international counterparts of any of the foregoing, and any confirmation patent or registration patent or patent of addition based on any such patent; (c) trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how, operating manuals, confidential or proprietary information, research in progress, algorithms, data, databases, data collections, designs, processes, procedures, methods, protocols, materials, formulae, drawings, schematics, blueprints, flow charts, models, strategies, prototypes, techniques, and the results of experimentation and testing, including samples, in each case, as specifically related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory; and (d) to the extent not described in clauses (a), (b) or (c) above, any and all IP Ancillary Rights specifically relating to any of the foregoing (other than all income, royalties, proceeds and liabilities at any time due and payable or asserted under or with respect to any of the foregoing), including, for the avoidance of doubt, all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights.

"Company IP Agreement" means each material contract or agreement, pursuant to which Parent or any of its Subsidiaries has the legal right to exploit Current Company IP or other Intellectual Property that is owned by another Person and material to the business of Parent and its Subsidiaries, to research, develop, manufacture, produce, use, supply, commercialize, market, import, store, transport, offer for sale, distribute or sell Product, including (a) the License Agreement, dated as of November 8, 2019, by and between Parent and Agenus Inc., and (b) the Collaboration Agreement, effective as of October 14, 2020, by and between Parent and The University of Texas M.D. Anderson Cancer Center.

"Competitor" means, at any time of determination, any Person that is engaged in the same, substantially the same or similar line of business as Parent and its Subsidiaries as of such time.

"Compliance Certificate" means that certain certificate in the form attached hereto as Exhibit E.

"Connection Income Taxes" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

"Contingent Obligation" means, for any Person, (a) any direct or indirect liability, contingent or not, of that Person for any indebtedness, lease, dividend, letter of credit or other obligation of another Person directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable (other than by endorsements of instruments in the course of collection) and (b) any obligation of that Person to pay an earn-out payment, milestone payment or similar contingent payment or contingent compensation (including purchase price adjustments but excluding royalties payable and sales milestones based on net sales) to a counterparty incurred or created in connection with an Acquisition, Transfer or Investment or otherwise in connection with any collaboration, development or similar agreement, in each instance where such contingent payment or compensation becomes due and payable upon the occurrence of an event or the performance of an act (and not solely with the passage of time). The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it reasonably determined by such Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement. Notwithstanding anything to the contrary in the foregoing, Permitted Equity Derivatives shall not constitute a Contingent Obligation.

"Control Agreement" means, with respect to any Credit Party, any control agreement entered into among such Credit Party, the Collateral Agent and, in the case of a Deposit Account, the bank or other depository or financial institution located in the United States at which such Credit Party maintains such Deposit Account, or, in the case of a Securities Account or a Commodity Account, the securities intermediary or commodity intermediary located in the United States at which such Credit Party maintain such Securities Account or Commodities Account, in either case, pursuant to which the Collateral Agent obtains control (within the meaning of the Code), or otherwise has a perfected first priority security interest (subject to any Permitted Liens), over such Collateral Account.

"Convertible Indebtedness Redemption" is defined in Section 2.2(c)(iii).

"Convertible Indebtedness Redemption Notice" is defined in Section 2.2(c)(iii).

"Copyrights" means any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret (and all related IP Ancillary Rights).

"Credit Extension" means any Term Loan or any other extension of credit by any Lender for Borrower's benefit pursuant to this Agreement.

"Credit Party" means Parent, each other Guarantor and Borrower.

"Current Company IP" is defined in Section 4.6(c).

"Daily Simple SOFR" means, for any day, SOFR, with the conventions for this rate (which will include a lookback) being established by the Collateral Agent in accordance with the conventions for this rate recommended by the Relevant Governmental Body for determining "Daily Simple SOFR" for bilateral business loans; provided, that if the Collateral Agent decides that any such convention is not administratively feasible for the Collateral Agent, then the Collateral Agent may establish another convention in its reasonable discretion.

"Data Protection Laws" means any and all applicable foreign or domestic (including U.S. federal, state and local), statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to the privacy, security, notification of breaches or confidentiality of Personal Data, including, to the extent applicable to the Parent or any of its Subsidiaries, HIPAA, Section 5 of the FTC Act and other consumer protection laws, Israeli Data Protection Law, GDPR, CCPA and genetic testing laws.

"Default" means any breach of or default under any term, provision, condition, covenant or agreement contained in this Agreement or any other Loan Document or any other event, in each case that, with the giving of notice or the lapse of time or both, would constitute an Event of Default.

"Default Rate" is defined in Section 2.3(b).

"Deposit Account" means any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"Disclosure Letter" means the disclosure letter, dated the Effective Date, delivered by the Credit Parties to the Collateral Agent pursuant to Section 3.1(a), as may be updated on the applicable Closing Date, if required, as permitted and in accordance with Section 3.1(b) and Section 3.2(a).

"Disqualified Assignee" means (a) any Competitor, or (b) any vulture or distressed debt fund.

"Disqualified Equity Interest" means any Equity Interest that, by its terms (or by the terms of any security or other Equity Interests into which it is convertible or for which it is exchangeable) or upon the happening of any event or condition: (a) matures or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise (except if redeemable or convertible into other Equity Interest that would not constitute a Disqualified Equity Interest or as a result of a change of control, asset sale or similar event so long as any and all rights of the holders thereof upon the occurrence of a change of control, asset sale or similar event shall be subject to the prior repayment in full in cash of the Term Loans and the satisfaction in full of all other Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) in accordance with the terms of this Agreement); (b) is redeemable at the option of the holder thereof, in whole or in part (except if redeemable or convertible into other Equity Interest that would not constitute a Disqualified Equity Interest or as a result of a change of control, asset sale or similar event so long as any rights of the holders thereof upon the occurrence of a change of control, asset sale or similar event shall be subject to the prior repayment in full in cash of the Term Loans and the satisfaction in full of all other Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto have been asserted) in accordance with this Agreement); (c) provides for the scheduled payments of dividends or distributions in cash; or (d) is convertible into or exchangeable for (i) Indebtedness which is not Permitted Indebtedness or (ii) any other Equity Interest that would constitute a Disqualified Equity Interest; in each case described in clauses (a) through (d) above, prior to the date that is 180 days after the Term Loan Maturity Date; provided that, if any such Equity Interest is issued pursuant to any plan for the benefit of any employee, director, manager or consultant of the Borrower or its Subsidiaries or by any such plan to such employee, director, manager or consultant, such Equity Interest shall not constitute a "Disqualified Equity Interest" solely because it may be required to be repurchased by the Borrower or its Subsidiaries in order to satisfy applicable statutory or regulatory obligations or as a result of the termination, death or disability of such employee, director, manager or consultant.

"Dollars," "**dollars**" or use of the sign "**$**" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "$" sign to denote its currency or may be readily converted into lawful money of the United States.

"Domestic Subsidiary" means, with respect to any Credit Party, a Subsidiary of such Credit Party that is incorporated or organized under the laws of the United States.

"Early Opt-in Effective Date" means, with respect to any Early Opt-in Election, the sixth (6th) Business Day after the date notice of such Early Opt-in Election is provided to the Lenders, so long as the Collateral Agent has not received, by 5:00 p.m. (New York City time) on the fifth (5th) Business Day after the date notice of such Early Opt-in Election is provided to the Lenders, written notice of objection to such Early Opt-in Election from Lenders comprising the Required Lenders.

"Early Opt-in Election" means the occurrence of:

(a) a notification by the Collateral Agent to (or the request by Borrower to the Collateral Agent to notify) each of the other parties hereto that at least five (5) currently outstanding U.S. dollar-denominated syndicated or bilateral credit facilities at such time contain (as a result of amendment or as originally executed) a SOFR-based rate (including SOFR, a term SOFR or any other rate based upon SOFR) as a benchmark rate (and such syndicated o bilateral credit facilities are identified in such notice and are publicly available for review), and

(b) the election by the Collateral Agent to trigger a fallback from USD LIBOR and the provision by the Collateral Agent of written notice of such election to Borrower and the Lenders.

"Effective Date" is defined in the preamble hereof.

"Environmental Claim" means any investigation, notice, notice of violation, claim, action, suit, proceeding, demand, abatement order or other order or directive (conditional or otherwise), by any Governmental Authority or any other Person, arising (i) pursuant to or in connection with any actual or

alleged violation of any Environmental Law; (ii) in connection with any Hazardous Material or any actual or alleged Hazardous Materials Activity; or (iii) in connection with any actual or alleged damage, injury, threat or harm to health, safety, natural resources or the environment.

"Environmental Laws" means any and all current or future, foreign or domestic, statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to (i) environmental matters, including those relating to any Hazardous Materials Activity; (ii) the generation, use, storage, transportation or disposal of Hazardous Materials; or (iii) occupational safety and health, industrial hygiene, land use or the protection of human, plant or animal health or welfare, in each case, in any manner applicable to any Credit Party or any of its Subsidiaries or any Facility.

"Equity Interests" means, with respect to any Person, collectively, any and all shares, interests, participations or other equivalents (however designated) of capital stock of a corporation, any and all equivalent ownership interests in such Person (other than a corporation), including partnership interests and membership interests, and any and all warrants, rights or options to purchase or other arrangements or rights to acquire (by purchase, conversion, dividend, distribution or otherwise) any of the foregoing (and all other rights, powers, privileges, interests, claims and other property in any manner arising therefrom or relating thereto); provided, however, that any Permitted Convertible Indebtedness or other Indebtedness convertible into Equity Interests (or into any combination of cash and Equity Interests based on the value of such Equity Interests) shall not constitute Equity Interests unless and until (and solely to the extent) so converted into Equity Interests.

"ERISA" means the Employee Retirement Income Security Act of 1974, and its regulations.

"ERISA Affiliate" means, with respect to any Person, any trade or business (whether or not incorporated) that, together with such Person, is treated as a single employer under Section 414(b) or (c) of the IRC or, solely for purposes of Section 302 of ERISA or Section 412 of the IRC, Section 412(m) or (o) of the IRC.

"ERISA Event" means (a) any "reportable event," as defined in Section 4043 of ERISA or the regulations issued thereunder, with respect to a Plan (other than an event for which the 30-day notice period is waived by regulation); (b) with respect to a Plan, the failure by Borrower or its Subsidiaries or their ERISA Affiliates to satisfy the minimum funding standard of Section 412 of the IRC and Section 302 of ERISA, whether or not waived; (c) the failure by Borrower or its Subsidiaries or their ERISA Affiliates to make by its due date a required installment under Section 430(j) of the IRC with respect to any Plan or to make any required contribution to a Multiemployer Plan; (d) the filing pursuant to Section 412(c) of the IRC or Section 302(c) of ERISA of an application for a waiver of the minimum funding standard with respect to any Plan; (e) the incurrence by Borrower or any of its ERISA Affiliates of any liability under Title IV of ERISA with respect to the termination of any Plan; (f) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates from the Pension Benefit Guaranty Corporation (referred to and defined in ERISA) or a plan administrator of any notice relating to the intention to terminate any Plan or Plans under Section 4041 or 4041A of ERISA or to appoint a trustee to administer any Plan under Section 4042 of ERISA, or the occurrence of any event or condition which could reasonably be expected to constitute grounds under ERISA for the termination of, or the appointment of a trustee to administer, any Plan under Section 4041 Section 4042 of ERISA; (g) the incurrence by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any liability with respect to the withdrawal from any Plan or Multiemployer Plan; (h) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any notice, concerning the imposition of Withdrawal Liability or a determination that a Multiemployer Plan is, or is expected to be, insolvent, within the meaning of Section 4245 or Section 4241, respectively, of ERISA; (i) the "substantial cessation of operations" by Borrower or its Subsidiaries or their ERISA Affiliates within the meaning of Section 4062(e) of ERISA with respect to a Plan; or (j) the occurrence of a nonexempt prohibited transaction (within the meaning of Section 4975 of the IRC or Section 406 of ERISA) which could reasonably be expected to result in material liability to Borrower or its Subsidiaries.

"Event of Default" is defined in Section 7.

"Exchange Act" means the Securities Exchange Act of 1934.

"Exchange Act Documents" means any and all documents filed by Parent with the SEC pursuant to the Exchange Act.

"Excluded Accounts" is defined in Section 5.5.

"Excluded Equity Interests" means, collectively: (i) any Equity Interests in any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) are validly prohibited by Requirements of Law; (ii) any Equity Interests in any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party and such consent, approval or waiver has not been obtained by Borrower following Borrower's commercially reasonable efforts to obtain the same; (iii) any Equity Interests in any Subsidiary that is a non-Wholly-Owned Subsidiary that the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, the Operating Documents or the joint venture agreement or shareholder agreement with respect to, or any other contract with such third party relating to such non-Wholly-Owned Subsidiary, including any contract evidencing Indebtedness of such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Document, joint venture agreement, shareholder agreement or other contract is in effect; and (iv) any Equity Interests in any other Subsidiary with respect to which, Borrower and the Collateral Agent reasonably determine by mutual agreement that the cost (including Tax costs) of granting the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a security interest in and Lien upon, and pledging to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Equity Interests, to secure the Obligations (and any guaranty thereof) are excessive, relative to the value to be afforded to the Secured Parties thereby.

"Excluded License" means an exclusive license or sublicense, to a Person other than a Subsidiary of Parent, of any Intellectual Property within the Territory covering a Product that is tantamount to a sale of substantially all rights to the Intellectual Property covering such Product because it conveys to the licensee or sublicensee exclusive rights to practice such Intellectual Property in the Territory for consideration that is not based upon (a) the future development or commercialization of Product in the Territory (e.g., pursuant to so-called earn-out payments or royalties based on net sales), or (b) the performance of services by the licensee or sublicensee (other than transition services), such as, for example, consideration of only upfront advances or initial license fees or similar initial payments in consideration of such rights with no anticipated subsequent payments or only *de minimis* subsequent payments to Parent or any of its Subsidiaries.

"Excluded Property" has the meaning set forth for such term in the Security Agreement.

"Excluded Subsidiaries" means, collectively: (i) any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) are validly prohibited by Requirements of Law; (ii) any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than Parent or an Affiliate of Parent) and such consent, approval or waiver has not been obtained by Parent or such Subsidiary following Parent's and such Subsidiary's commercially reasonable efforts to obtain the same; (iii) any Subsidiary that is a non-Wholly-Owned Subsidiary, with respect to which, the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, the properties and assets of such non-Wholly-Owned Subsidiary, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Parent or an Affiliate of Parent) the right to terminate its obligations under, such non-Wholly-Owned Subsidiary's Operating Documents or the joint venture agreement or shareholder agreement with respect thereto or any other contract with such third party relating to such non-Wholly-Owned Subsidiary, including any contract evidencing Indebtedness of such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Document, joint venture agreement, shareholder agreement or other contract is in effect; and (iv) any Subsidiary that owns properties and assets with an aggregate fair market value (as reasonably determined in good faith by a Responsible Officer of Parent) of less than $5,000,000; (v) any Foreign Subsidiary; and (vi) any other Subsidiary with respect to which, Parent and the Collateral Agent reasonably determine by mutual agreement that the cost (including Tax costs) of granting the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a security interest in and Lien upon, and pledging to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests of such Subsidiary to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to the Secured Parties thereby.

"Excluded Taxes" means any of the following Taxes imposed on or with respect to Lender or required to be withheld or deducted from a payment to Lender, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of Lender being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) U.S. federal withholding Taxes imposed on amounts payable to or for the account of Lender with respect to any Obligation pursuant to a law in effect on the date on which (i) Lender acquires such interest in any Obligation or (ii) Lender changes its lending office, except in each case to the extent that, pursuant to Section 2.6, amounts with respect to such Taxes were payable either to Lender's assignor immediately before Lender became a party hereto or to Lender immediately before it changed its lending office, (c) Taxes attributable to Lender's failure to comply with Section 2.6(d), and (d) any withholding Taxes imposed under FATCA.

"Export and Import Laws" means any applicable law, regulation, order or directive that applies to the import, export, re-export, transfer, disclosure or provision of goods, software, technology or technical assistance including, without limitation, restrictions or controls administered pursuant to the U.S. Export Administration Regulations, 15 C.F.R. Parts 730-774, administered by the U.S. Department of Commerce, Bureau of Industry and Security; U.S. Customs regulations; and similar import and export laws, regulations, orders and directives of other jurisdictions to the extent applicable.

"Facility" means, with respect to any Credit Party, any real property (including all buildings, fixtures or other improvements located thereon) now, hereafter or heretofore owned, leased, operated or used by such Credit Party or any of its Subsidiaries or any of their respective predecessors or Affiliates.

"FATCA" means Sections 1471 through 1474 of the IRC, as of the date of this Agreement (including, for the avoidance of doubt, any agreements between the governments of the United States and the jurisdiction in which the applicable Lender is resident implementing such provisions), or any amended or successor version that is substantively comparable and not materially more onerous to comply with, and any current or future regulations promulgated thereunder or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the IRC, any intergovernmental agreement entered into in connection with the implementation of the foregoing sections of the IRC and any fiscal or regulatory legislation, regulations, rules or practices adopted pursuant to, or official interpretations implementing such Sections of the IRC or intergovernmental agreements.

"FCA" is defined in Section 2.3(e)(i).

"FCPA" is defined in Section 4.18(a).

"FDA" means the United States Food and Drug Administration (and any foreign or United States state equivalent).

"FDA Laws" means all applicable statutes (including the FDCA), rules and regulations implemented administered or enforced by the FDA (and any foreign or United States state equivalents), including FDA Guidance Documents.

"FDA Guidance Documents" means all applicable guidance documents issued by the FDA.

"FDCA" is defined in Section 4.19(b).

"Federal Reserve Board" means the Board of Governors of the Federal Reserve System.

"Floor" means the benchmark rate floor provided in this Agreement initially (in clause (b) of the definition of "LIBOR Rate") with respect to USD LIBOR.

"Foreign Lender" means a Lender that is not a "United States person" as defined in Section 7701(a)(30) of the IRC.

"Foreign Subsidiary" means, with respect to any Credit Party, any Subsidiary of such Credit Party that is not a Domestic Subsidiary.

"Foreign Subsidiary Holdco" means, with respect to any Credit Party, a Subsidiary of such Credit Party that (i) is organized, incorporated or formed under the laws of the United States and (ii) has no material assets other than equity in one or more Foreign Subsidiaries or Indebtedness of one or more Foreign Subsidiaries and any other assets incidental thereto.

"GDPR" means, collectively, (i) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (the "**EU GDPR**") and (ii) the EU GDPR as it forms part of the laws of the United Kingdom by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (the "**UK GDPR**").

"Good Clinical Practices" means the standards set forth in 21 C.F.R. Parts 50, 54, 56, 312, 314 and 316 (and any foreign or United States state equivalents) and FDA's implementing guidance documents (and any foreign or United States state equivalents), and FDA-adopted International Council for Harmonisation ("**ICH**") Good Clinical Practice guidance, including E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1).

"Good Laboratory Practices" means the standards set forth in 21 C.F.R. Part 58 (and any foreign or United States state equivalent) and FDA's implementing guidance documents (and any foreign or United States state equivalents).

"Good Manufacturing Practices" means the standards set forth in 21 C.F.R. Parts 210, 211, 600 and 610 (and any foreign or United States state equivalents) and FDA's implementing guidance documents (and any foreign or United States state equivalents).

"Governmental Approval" means any consent, authorization, approval, licensure, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"Governmental Authority" means any nation or government, any state or other political subdivision thereof, any agency (including Regulatory Agencies), government department, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"Governmental Payor Programs" means all governmental third party payor programs in which any Credit Party or its Subsidiaries participates, including Medicare, Medicaid, TRICARE or any other U.S. federal or state health care programs.

"Guarantor" means, at any time, any Person that is, pursuant to the terms of any Loan Document, a guarantor of any of the Obligations at that time.

"Hazardous Materials" means any chemical, material or substance, exposure to which is prohibited, limited or regulated by any Governmental Authority or which may or could pose a hazard to the health and safety of the owners, occupants or any Persons in the vicinity of any Facility or to the indoor or outdoor environment.

"Hazardous Materials Activity" means any past, current, proposed or threatened activity, event or occurrence involving any Hazardous Materials, including the use, manufacture, possession, storage, holding, presence, existence, location, Release, threatened Release, discharge, placement, generation, transportation, processing, construction, treatment, abatement, removal, remediation, disposal, disposition or handling of any Hazardous Materials, and any corrective action or response action with respect to any of the foregoing.

"Health Care Laws" means, collectively: (a) applicable federal, state or local laws, rules, regulations, codes, orders, ordinances, statutes and requirements issued under or in connection with Medicare, Medicaid or any other Government Payor Program; (b) applicable federal and state laws and regulations governing the privacy, security, notification of breaches regarding and other confidentiality of health information, including HIPAA; (c) applicable federal, state and local fraud and abuse laws of any Governmental Authority, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code and the regulations promulgated pursuant to such statutes; (d) the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173) and the regulations promulgated thereunder; (e) the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h); (f) any applicable reporting and disclosure requirements, including any arising under Section 603 of the Veteran's Health Care Act (Quarterly and Annual Non-Federal Average Manufacturer Price and Federal Ceiling Price), Best Price, Federal Supply Schedule Contract Prices and Tricare Retail Pharmacy Refunds, and Medicare Part D; (g) applicable federal, state or local laws, rules, regulations, ordinances, statutes and requirements relating to (x) the regulation of managed care, third party payors and Persons bearing the financial risk for the provision or arrangement of health care services, (y) billings to insurance companies, health maintenance organizations and other Managed Care Plans or otherwise relating to insurance fraud and (z) any insurance, health maintenance organization or managed care Requirements of Law; and (h) any other applicable domestic or foreign health care laws, rules, codes, regulations, manuals, orders, ordinances, and statutes relating to the research, development, testing, approval, licensure, post-approval or post-licensure monitoring, post-approval or post-licensure requirements, post-approval or post-licensure commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of or payment for Product.

"Hedging Agreement" means any interest rate, currency, commodity or equity swap, collar, cap, floor or forward rate agreement, or other agreement or arrangement designed to protect a Person against fluctuations in interest rates, currency exchange rates or commodity or equity prices or values (including any option with respect to any of the foregoing and any combination of the foregoing agreements or arrangements), and any confirmation execution in connection with any such agreement or arrangement. Notwithstanding anything to the contrary in the foregoing, any Permitted Equity Derivative shall not constitute a Hedging Agreement.

"HIPAA" means the Health Insurance Portability and Accountability Act of 1996, as amended and supplemented by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, any and all rules or regulations promulgated from time to time thereunder, and any U.S. state or federal laws with regard to the security, privacy, or notification of breaches of the confidentiality of health information which are not preempted pursuant to 45 C.F.R. Part 160, Subpart B.

"IBA" is defined in Section 2.3(e)(i).

"IFRS" means international accounting standards within the meaning of IAS Regulation 1606/2002 to the extent applicable to the relevant financial statements.

"Indebtedness" means, with respect to any Person, without duplication: (a) all indebtedness for advanced or borrowed money of, or credit extended to, such Person; (b) all obligations issued, undertaken or assumed by such Person as the deferred purchase price of assets, properties, services or rights (other than (i) accrued expenses and trade payables entered into in the ordinary course of business which are not more than one hundred and eighty (180) days past due or subject to a bona fide dispute, (ii) obligations to pay for services provided by employees and individual independent contractors in

the ordinary course of business which are not more than one hundred and twenty (120) days past due or subject to a bona fide dispute, (iii) liabilities associated with customer prepayments and deposits, and (iv) prepaid or deferred revenue arising in the ordinary course of business), including (A) any obligation or liability to pay deferred purchase price or other similar deferred consideration for such assets, properties, services or rights where such deferred purchase price or consideration becomes due and payable solely upon the passage of time, and (B) any obligation described in clause (b) of the definition of "Contingent Obligation" that is due and payable (or that becomes due and payable) solely with the passage of time (and not upon the occurrence of an event or the performance of an act); (c) the face amount of all letters of credit issued for the account of such Person and, without duplication, all drafts drawn thereunder and all reimbursement or payment obligations with respect to letters of credit, surety bonds, performance bonds and other similar instruments issued by such Person; (d) all obligations of such Person evidenced by notes, bonds, debentures or other debt securities or similar instruments (including debt securities convertible into Equity Interests, including Permitted Convertible Indebtedness)), including obligations so evidenced incurred in connection with the acquisition of properties, assets or businesses; (e) all indebtedness of such Person created or arising under any conditional sale or other title retention agreement or incurred as financing, in either case with respect to property acquired by such Person (even though the rights and remedies of the seller or bank under such agreement in the event of default are limited to repossession or sale of such property); (f) all Capital Lease Obligations of such Person; (g) the principal balance outstanding under any synthetic lease, off-balance sheet loan or similar off balance sheet financing product by such Person; (h) Disqualified Equity Interests; (i) all indebtedness referred to in clauses (a) through (g) above of other Persons secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien upon or in assets or properties (including accounts and contracts rights) owned by such Person, even though such Person has not assumed or become liable for the payment of such indebtedness of such other Persons; and (i) all Contingent Obligations of such Person described in clause (a) of the definition thereof in respect of Indebtedness. For the avoidance of doubt, "Indebtedness" shall include Permitted Convertible Indebtedness, but shall not include any Permitted Equity Derivative.

"Indemnified Liabilities" means, collectively, any and all liabilities, obligations, losses, damages (including natural resource damages), penalties, claims, actions, judgments, suits, costs, reasonable and documented out-of-pocket fees, expenses and disbursements of any kind or nature whatsoever (including the reasonable and documented fees and disbursements of counsel for Indemnified Persons (it being agreed that such legal counsel fees and expenses shall be limited to one primary legal counsel, one local legal counsel and one intellectual property legal counsel (as and to the extent applicable) for the Indemnified Persons) in connection with any investigative, administrative or judicial proceeding or hearing commenced or threatened in writing by any Person, whether or not any such Indemnified Person shall have commenced such proceeding or hearing or be designated as a party or a potential party thereto, and any fees or expenses incurred by Indemnified Persons in enforcing the indemnity hereunder), whether direct, indirect or consequential and whether based on any federal, state or foreign laws, statutes, rules or regulations, on common law or equitable cause or on contract or otherwise, that may be imposed on, incurred by, or asserted against any such Indemnified Person, in any manner relating to or arising out of this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby (including any Lender's agreement to make Credit Extensions or the use or intended use of the proceeds thereof, or any enforcement of any of the Loan Documents (including any sale of, collection from, or other realization upon any of the Collateral or the enforcement of any guaranty of the Obligations)).

"Indemnified Person" is defined in Section 11.2(a).

"Indemnified Taxes" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of any Credit Party under any Loan Document and (b) to the extent not otherwise described in clause (a) above, Other Taxes.

"Insolvency Proceeding" means, with respect to any Person, any proceeding by or against such Person under the Bankruptcy Code, or any other domestic or foreign bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief; provided, however, that, solely with respect to any Person incorporated, organized or formed in any jurisdiction other than the United States, "Insolvency Proceeding" shall not include any winding-up petition against such Credit Party which is frivolous or vexatious and is discharged or dismissed within thirty (30) days of the commencement thereof or any step or procedure in connection with any transaction otherwise permitted under this Agreement.

"Intellectual Property" means all:

(a) Copyrights, Trademarks, and Patents;

(b) trade secrets and trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals;

(c) (i) all computer programs, including source code and object code versions, (ii) all data, databases and compilations of data, whether machine readable or otherwise, and (iii) all documentation, training materials and configurations related to any of the foregoing (collectively, "**Software**");

(d) all right, title and interest arising under any contract or Requirements of Law in or relating to Internet Domain Names;

(e) design rights;

(f) IP Ancillary Rights (including all IP Ancillary Rights related to any of the foregoing); and

(g) all other intellectual property or industrial property rights.

"Interest Date" means the last day of each calendar quarter.

"Interest Period" means (a) the period commencing on (and including) the Tranche A Closing Date and ending on (and including) the first Interest Date occurring in the calendar quarter immediately following the Tranche A Closing Date, provided, that if such Interest Date is not a Business Day, the applicable Interest Period shall end on the first Business Day immediately following such Interest Date, and (b) thereafter, each period beginning on (and including) the first day following the end of the preceding Interest Period and ending on the earlier of (and including) (x) the next Interest Date, provided, that if any such last day is not a Business Day, the applicable Interest Period shall end on the first Business Day immediately preceding such Interest Date, (y) the next Payment Date, provided, that if any such day is not a Business Day, the applicable Interest Period shall end on the first Business Day immediately following such Payment Date and (z) the Term Loan Maturity Date. For the avoidance of doubt, if an Interest Period ends on a Payment Date, the next Interest Period shall commence on (and include) the first day following such Payment Date and shall end on (and include) the earlier of the next Interest Date, the next Payment Date or the Term Loan Maturity Date, as described above.

"Interest Rate Determination Date" means (a) initially, the Closing Date and (b) thereafter, the first day of each Interest Period (or, if such day is not a Business Day, the first Business Day immediately following such day).

"Internet Domain Name" means all right, title and interest (and all related IP Ancillary Rights) arising under any contract or Requirements of Law in or relating to Internet domain names.

"Inventory" means all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes all merchandise (including Product), materials (including raw materials), parts, components (including component materials and component raw materials), supplies, packing and shipping materials, work in process and finished products, technology (including software, systems, and solutions), and all elements needed to fulfill obligations related to Product under any Manufacturing Agreements including such inventory as is temporarily out of a Credit Party's or Subsidiary's custody or possession or in transit (prior to title having transferred) and including any returned goods and any documents of title representing any of the above.

"Investment" means (a) any beneficial ownership interest in any Person (including Equity Interests), (b) any Acquisition or (c) the making of any advance, loan, extension of credit or capital contribution in or to, any Person. The amount of an Investment shall be the amount actually invested (which, in the case of any Investment by a Credit Party or any of its Subsidiaries constituting the contribution of an asset or property, shall be based on the good faith estimate of the fair market value of such asset or property at the time such Investment is made as reasonably determined by a Responsible Officer of such Credit Party), less the amount of cash received or returned for such Investment, without adjustment for subsequent increases or decreases in the value of such Investment or write-ups, write-downs or write-offs with respect thereto; provided that in no event shall such amount be less than zero.

"IP Agreements" means, collectively, (a) those certain IP Security Agreement(s) entered into by and between Parent and the Collateral Agent, dated as of the Tranche A Closing Date, and (b) any IP Security Agreement entered into by and between any relevant Credit Party and the Collateral Agent after the Tranche A Closing Date in accordance with the Loan Documents.

"IP Ancillary Rights" means, with respect to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals, all income, royalties, proceeds and liabilities at any time due or payable or asserted under or with respect to any of the foregoing or otherwise with respect thereto, including all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights.

"IP Security Agreement" means "IP Security Agreement", as such term is defined in the Security Agreement.

"IRC" means the Internal Revenue Code of 1986, as amended, or any successor statute.

"IRS" means the United States Internal Revenue Service or any successor agency.

"Israeli Data Protection Law" means, collectively, the Israeli Protection of Privacy Law, 5741-1981 (including any regulations promulgated thereunder), the Israeli Protection of Privacy (Data Security) Regulations, 5777-2017, the guidelines issued by the Israeli Privacy Protection Authority, the Israeli Basic Law: Human Dignity and Liberty, 5752-1992, the Israeli Patient's Rights Law, 5756-1996; the directives and applicable circulars issued by the Israeli Ministry of Health relating to Secondary Use of Medical Data, and other Israeli statutes and regulations concerning protection of privacy, information security, or processing of personal data.

"Israeli Security Agreement" means, collectively, (a) that certain Israeli law-governed Fixed Charge Debenture (Unlimited in Amount), dated as of the Tranche A Closing Date, by and between Parent and the Collateral Agent, for the benefit of Lenders and the other Secured Parties, pursuant to which Parent grants the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first ranking fixed charge over all of Parent's rights, title, interest and benefits in the Charged Assets (as such term is defined therein), and (b) that certain Israeli law-governed Floating Charge Debenture (Unlimited in Amount), dated as of the Tranche A Closing Date, by and between Parent and the Collateral Agent, for the benefit of Lenders and the other Secured Parties, pursuant to which Parent grants the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first ranking floating charge over all of Parent's rights, title, interest and benefits in the Charged Assets (as such term is defined therein).

"JELMYTO®" is defined in the definition of Product.

"JELMYTO® Revenue Forecast" means that certain Jelmyto Revenue Forecast included in the Project Upside Confidential Investor Model dated December 2021, made available by or on behalf of Parent to the Collateral Agent and Lenders on the Debtdomain virtual deal site for Project Upside and included in Schedule 5.17 of the Disclosure Letter.

"Knowledge" means, with respect to any Person, the actual knowledge, after reasonable investigation, of the Responsible Officers of such Person.

"Lender" means each Person signatory hereto as a "Lender" and its successors and assigns.

"Lender Expenses" means, collectively:

(a) all reasonable and documented out-of-pocket fees and expenses of the Collateral Agent and, as applicable, each Lender (and their respective successors and assigns) and their respective Related Parties (including the reasonable and documented out-of-pocket fees, expenses and disbursements of any legal counsel, manufacturing consultants or intellectual property experts therefor for the Collateral Agent, Lenders and such Related Parties taken as a whole), (i) incurred in connection with developing, preparing, negotiating, syndicating, executing and delivering, and interpreting, investigating and administering, the Loan Documents (or any term or provision thereof), any commitment, proposal letter, letter of intent or term sheet therefor or any other document prepared in connection therewith, (ii) incurred in connection with the consummation and administration of any transaction contemplated therein, (iii) incurred in connection with the performance of any obligation or agreement contemplated therein, (iv) incurred in connection with any modification or amendment of any term or provision of or any supplement to or the termination (in whole or in part) of, any Loan Document, (v) incurred in connection with internal audit reviews and Collateral audits, or (vi) otherwise incurred with respect to the Credit Parties in connection with the Loan Documents, including any filing or recording fees and expenses; and

(b) all reasonable and documented out-of-pocket costs and expenses incurred by the Collateral Agent and each Lender (and their respective successors and assigns) and their respective Related Parties (including the reasonable and documented out-of-pocket fees, expenses and disbursements of any legal counsel therefor for the Collateral Agent, Lenders and such Related Parties taken as a whole) in connection with (i) any refinancing or restructuring of the credit arrangements provided hereunder in the nature of a "work-out", (ii) the enforcement or preservation of any right or remedy under any Loan Document, any Obligation, with respect to the Collateral or any other related right or remedy, or (iii) the commencement, defense, conduct of,

intervention in, or the taking of any other action with respect to, any proceeding (including any Insolvency Proceeding) related to any Credit Party or any Subsidiary of any Credit Party in respect of any Loan Document or Obligation, or otherwise in connection with any Loan Document or Obligation (or the response to and preparation for any subpoena or request for document production relating thereto); provided, that, except with respect to an Insolvency Proceeding, to the extent such enforcement entails the Collateral Agent or any Lender commencing legal action of any sort against Borrower or Parent, any fees and expenses incurred in connection therewith shall only be payable by Borrower to the extent the Collateral Agent or any Lender is successful in such legal action.

"Lender Transfer" is defined in Section 11.1(b).

"LIBOR Rate" means, as of any Interest Rate Determination Date (and for the Interest Period that follows such Interest Rate Determination Date), the rate per annum equal to the greater of (a) USD LIBOR as published on the applicable Bloomberg LIBOR page administered by the ICE Benchmark Administration for Dollars for a period equal in length to three (3) months to such Interest Period (or, in the event such rate does not appear on such page or screen, on any successor or substitute page on such screen that displays such rate, the rate per annum equal to the rate determined by the Collateral Agent to be the average of the rates per annum at which deposits in Dollars for delivery on the first day of such Interest Period in same day funds in the approximate amount of the Term Loans with a term equivalent to such Interest Period would be offered by three (3) major banks in the London interbank Eurodollar market at their request, determined as of approximately 11:00 a.m., London time, on such Interest Rate Determination Date), and (b) 1.25% per annum. Unless otherwise specified in any amendment to this Agreement entered into in accordance with Section 2.3(e), in the event that a Benchmark Replacement with respect to the LIBOR Rate is implemented, then all references herein to LIBOR Rate shall be deemed references to such Benchmark Replacement.

"Lien" means a claim, mortgage, deed of trust, levy, charge, pledge, security interest or other encumbrance of any kind or assignment for security purposes, whether voluntarily incurred or arising by operation of law or otherwise against any property or assets.

"Loan Documents" means, collectively, this Agreement, the Disclosure Letter, the Term Loan Notes, the Security Agreement, the Israeli Security Agreement, the RTW Intercreditor Agreement, the IP Agreements, the Perfection Certificate, any Control Agreement, any Collateral Access Agreement, any other Collateral Document, any guaranties executed by a Guarantor in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties in connection with this Agreement, and any other present or future agreement between or among a Credit Party, the Collateral Agent and any Lender in connection with this Agreement, including in each case, for the avoidance of doubt, any annexes, exhibits or schedules thereto.

"Makewhole Amount" means the Tranche A Makewhole Amount or the Tranche B Makewhole Amount (as applicable) or the combination thereof, as the context dictates.

"Managed Care Plans" means all health maintenance organizations, preferred provider organizations, individual practice associations, competitive medical plans and similar arrangements.

"Manufacturing Agreement" means (a) any contract or agreement entered into on or prior to the Effective Date by any Credit Party or any of its Subsidiaries with third parties for (i) the clinical or commercial manufacture or in-bound supply in the Territory of Product for any indication, or (ii) for the commercial manufacture or in-bound supply of the active pharmaceutical ingredient incorporated therein that was included in the NDA for Product (with the Manufacturing Agreements in effect as of the Effective Date being set forth in Schedule 12.1 of the Disclosure Letter), and (b) any future contract or agreement entered into after the Effective Date by any Credit Party or any of its Subsidiaries with third parties for (i) the clinical or commercial manufacture or in-bound supply in the Territory of Product for any indication or (ii) for the commercial manufacture or in-bound supply of the active ingredient incorporated therein.

"Margin Stock" means "margin stock" within the meaning of Regulations U and X of the Federal Reserve Board as now and from time to time hereafter in effect.

"Material Adverse Change" means any material adverse change in or material adverse effect on: (a) the business, financial condition, properties or assets (including all or any portion of the Collateral that is material to the exclusivity of JELMYTO®), liabilities (actual or contingent), operations or performance of the Credit Parties, taken as a whole, since December 31, 2020; (b) without limiting the generality of clause (a) above, (i) the rights of the Credit Parties, taken as a whole, in or related to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of JELMYTO® in the Specified Territory, (ii) any rights that are material to the business and operations of the Credit Parties and their Subsidiaries, taken as a whole, under any Material Contract, or (iii) the period of regulatory exclusivity granted by the FDA for JELMYTO® (including Orphan Drug exclusivity); (c) the ability of the Credit Parties, taken as a whole, to fulfill the payment or performance obligations under this Agreement or any other Loan Document; or (d) the binding nature or validity of, or the ability of the Collateral Agent or any Lender to enforce, the Loan Documents or any of its rights or remedies under the Loan Documents (except to the extent resulting from any act or omission to act on the part of the Collateral Agent or any Lender); provided, however, that, for purposes of clauses (a) and (b) above, the parties hereto agree that no single clinical or regulatory failure shall, in and of itself, constitute or be deemed to constitute a Material Adverse Change hereunder. Notwithstanding the foregoing, none of the following events shall, in and of itself, constitute or be deemed to constitute a Material Adverse Change if and only so long as, in each case of sub-clauses (i) through (iv) below, such event does not involve or relate to JELMYTO®: (i) adverse results or delays in any nonclinical or clinical trial; (ii) the failure to achieve any clinical or non-clinical trial goals or objectives, including the failure to demonstrate the desired safety or efficacy of any drug or companion diagnostic; (iii) any denial, delay or limitation of approval of the FDA (or foreign equivalents) or any other Governmental Authority; or (iv) a change in or discontinuation of a strategic partnership or other collaboration or license arrangement.

"Material Contract" means any contract or other arrangement to which any Credit Party or any of its Subsidiaries is a party (other than the Loan Documents) or by which any of its assets or properties are bound, in each case, relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory, for which the breach of, default or nonperformance under, cancellation or termination of or the failure to renew could reasonably be expected to result in a Material Adverse Change under clauses (a), (b)(i), (b)(iii), (c) or (d) of the definition thereof. For the avoidance of doubt, each Manufacturing Agreement and each Company IP Agreement is a Material Contract and the Pre-Paid Forward Contract and each other PPFC Document is a Material Contract. For the avoidance of doubt, the following agreements are not Material Contracts: (a) any customer contracts, (b) any purchase orders or statements of work entered into from time to time in the ordinary course of business pursuant to Manufacturing Agreements, (c) agreements or other contractual arrangements in connection with capital expenditures in the ordinary course of business, (d) agreements or other contractual arrangements entered into in the ordinary course of business in connection with the purchase of materials or the sale of third party products for further distribution and (e) distribution agreements entered into in the ordinary course of business with third parties for the sale of Product in a specific territory outside of the United States.

"Medicaid" means the health care assistance program established by Title XIX of the SSA (42 U.S.C. 1396 et seq.).

"Medicare" means the health insurance program for the aged and disabled established by Title XVIII of the SSA (42 U.S.C. 1395 et seq.).

"Mortgage" means any deed of trust, leasehold deed of trust, mortgage, leasehold mortgage, deed to secure debt, leasehold deed to secure debt or other document creating a Lien on real estate or any interest in real estate.

"Multiemployer Plan" means a multiemployer plan within the meaning of Section 4001(a)(3) or Section 3(37) of ERISA (a) to which Parent or its Subsidiaries or their respective ERISA Affiliates is then making or accruing an obligation to make contributions; (b) to which Parent or its Subsidiaries or their respective ERISA Affiliates has within the preceding five (5) plan years made contributions; or (c) with respect to which Parent or its Subsidiaries could incur material liability.

"NDA" means a new drug application, submitted to the FDA pursuant to 21 U.S.C. § 355 seeking authorization to market a new drug in the United States.

"Net Sales" means, as of any date of determination, the net consolidated product revenue (consistent with the calculation of same in Parent's financial statements) of Parent and its Subsidiaries of JELMYTO® for the twelve (12) months prior to such date (excluding, for the avoidance of doubt, any (i) upfront or milestone payments received by Parent or any of its Subsidiaries, (ii) advancements, payments or reimbursements of expenses of Parent or any of its Subsidiaries, and (iii) any other non-sales-based revenue or proceeds received by Parent or any of its Subsidiaries), determined on a consolidated basis in accordance with Applicable Accounting Standards as set forth in Parent's financial statements or as otherwise evidenced in a manner reasonably satisfactory to the Required Lenders.

"Obligations" means, collectively, the Credit Parties' obligations to pay when due any and all debts, principal, interest, Lender Expenses, the Additional Consideration, the Makewhole Amount, the Prepayment Premium and any other fees, expenses, indemnities and amounts any Credit Party owes any Lender or the Collateral Agent now or later, under this Agreement or any other Loan Document, including interest accruing after Insolvency Proceedings begin (whether or not allowed), and to perform Borrower's (or Parent's, as applicable) duties under the Loan Documents.

"OFAC" is defined in Section 4.18(c).

"OFAC Lists" means, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"Operating Documents" means, collectively with respect to any Person, such Person's formation and constitutional documents and, (a) if such Person is a corporation, its bylaws (or similar organizational regulations), (b) if such Person is an exempted company or a company limited by shares, its memorandum and articles of association (or similar organizational regulations), (c) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (d) if such Person is a partnership, its partnership agreement (or similar agreement), in each case including all amendments, restatements, supplements and modifications thereto.

"ordinary course of business" means, in respect of any transaction involving any Person, the ordinary course of such Person's business, undertaken by such Person in good faith and not for purposes of evading any covenant, prepayment obligation or restriction in any Loan Document.

"Orphan Drug" means a drug that meets the definition for "orphan drug" provided in 21 C.F.R. § 316.3(b)(10), which has been granted an orphan drug designation by the Secretary of Health and Human Services or the FDA under 21 U.S.C. § 360bb.

"Other Connection Taxes" means, with respect to any Lender, Taxes imposed as a result of a present or former connection between such Lender and the jurisdiction imposing such Tax (other than connections arising solely from such Lender having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Term Loan or Loan Document).

"Other Taxes" means all present or future stamp, court or documentary, intangible, recording, excise, filing, value added Taxes, mortgage or property Taxes, charges or similar levies or similar Taxes that arise from any payment made hereunder, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to a Lender Transfer.

"Participant Register" is defined in Section 11.1(d).

"Patents" means all patents and patent applications (including any improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications), any patent issued with respect to any of the foregoing patent applications, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign and international counterparts of any of the foregoing. For the avoidance of doubt, patents and patent applications under this definition include individual patent claims and include all patents and patent applications filed with the U.S. Patent and Trademark Office or which could be nationalized in the United States.

"Patriot Act" is defined in Section 3.1(h).

"Payment Date" means, with respect to the Term Loans and as the context dictates: (a) the first Interest Date occurring in the calendar quarter immediately following the Tranche A Closing Date; (b) thereafter, each succeeding Interest Date; and (c) the Term Loan Maturity Date.

"Perfection Certificate" is defined in Section 4.6.

"Permitted Acquisition" means any Acquisition, so long as:

(a) no Default or Event of Default shall have occurred and be continuing as of, or could reasonably be expected to result from, the consummation of such Acquisition;

(b) the properties or assets being acquired or licensed, or the Person whose Equity Interests are being acquired, are useful in or engaged in, as applicable, (i) the same, similar or related line of business as that then-conducted by Parent and its Subsidiaries, or (ii) a line of business that is related or ancillary to or in furtherance of a line of business as that then-conducted by Parent and its Subsidiaries;

(c) in the case of any Asset Acquisition, any and all assets are being acquired or licensed in such Acquisition by a Credit Party and, within the timeframes expressly set forth in Section 5.12 with respect to all such assets constituting Collateral, such Credit Party shall have executed and delivered or authorized, as applicable, any and all joinders, security agreements, financing statements and any other documentation, and made such other deliveries, required by Section 5.12 or reasonably requested by the Collateral Agent in order to include such newly acquired or licensed assets within the Collateral, in each case to the extent required by Section 5.12;

(d) in the case of any Stock Acquisition, any and all Equity Interests are being acquired in such Acquisition directly by a Credit Party and, within the timeframes expressly set forth in Section 5.13, such Credit Party shall have complied with its obligations under Section 5.13, in each case to the extent such Equity Interests are subject thereto; and

(e) any Indebtedness or Liens assumed in connection with such Acquisition are otherwise permitted under Section 6.4 or 6.5, respectively.

"Permitted Convertible Indebtedness" means Indebtedness of the Parent or any Subsidiary of Parent that is a Credit Party having a feature which entitles the holder thereof in certain circumstances to convert or exchange all or a portion of such Indebtedness into Equity Interests in Parent or such Subsidiary (or other securities or property following a merger event or other change of the common stock of Parent or such Subsidiary), cash or any combination of cash and such Equity Interests (or such other securities or property) based on the market price of such Equity Interests (or such other securities or property); provided, however, that (a) such Indebtedness shall be unsecured, (b) such Indebtedness shall not be guaranteed by any Subsidiary of Parent, (c) such Indebtedness shall bear interest at a rate per annum not to exceed five percent (5.0%), (d) such Indebtedness shall not include covenants and defaults (other than covenants and defaults customary for convertible indebtedness but not customary for loans, as determined by Parent in its good faith judgment) that are, taken as a whole, more restrictive on the Credit Parties than the provisions of this Agreement (as determined by Parent in its good faith judgment), (e) immediately prior to and after giving effect to the incurrence of such Indebtedness, no Default or Event of Default shall have occurred and be continuing or could reasonably be expected to occur as a result therefrom (after giving effect to this Agreement), (f) such Indebtedness shall not (i) mature or be mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, (ii) be redeemable at the option of the holder thereof, in whole or in part or (iii) provide for the scheduled payment of dividends or distributions (other than scheduled cash interest payments) in cash, in each case of the foregoing sub-clauses (i), (ii) and (iii), earlier than twelve (12) months after the Term Loan Maturity Date (it being understood, for the avoidance of doubt, that (w) a redemption right of Parent or such Subsidiary in respect of such Indebtedness, (x) conversion rights of holders in respect of such Indebtedness, (y) acceleration rights of holders of such Indebtedness upon the occurrence of an event of default specified in the agreement governing such Indebtedness and (z) the obligation to pay customary amounts to holders of such Indebtedness in connection with a "change of control" or "fundamental change", in each case, shall not be considered in connection with the determination of scheduled maturity date for purposes of this clause (f)); (g) immediately after giving effect to the creation, incurrence or assumption of any such Indebtedness, the amount of all Permitted Convertible Indebtedness then-outstanding shall not exceed $200,000,000 in the aggregate; (h) as of the date of pricing for, and as of the Trading Day immediately preceding the creation, incurrence or assumption of, any such Indebtedness, (i) Parent's market capitalization is greater than $750,000,000, and (ii) either (A) the trailing twelve-month Net Sales of JELMYTO® are greater than $150,000,000 or (B) the first FDA approval of UGN-102 has been obtained for marketing and distribution in the United States; and (h) Parent shall have delivered to the Collateral Agent a certificate of a Responsible Officer of Parent certifying as to the foregoing clauses (a) through (h) with respect to any such Indebtedness.

"Permitted Distributions" means, in each case subject to Section 6.8 if applicable:

(a) dividends, distributions or other payments by any Wholly-Owned Subsidiary of Parent on its Equity Interests to, or the redemption, retirement or purchase by any Wholly-Owned Subsidiary of Parent of its Equity Interests from, Parent or any other Wholly-Owned Subsidiary of Parent;

(b) dividends, distributions or other payments by any non-Wholly-Owned Subsidiary on its Equity Interests to, or the redemption, retirement or purchase by any non-Wholly-Owned Subsidiary of its Equity Interests from, Parent or any other Subsidiary or each other owner of such non-Wholly-Owned Subsidiary's Equity Interests based on their relative ownership interests of the relevant class of such Equity Interests;

(c) exchanges, redemptions or conversions by Parent in whole or in part any of its Equity Interests for or into another class of its Equity Interests or rights to acquire its Equity Interests or with proceeds from substantially concurrent equity contributions or issuances of new Equity Interests;

(d) any such payments arising from a Permitted Acquisition or other Permitted Investment by Parent or any of its Subsidiaries;

(e) the payment of dividends by Borrower solely in non-cash pay and non-redeemable capital stock (including, for the avoidance of doubt, dividends and distributions payable solely in Equity Interests);

(f) cash payments in lieu of the issuance of fractional shares arising out of stock dividends, splits or combinations or in connection with the exercise of warrants, options or other securities convertible into or exchangeable for Equity Interests;

(g) in connection with any Acquisition or other Investment by Parent or any of its Subsidiaries, (i) the receipt or acceptance of the return to Parent or any of its Subsidiaries of Equity Interests of Parent constituting a portion of the purchase price consideration in settlement of indemnification claims, or as a result of a purchase price adjustment (including earn-outs or similar obligations) and (ii) payments or distributions to equity holders pursuant to appraisal rights required under Requirements of Law;

(h) the distribution of rights pursuant to any shareholder rights plan or the redemption of such rights for nominal consideration in accordance with the terms of any shareholder rights plan;

(i) dividends, distributions or payments on its Equity Interests by any Subsidiary to any Credit Party;

(j) dividends, distributions or payments on its Equity Interests by any Subsidiary that is not a Credit Party to any other Subsidiary that is not a Credit Party;

(k) purchases of Equity Interests of Parent or its Subsidiaries in connection with the exercise of stock options by way of cashless exercise, or in connection with the satisfaction of withholding tax obligations;

(l) issuance to directors, officers, employees or contractors of Borrower of common stock of Borrower upon the vesting of restricted stock, restricted stock units, or other rights to acquire common stock of Borrower, in each case pursuant to plans or agreements approved by Borrower's Board of Directors or stockholders;

(m) the repurchase, retirement or other acquisition or retirement for value of Equity Interests of Parent or any of its Subsidiaries held by any future, present or former employee, consultant, officer or director (or spouse, ex-spouse or estate of any of the foregoing or trust for the benefit of any of the foregoing or any lineal descendants thereof) of Parent or any of its Subsidiaries pursuant to any management equity plan or stock option plan or any other management or employee benefit plan or agreement, or any stock subscription or shareholder agreement or employment agreement; provided, however, that the aggregate payments made under this clause (m) do not exceed in any calendar year the sum of (i) $3,000,000 plus (ii) the amount of any payments received in such calendar year under key-man life insurance policies;

(n) dividends or distributions on its Equity Interests by Parent or any of its Subsidiaries payable solely in additional shares of its common stock; and

(o) solely in connection with Permitted Convertible Indebtedness and any Refinancing Convertible Debt relating thereto, the Credit Parties or its Subsidiaries may enter into Permitted Equity Derivatives (and may settle, terminate or unwind any such Permitted Equity Derivatives in connection with any refinancing, early conversion or maturity of such Permitted Convertible Indebtedness).

"Permitted Equity Derivative" means any call or capped option (or substantively equivalent equity derivative transaction) or call spread transaction relating to the Equity Interests of Parent or any other Credit Party purchased by Parent or such Credit Party in connection with the issuance of Permitted Convertible Indebtedness and any Refinancing Convertible Debt relating thereto by Parent or such other Credit Party, provided, that the purchase price for such call or capped option does not exceed the net cash proceeds received by Parent or such other Credit Party from the issuance of such Permitted Convertible Indebtedness or Refinancing Convertible Debt.

"Permitted Indebtedness" means:

(a) Indebtedness of the Credit Parties to Secured Parties under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and shown on Schedule 12.2 of the Disclosure Letter;

(c) Permitted Convertible Indebtedness not to exceed $200,000,000 in the aggregate at any time outstanding; provided that Permitted Convertible Indebtedness will not be deemed to be outstanding, to the extent that in connection with the issuance of any Refinancing Convertible Debt, the Permitted Convertible Indebtedness to be refinanced is cancelled within three (3) Business Days of the incurrence of such Refinancing Convertible Debt;

(d) Indebtedness not to exceed $5,000,000 in the aggregate at any time outstanding, consisting of (i) Indebtedness incurred to finance the purchase, construction, repair, or improvement of fixed assets and (ii) Capital Lease Obligations;

(e) Indebtedness in connection with trade credit, corporate credit cards, purchasing cards or bank card products, provided, that any such Indebtedness that is secured shall not exceed $1,000,000 in the aggregate at any time outstanding;

(f) guarantees of Permitted Indebtedness;

(g) Indebtedness consisting of indemnity obligations and royalty payments or sales milestones based on net sales incurred in connection with any Permitted Acquisition, Permitted Transfer, Permitted Investment or any in-licensing or any collaboration, co-promotion or co-marketing arrangement; in each instance only if such Indebtedness is due and payable upon the occurrence of an event or the performance of an act (and not solely with the passage of time);

(h) Indebtedness of Parent or any of its Subsidiaries with respect to letters of credit, bank guarantees, bankers' acceptances, warehouse receipts or similar instruments outstanding and to the extent secured, secured solely by cash or Cash Equivalents, in each case entered into in the ordinary course of business;

(i) Indebtedness owed: (i) by a Credit Party to another Credit Party; (ii) by a Subsidiary of Parent that is not a Credit Party to another Subsidiary of Parent that is not a Credit Party; (iii) by a Credit Party to a Subsidiary of Parent that is not a Credit Party; or (iv) by a Subsidiary of Parent that is not a Credit Party to a Credit Party, not to exceed $5,000,000 in the aggregate at any time outstanding;

(j) Indebtedness consisting of Contingent Obligations described in clause (a) of the definition thereof: (i) of a Credit Party of Permitted Indebtedness of another Credit Party (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder); (ii) of a Subsidiary of Parent which is not a Credit Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of another Subsidiary of Parent which is not a Credit Party; (iii) of a Subsidiary of Parent which is not a Credit Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of a Credit Party; or (iv) of a Credit Party of Permitted Indebtedness (or obligations that do not constitute Indebtedness hereunder and are not prohibited hereunder) of a Subsidiary of Parent which is not a Credit Party not to exceed $10,000,000 in the aggregate at any time outstanding;

(k) Indebtedness not to exceed $5,000,000 in the aggregate at any time outstanding *plus* any additional amounts payable in Equity Interests and cash in lieu of fractional shares consisting of earn-outs and other obligations in respect of deferred purchase price of assets, property, services or rights, incurred in connection with any Permitted Acquisition, Permitted Transfer, Permitted Investment or any in-licensing or any collaboration, co-promotion or co-marketing arrangement;

(l) Indebtedness of any Person that becomes a (direct or indirect) Subsidiary of Parent (or of any Person not previously a Subsidiary that is merged or consolidated with or into a Subsidiary of Parent in a transaction permitted hereunder) after the Effective Date; provided, that all such Indebtedness is at all times Subordinated Debt;

(m) (i) Indebtedness with respect to workers' compensation claims, payment obligations in connection with health, disability or other types of social security benefits, unemployment or other insurance obligations, reclamation and statutory obligations or (ii) Indebtedness related to employee benefit plans, including annual employee bonuses, accrued wage increases and 401(k) plan matching obligations; in each case, incurred in the ordinary course of business;

(n) Indebtedness in respect of performance bonds, bid bonds, appeal bonds, surety bonds and completion guarantees and similar obligations arising in the ordinary course of business;

(o) Indebtedness in respect of netting services, overdraft protection and other cash management services, in each case in the ordinary course of business;

(p) Indebtedness consisting of the financing of insurance premiums in the ordinary course of business;

(q) Indebtedness consisting of guarantees resulting from endorsement of negotiable instruments for collection by any Credit Party in the ordinary course of business;

(r) unsecured Indebtedness incurred in connection with any items of Permitted Distributions in clause (m) of the definition of "Permitted Distributions";

(s) other unsecured Indebtedness in an aggregate amount not to exceed $5,000,000 at any time outstanding; and

(t) subject to the proviso immediately below, extensions, refinancings, renewals, modifications, amendments, restatements and, in the case of any items of Permitted Indebtedness in clause (b) of the definition thereof or Permitted Indebtedness constituting notes governed by an indenture (including Permitted Convertible Indebtedness), exchanges, of any items of Permitted Indebtedness in clauses (a) through (s) above, provided, that in the case of clause (b) above, the principal amount thereof is not increased (other than by any reasonable amount of premium (if any), interest (including post-petition interest), fees, expenses, charges or additional or contingent interest reasonably incurred in connection with the same and the terms thereof); provided, further, that in the case of any Indebtedness permitted under clause (c) of the definition thereof, (x) the maturity thereof is not shortened to before the Term Loan Maturity Date, (y) the amount of such Indebtedness at the time of, and taking into effect, such extension, refinancing, renewal, modification, amendment, restatement or exchange, together with all other Permitted Convertible Indebtedness then-outstanding, does not exceed $200,000,000 in the aggregate, and (z) there is no change to or addition of any direct or indirect obligor with respect thereto.

Notwithstanding the foregoing, "Permitted Indebtedness" shall not include any Hedging Agreements.

Notwithstanding the foregoing or anything in this Agreement to the contrary, no direct or indirect synthetic royalty or similar financing transaction involving the sale of revenues or royalties entered into after the Tranche A Closing Date and, except to the extent incurred in connection with any Permitted Acquisitions, Permitted Investments, in-licensing agreements or any collaboration, co-promotion or co-marketing arrangements, in each case entered into by any Credit Party or any of its Subsidiaries, no Indebtedness constituting royalty payments or sales milestones based on net sales that is, directly or indirectly, created, incurred, assumed or guaranteed after the Tranche A Closing Date by a Credit Party or any of its Subsidiaries, shall in any instance be permitted under this Agreement without the prior written consent of the Collateral Agent or the Required Lenders.

"Permitted Investments" means:

(a) Investments (including Investments in Subsidiaries) existing on the Effective Date and shown on Schedule 12.3 of the Disclosure Letter, including any extensions, renewals or reinvestments thereof;

(b) Investments consisting of cash and Cash Equivalents;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business;

(d) subject to Section 5.5, Investments consisting of deposit accounts or securities accounts;

(e) Investments in connection with Permitted Transfers;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of accounts receivable of, or prepaid royalties and other credit extensions or advances, to customers, suppliers or manufacturers who are not Affiliates, in the ordinary course of business or otherwise to support capacity demand; provided that this clause (h) shall not apply to Investments of any Credit Party in any of its Subsidiaries;

(i) joint ventures or strategic alliances consisting of the licensing or development of technology or the providing of technical support;

(j) Investments (i) required in connection with a Permitted Acquisition (including the formation of any Subsidiary for the purpose of effectuating such Permitted Acquisition, the capitalization of such Subsidiary whether by capital contribution or intercompany loans to the extent otherwise permitted by the terms of this Agreement, related Investments in Subsidiaries necessary to consummate such Permitted Acquisition and the receipt of any non-cash consideration in such Permitted Acquisition) and (ii) consisting of earnest money or escrow deposits required in connection with a Permitted Acquisition or other acquisition of properties or assets not otherwise prohibited hereunder;

(k) Investments constituting the formation of any Subsidiary for the purpose of consummating a merger or acquisition transaction permitted by Section 6.3(a)(i) through (iv) hereof, which such transaction is otherwise a Permitted Investment;

(l) Investments of any Person that (i) becomes a Subsidiary of Parent (or of any Person not previously a Subsidiary of Parent that is merged or consolidated with or into a Subsidiary of Parent in a transaction permitted hereunder) after the Effective Date, or (ii) are assumed after the Effective Date by Parent or any Subsidiary of Parent in connection with an acquisition of assets from such Person by Parent or such Subsidiary, in either case, in a Permitted Acquisition; provided, that in each case, any such Investment (x) exists at the time such Person becomes a Subsidiary of Parent (or is merged or

consolidated with or into a Subsidiary of Parent) or such assets are acquired, (y) was not made in contemplation of or in connection with such Person becoming a Subsidiary of Parent (or merging or consolidating with or into a Subsidiary of Parent) or such acquisition of assets, and (z) could not reasonably be expected to result in a Default or an Event of Default;

(m) Investments arising as a result of the licensing of Intellectual Property in the ordinary course of business and not prohibited under this Agreement;

(n) to the extent constituting an Investment, any Permitted Equity Derivative, including the payment of premiums in connection therewith;

(o) Investments by: (i) any Credit Party in any other Credit Party; (ii) any Subsidiary of Parent which is not a Credit Party in another Subsidiary of Parent which is not a Credit Party; (iii) any Subsidiary of Parent which is not a Credit Party in any Credit Party; (iv) any Credit Party in a Subsidiary of Parent which is not a Credit Party, not to exceed $5,000,000 in the aggregate outstanding at any time; and (v) Parent and its Subsidiaries consisting of Equity Interests in their respective Subsidiaries existing on (x) the Tranche A Closing Date and (y) each other Closing Date, in each case of this sub-clause (y), only if the formation or acquisition of, or merger or consolidation resulting in a Person becoming, a Subsidiary is not prohibited hereunder;

(p) Repurchases of capital stock of Parent or any of its Subsidiaries deemed to occur upon the exercise of options, warrants or other rights to acquire capital stock of Parent or such Subsidiary solely to the extent that shares of such capital stock represent a portion of the exercise price of such options, warrants or such rights;

(q) Investments consisting of non-cash consideration received for any Permitted Transfer;

(r) Investments consisting of acquisitions from third parties of inventory, equipment, office supplies, software and other similar assets in the ordinary course of business;

(s) Investments consisting of in-licensing agreements, provided that no Indebtedness that is not Permitted Indebtedness is incurred or assumed in connection therewith;

(t) [Reserved]; and

(u) other Investments in an aggregate amount not to exceed $5,000,000 outstanding at any time;

(v) provided, however, that, none of the foregoing Investments shall be a "Permitted Investment" if any Indebtedness or Liens assumed in connection with such Investment are not otherwise permitted under Section 6.4 or 6.5, respectively.

Notwithstanding the foregoing, other than in connection with clause (n) above, "Permitted Investments" shall not include any Hedging Agreements.

"Permitted Licenses" means, collectively: (a) any non-exclusive license or covenant not to sue in any geography within the Territory, of or with respect to any Intellectual Property (including, for clarity, any Company IP); (b) any exclusive license or covenant not to sue as to any geography within the Territory other than the U.S., of or with respect to any Intellectual Property (including, for clarity, any Company IP); (c) any non-exclusive grant or covenant not to sue in any geography within the Territory, or any exclusive grant or covenant not to sue as to any geography within the Territory other than the U.S., of development, manufacturing, production, commercialization, marketing, co-promotion, distribution, sale, lease or similar commercial rights with respect to Product; and (d) any intercompany license, covenant not to sue, or other similar arrangement (i) in any geography within the Territory, between or among Credit Parties, and (ii) in any geography within the Territory other than the U.S., between or among Credit Parties and their respective Subsidiaries. Notwithstanding the foregoing or any other provision of this Agreement, no Excluded License entered into after the Tranche A Closing Date shall be a "Permitted License" hereunder without the prior written consent of the Collateral Agent or the Required Lenders.

"Permitted Liens" means:

(a) Liens in favor and for the benefit of any Lender and the other Secured Parties securing the Obligations pursuant to any Loan Document;

(b) Liens existing on the Effective Date and set forth on Schedule 12.4 of the Disclosure Letter;

(c) Liens for Taxes, assessments or governmental charges incurred in the ordinary course of business and which are not yet due and payable or if due and payable, (i) are being contested in good faith and by appropriate proceedings promptly instituted and diligently conducted and (ii) for which adequate reserves therefor have been set aside on the books of the applicable Person and maintained in conformity with Applicable Accounting Standards, if required;

(d) Pledges or deposits made in the ordinary course of business (other than Liens imposed by ERISA) in connection with workers' compensation, payroll taxes, employment insurance, unemployment insurance, old-age pensions, or other similar social security legislation, (ii) pledges or deposits made in the ordinary course of business securing liability for reimbursement or indemnification obligations of (including obligations in respect of letters of credit or bank guarantees for the benefit of) insurance carriers providing property, casualty or liability insurance to Parent or any of its Subsidiaries, (iii) subject to Section 6.2(b), statutory or common law Liens of landlords, (iv) Liens otherwise arising by operation of law in favor of the owner or sublessor of leased premises and confined to the property rented, (v) Liens that are restrictions on transfer of securities imposed by applicable securities laws, (vi) Liens resulting from a filing by a lessor as a precautionary filing for a true lease, and (vii) pledges or deposits to secure performance of tenders, bids, leases, statutory or regulatory obligations, surety and appeal bonds, government contracts, performance and return-of-money bonds and other obligations of like nature, in each case other than for borrowed money and entered into in the ordinary course of business;

(e) Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting an Event of Default under either Section 7.4 or 7.7;

(f) Liens (including the right of set-off) in favor of banks or other financial institutions incurred on deposits made in accounts held at such institutions in the ordinary course of business; provided that such Liens (i) are not given in connection with the incurrence of any Indebtedness, (ii) relate solely to obligations for administrative and other banking fees and expenses incurred in the ordinary course of business in connection with the establishment or maintenance of such accounts and (iii) are within the general parameters customary in the banking industry;

(g) Liens that are contractual rights of set-off (i) relating to pooled deposit or sweep accounts of Parent or any of its Subsidiaries to permit satisfaction of overdraft or similar obligations incurred in the ordinary course of business or (ii) relating to purchase orders and other agreements entered into with customers of Parent or any of its Subsidiaries in the ordinary course of business, including vendors' liens to secure payment arising under Article 2 of the Code or similar provisions of Requirements of Law in the ordinary course of business, covering only the goods sold and securing only the unpaid purchase price for such goods and related expenses;

(h) Liens solely on any cash earnest money deposits made by Parent or any of its Subsidiaries in connection with any Permitted Acquisition, Permitted Investment or other acquisition of assets or properties not otherwise prohibited under this Agreement;

(i) Liens existing on assets or properties at the time of its acquisition or existing on the assets or properties of any Person at the time such Person becomes a Subsidiary of Parent, in each case after the Effective Date; provided that (i) neither such Lien was created nor the Indebtedness secured thereby was incurred in contemplation of such acquisition or such Person becoming a Subsidiary of Parent, (ii) such Lien does not extend to or cover any other assets or properties (other than the proceeds or products thereof and other than after-acquired assets or properties subject to a Lien securing Indebtedness and other obligations incurred prior to such time and which Indebtedness and other obligations are permitted hereunder that requires, pursuant to its terms and conditions in effect at such time, a pledge of after-acquired assets or properties, it being understood that such requirement shall not be permitted to apply to any assets or properties to which such requirement would not have applied but for such acquisition), (iii) the Indebtedness and other obligations secured thereby is permitted under Section 6.4 hereof and (iv) such Liens are of the type otherwise permitted under Section 6.5 hereof;

(j) Liens securing Indebtedness permitted under clause (d) of the definition of "Permitted Indebtedness" (including any extensions, refinancings, modifications, amendments or restatements of such Indebtedness permitted under clause (t) of the definition of "Permitted Indebtedness"); provided, that such Lien does not extend to or cover any assets or properties other than those that are (i) subject to such Capital Lease Obligations or (ii) acquired with or otherwise financed or refinanced by such Indebtedness;

(k) servitudes, easements, rights-of-way, restrictions and other similar encumbrances on real property imposed by Requirements of Law and encumbrances consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor defects or other irregularities in title which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any Credit Party or any Subsidiary of any Credit Party;

(l) to the extent constituting a Lien, escrow arrangements securing indemnification obligations associated with any Permitted Acquisition or Permitted Investment;

(m) (i) leases or subleases of real property granted in the ordinary course of business (including, if referring to a Person other than a Credit Party or a Subsidiary, in the ordinary course of such Person's business), (ii) licenses, sublicenses, leases or subleases of personal property (other than Intellectual Property) granted to third parties in the ordinary course of business, in each case which do not interfere in any material respect with the operations of the business of any Credit Party or any of its Subsidiaries and do not prohibit granting the Collateral Agent a security interest in any Credit Party's personal property held at such location for the benefit of the Lenders and other Secured Parties, (iii) Permitted Licenses, and (iv) retained interests of lessors or licensors or similar party under any in-licenses;

(n) Liens on cash or other current assets pledged to secure (i) Indebtedness in respect of corporate credit cards, purchasing cards or bank card products, provided, that such Liens shall not secure more than $1,000,000 of such Indebtedness in the aggregate at any time, or (ii) Indebtedness in the form of letters of credit or bank guarantees;

(o) Liens on any properties or assets of Parent or any of its Subsidiaries which do not constitute Collateral under the Loan Documents, other than (i) any Company IP that does not constitute Collateral under the Loan Documents but is related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory and (ii) Equity Interests of any Subsidiary;

(p) Liens on any properties or assets of Parent or any of its Subsidiaries imposed by law or regulation which were incurred in the ordinary course of business, including landlords', carriers', warehousemen's, mechanics', materialmen's, contractors', suppliers of materials', architects' and repairmen's Liens, and other similar Liens arising in the ordinary course of business; provided that such Liens (i) do not materially detract from the value of such properties or assets subject thereto or materially impair the use of such properties or assets subject thereto in the operations of the business of Parent or such Subsidiary or (ii) are being contested in good faith by appropriate proceedings which conclusively operate to stay the sale or forfeiture of any portion of such properties or assets subject thereto, and for which adequate reserves have been set aside on the books of the applicable Person and maintained in conformity with Applicable Accounting Standards, if required;

(q) Liens in favor of customs and revenue authorities arising as a Requirement of Law which were incurred in the ordinary course of business, to secure payment of customs duties in connection with the importation of goods in the ordinary course of business;

(r) Liens on any goods sold to Parent or any of its Subsidiaries in the ordinary course of business in favor of the seller thereof, but only to the extent securing the unpaid purchase price for such goods and any related expenses; and

(s) subject to the provisos immediately below, the modification, replacement, extension or renewal of the Liens described in clauses (a) through (r) above; provided, however, that any such modification, replacement, extension or renewal must (i) be limited to the assets or properties encumbered by the existing Lien (and any additions, accessions, parts, improvements and attachments thereto and the proceeds thereof) and (ii) not increase the principal amount of any Indebtedness secured by the existing Lien (other than by any reasonable premium or other reasonable amount paid and fees and expenses reasonably incurred in connection therewith); provided, further, that to the extent any of the Liens described in clauses (a) through (r) above secure Indebtedness of a Credit Party, such Liens, and any such modification, replacement, extension or renewal thereof, shall constitute Permitted Liens if and only to the extent that such Indebtedness is permitted under Section 6.4 hereof.

"Permitted Negative Pledges" means:

(a) prohibitions or limitations with regard to specific properties or assets encumbered by Permitted Liens, if and only to the extent each such prohibition or limitation applies only to such properties or assets;

(b) prohibitions or limitations set forth in any lease, license or other similar agreement entered into in the ordinary course of business;

(c) prohibitions or limitations relating to Permitted Indebtedness, in the case of each relevant agreement, document or instrument if and only to the extent such prohibitions or limitations, taken as a whole, are not materially more restrictive than the prohibitions and limitations set forth in this Agreement and the other Loan Documents, taken as a whole (as reasonably determined by a Responsible Officer of Parent in good faith);

(d) customary provisions restricting assignments, subletting, sublicensing or other transfer of properties or assets subject thereto set forth in leases, subleases, licenses (including Permitted Licenses) and other similar agreements that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such restriction applies only to the properties or assets subject to such leases, subleases, licenses or agreements, and customary provisions restricting assignment, pledges or transfer of any agreement entered into in the ordinary course of business;

(e) prohibitions or limitations imposed by Requirements of Law;

(f) prohibitions or limitations that exist as of the Effective Date under Indebtedness existing on the Effective Date;

(g) customary prohibitions or limitations arising in connection with any Permitted Transfer or contained in any agreement relating to any Permitted Transfer pending the consummation of such Permitted Transfer;

(h) customary provisions in shareholders' agreements, joint venture agreements, Operating Documents or similar binding agreements relating to, or any agreement evidencing Indebtedness of, any joint venture entity or non-Wholly-Owned Subsidiary and applicable solely to such joint venture entity or non-Wholly-Owned Subsidiary and the Equity Interests issued thereby;

(i) customary net worth provisions set forth in real property leases entered into by Subsidiaries of Borrower, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Parent in good faith);

(j) customary net worth provisions set forth in customer agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Parent in good faith);

(k) restrictions on cash or other deposits (including escrowed funds) imposed by agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document;

(l) prohibitions or limitations set forth in any agreement in effect at the time any Person becomes a Subsidiary (but not any amendment, modification, restatement, renewal, extension, supplement or replacement expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary and each such prohibition or limitation does not apply to Borrower or any other Subsidiary (other than such Person and any other Person that is a Subsidiary of such first Person at the time such first Person becomes a Subsidiary);

(m) prohibitions or limitations imposed by any Loan Document;

(n) customary provisions set forth in joint venture agreements or agreements governing minority investments that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to the joint venture entity or minority investment that is the subject of such agreement;

(o) limitations imposed with respect to any license acquired in a Permitted Acquisition;

(p) customary provisions restricting assignments or other transfer of properties or assets subject thereto set forth in any agreement entered into in the ordinary course of business, if and only to the extent each such restriction applies only to the properties or assets subject to such agreement;

(q) prohibitions or limitations imposed by any agreement evidencing any Permitted Indebtedness of the type described in clause (d) of the definition of "Permitted Indebtedness"; and

(r) prohibitions or limitations imposed by any amendments, modifications, restatements, renewals, extensions, supplements or replacements of any of the agreements referred to in clauses (a) through (q) above, except to the extent that any such amendment, modification, restatement, renewal, extension, supplement or replacement expands the scope of any such prohibition or limitation.

"Permitted Subsidiary Distribution Restrictions" means, in each case notwithstanding Section 6.8:

(a) prohibitions or limitations with regard to specific properties or assets encumbered by Permitted Liens, if and only to the extent each such prohibition or limitation applies only to such properties or assets;

(b) prohibitions or limitations set forth in any lease, license or other similar agreement entered into in the ordinary course of business;

(c) prohibitions or limitations relating to Permitted Indebtedness, in the case of each relevant agreement, document or instrument if and only to the extent such prohibitions or limitations, taken as a whole, are not materially more restrictive than the prohibitions and limitations set forth in this Agreement and the other Loan Documents, taken as a whole (as reasonably determined by a Responsible Officer of Parent in good faith);

(d) customary provisions restricting assignments, subletting, sublicensing or other transfer of properties or assets subject thereto set forth in leases, subleases, licenses (including Permitted Licenses) and other similar agreements that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such restriction applies only to the properties or assets subject to such leases, subleases, licenses or agreements, and customary provisions restricting assignment, pledges or transfer of any agreement entered into in the ordinary course of business;

(e) prohibitions or limitations on the transfer or assignment of any properties, assets or Equity Interests set forth in any agreement entered into in the ordinary course of business that is not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to such properties, assets or Equity Interests;

(f) prohibitions or limitations imposed by Requirements of Law;

(g) prohibitions or limitations that exist as of the Effective Date under Indebtedness existing on the Effective Date;

(h) customary prohibitions or limitations arising in connection with any Permitted Transfer or contained in any agreement relating to any Permitted Transfer pending the consummation of such Permitted Transfer;

(i) customary provisions in shareholders' agreements, joint venture agreements, Operating Documents or similar binding agreements relating to, or any agreement evidencing Indebtedness of, any joint venture entity or non-Wholly-Owned Subsidiary and applicable solely to such joint venture entity or non-Wholly-Owned Subsidiary and the Equity Interests issued thereby;

(j) customary net worth provisions set forth in real property leases entered into by Subsidiaries of Borrower, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Parent in good faith);

(k) customary net worth provisions set forth in customer agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Parent in good faith);

(l) restrictions on cash or other deposits (including escrowed funds) imposed by agreements entered into in the ordinary course of business that are not otherwise prohibited under this Agreement or any other Loan Document;

(m) prohibitions or limitations set forth in any agreement in effect at the time any Person becomes a Subsidiary (but not any amendment, modification, restatement, renewal, extension, supplement or replacement expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary and each such prohibition or limitation does not apply to Borrower or any other Subsidiary (other than such Person and any other Person that is a Subsidiary of such first Person at the time such first Person becomes a Subsidiary);

(n) prohibitions or limitations imposed by any Loan Document;

(o) customary provisions set forth in joint venture agreements or agreements governing minority investments that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to the joint venture entity or minority investment that is the subject of such agreement;

(p) customary provisions restricting assignments or other transfer of properties or assets subject thereto set forth in any agreement entered into in the ordinary course of business, if and only to the extent each such restriction applies only to the properties or assets subject to such agreement;

(q) prohibitions or limitations imposed by any agreement evidencing any Permitted Indebtedness of the type described in clause (d) of the definition of "Permitted Indebtedness"; and

(r) prohibitions or limitations imposed by any amendments, modifications, restatements, renewals, extensions, supplements or replacements of any of the agreements referred to in clauses (a) through (q) above, except to the extent that any such amendment, modification, restatement, renewal, extension, supplement or replacement expands the scope of any such prohibition or limitation.

"Permitted Transaction" is defined in Section 2.2(c)(iii).

"Permitted Transfers" means:

(a) Transfers of any properties or assets which do not constitute Collateral under the Loan Documents, other than any Company IP that does not constitute Collateral under the Loan Documents but is related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Specified Territory (other than, for the avoidance of doubt, any such Company IP Transferred pursuant to any Permitted License);

(b) Transfers of Inventory in the ordinary course of business;

(c) Transfers of surplus, damaged, worn out or obsolete equipment that is, in the reasonable judgment of a Responsible Officer of Parent exercised in good faith, no longer economically practicable to maintain or useful in the ordinary course of business, and Transfers of other properties or assets in lieu of any pending or threatened institution of any proceedings for the condemnation or seizure of such properties or assets or for the exercise of any right of eminent domain;

(d) Transfers made in connection with Permitted Liens, Permitted Acquisitions or Permitted Investments;

(e) Transfers of cash and Cash Equivalents made in connection with Permitted Distributions or otherwise in the ordinary course of business for equivalent value and in a manner that is not prohibited under this Agreement or the other Loan Documents;

(f) Transfers (i) between or among Credit Parties, provided that, with respect to any properties or assets constituting Collateral under the Loan Documents, any and all steps as may be required to be taken in order to create and maintain a first priority security interest in and Lien upon such properties and assets in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties are taken contemporaneously with the completion of any such Transfer, and (ii) between or among non-Credit Parties;

(g) (i) the sale or issuance of Equity Interests of any Subsidiary of Parent to any Credit Party or Subsidiary, provided, that any such sale or issuance by a Credit Party shall be to another Credit Party; and (ii) the sale, transfer, issuance or other disposition of a *de minimis* number of shares of the Equity Interests of any Subsidiary of Parent in order to qualify members of the governing body of such Subsidiary if required by Requirements of Law;

(h) the discount without recourse or sale or other disposition of unpaid and overdue accounts receivable arising in the ordinary course of business in connection with the compromise, collection or settlement thereof and not part of a financing transaction;

(i) any abandonment, disclaimer, forfeiture, dedication to the public, cancellation, non-renewal or discontinuance of use or maintenance of Company IP that a Responsible Officer of Parent reasonably determines in good faith (i) is no longer economically practicable to maintain or useful in the ordinary course of business and that (ii) could not reasonably be expected to be adverse to the rights, remedies and benefits available to, or conferred upon, the Collateral Agent or any Lender under any Loan Document in any material respect;

(j) Transfers by Parent or any of its Subsidiaries pursuant to any Permitted License;

(k) intercompany licenses or grants of rights of distribution, co-promotion or similar commercial rights (i) between or among the Credit Parties, or (ii) between or among the Credit Parties and Subsidiaries that are not Credit Parties entered into prior to the Effective Date, and renewals, replacements and extensions thereof (including additional licenses or grants in relation to new territories) on comparable terms in the ordinary course of business;

(l) licenses, sublicenses, leases or subleases, in each case other than relating to any Company IP, granted to third parties in the ordinary course of business and not material to the research, development, manufacture, production, use (by any Credit Party or its Subsidiaries), commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory;

(m) the abandonment disclaimer, forfeiture, dedication to the public, or other disposition of any Company IP that is (i) not material to the research, development, manufacture, production, use (by any Credit Party or its Subsidiaries), commercialization, marketing, importing, storage, transport, packaging, labelling, promotion, advertising, offer for sale, distribution or sale of Product in the Territory or (ii) no longer used or useful in any material respect in any Product line of business of Parent and its Subsidiaries;

(n) any involuntary disposition or any sale, lease, license or other disposition of property (other than, for the avoidance of doubt, any Company IP) in settlement of, or to make payment in satisfaction of, any property or casualty insurance;

(o) sales, leases, licenses, transfers or other dispositions of property to the extent that (i) such property is exchanged for credit against the purchase price of similar replacement property or (ii) the proceeds of such sale, lease, license, transfer or other disposition are promptly applied to the purchase price of similar replacement property;

(p) any early unwind, settlement or termination of any Permitted Equity Derivative; and

(q) other Transfers made in the ordinary course of business on commercially reasonable arm's length terms.

"Person" means any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, exempted company, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"Personal Data" means information protected as "personal data," "personal information," "personally identifiable information," "protected health information," "identifiable private information," or any similar terms under applicable Data Protection Laws.

"Plan" means any employee pension benefit plan (other than a Multiemployer Plan) subject to the provisions of Title IV of ERISA or Section 412 of the IRC or Section 302 of ERISA which is maintained or contributed to by Borrower or its Subsidiaries or their respective ERISA Affiliates or with respect to which Borrower or its Subsidiaries have any liability (including under Section 4069 of ERISA).

"PPFC Documents" means, collectively, the Pre-Paid Forward Contract and each other "Transaction Document" (as such term is defined in the Pre-Paid Forward Contract).

"Pre-Paid Forward Contract" means that certain Pre-Paid Forward Contract, dated as of March 18, 2021 and amended as of April 30, 2021, by and between Parent and RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2).

"Prepayment Premium" means the Tranche A Prepayment Premium or the Tranche B Prepayment Premium (as applicable) or the combination thereof, as the context dictates.

"Product" means: (a)(i) the pharmaceutical product known as JELMYTO® (mitomycin) (and foreign-named equivalents) for pyelocalyceal solution and any successors thereto (collectively, "**JELMYTO®**"), (ii) any pharmaceutical product for the treatment of upper tract urothelial cancer in a hydrogel formulation that contains any radioisomer, stereoisomer, racemates, solvates, salt forms, bases, anhydrides, hydrates, polymorphs, metabolites, ester forms deuterated forms or pro-drugs of mitomycin, and (iii) any pharmaceutical product that contains any of the foregoing, including an active ingredient thereof, in each case of sub-clauses (a)(i) – (a)(iii) above, in any dosage form, dosing regimen, strength or route of administration; (b)(i) the pharmaceutical product known as UGN-102 (mitomycin) for intravesical solution and any successors thereto, (ii) any pharmaceutical product for the treatment of bladder cancer in a hydrogel formulation that contains any radioisomer, stereoisomer, racemates, solvates, salt forms, bases, anhydrides, hydrates, polymorphs, metabolites, ester forms deuterated forms or pro-drugs of mitomycin, and (iii) any pharmaceutical product that contains any of the foregoing, including an active ingredient thereof, in each case of sub-clauses (b)(i) – (b)(iii) above, in any dosage form, dosing regimen, strength or route of administration; and (c) the pharmaceutical products known as UGN-301 (anti-CTLA-4) and UGN-201 (TLR 7 agonist) and any successors thereto, alone or in combination with each other, in any dosage form, dosing regimen, strength or route of administration for the treatment of bladder cancer).

"Refinancing Convertible Debt" is defined in Section 2.2(c)(iii).

"Register" is defined in Section 2.8(a).

"Registered Organization" means any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"Regulatory Agency" means a U.S. or foreign Governmental Authority with responsibility for the approval or licensure of the marketing and sale of pharmaceuticals or other regulation of pharmaceuticals, or otherwise having authority to regulate Product, including the FDA.

"Regulatory Approval" means all approvals (including orphan-drug exclusive approval under 21 C.F.R. § 316.34), designations (including orphan-drug designation under 21 C.F.R. § 316.24), licensures, product or establishment licenses, registrations or authorizations of any Regulatory Agency necessary for the manufacture, use, import, export, storage, transport, offer for sale, or distribution or sale of Product.

"Regulatory Submission Material" means all regulatory filings, submissions, approvals, licensures, and authorizations related to any research, development, manufacture, production, use, commercialization, post-approval or post-licensure monitoring and reporting, marketing, importing, storage, transport, offer for sale, distribution or sale of Product in the Territory, including all data and information provided in, and used to develop, any of the foregoing.

"Related Parties" means, with respect to any Person, such Person's Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of such Person and of such Person's Affiliates.

"Release" means any release, spill, emission, leaking, pumping, pouring, injection, escaping, deposit, disposal, discharge, dispersal, dumping, leaching or migration of any Hazardous Material into the indoor or outdoor environment (including the abandonment or disposal of any barrels, containers or other closed receptacles containing any Hazardous Material), including the movement of any Hazardous Material through the air, soil, surface water or groundwater.

"Relevant Governmental Body" means the Board of Governors of the Federal Reserve System or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Board of Governors of the Federal Reserve System or the Federal Reserve Bank of New York, or any successor thereto.

"Required Lenders" means, (a) prior to the Tranche A Closing Date, Lenders obligated with respect to greater than fifty percent (50%) of the Term Loan Commitments and (b), as of any date of determination thereafter, Lenders representing greater than fifty percent (50%) of the principal amount of the Term Loans outstanding as of such date.

"Requirements of Law" means, as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, order, policy, rule or regulation or determination of an arbitrator or a court or other Governmental Authority (including Environmental Laws, Health Care Laws, Data Protection Laws and FDA Laws, and all applicable statutes, rules, regulations, standards, guidelines, policies and orders administered or issued by any foreign Governmental Authority) in each case, applicable to and binding upon such Person or any of its assets or properties or to which such Person or any of its assets or properties are subject, including, with respect to Borrower, the rules or requirements of any applicable U.S. national securities exchange applicable to Borrower or any of its Equity Interests.

"Responsible Officers" means, with respect to any Credit Party: (a) collectively, for purposes of determining the Knowledge Persons of such Credit Party, each of the Chief Executive Officer, Chief Financial Officer, General Counsel, Chief Medical Officer, Chief Commercial Officer, Chief Business Officer, Executive Vice-President, Research and Development and Technical Operations and Executive Vice-President, Regulatory Affairs and Quality of such Credit Party or, in each case, if none, of Parent; and (b) collectively, for purposes of determining the Persons authorized to provide the certifications of a Responsible Officer of such Credit Party required under the Loan Documents, each of the Chief Executive Officer, Chief Financial Officer and General Counsel of such Credit Party or, in each case, if none, of Parent.

"Restricted License" any material license or other material agreement of the kind or nature subject or purported to be subject from time to time to a Lien under any Collateral Document, with respect to which a Credit Party is the licensee and pursuant to which such Credit Party controls the Company IP, (a) that prohibits or otherwise restricts such Credit Party from granting a security interest in its interest therein to the Collateral Agent, for the benefit of Lenders and the other Secured Parties (other than as a result of customary anti-assignment provisions) in a manner enforceable under Requirements of Law, or (b) for which a breach of or default under could reasonably be expected to interfere with the Collateral Agent's or any Lender's right to sell any Collateral. For the avoidance of doubt, software, open source code, application programming interfaces and/or trademarks, copyrights or patents of others that are commercially available to the public under the shrinkwrap licenses, clickwrap licenses, online terms of service or other terms of use or similar agreements and intellectual property rights of customers used by Borrower in the course of providing service to third parties in the ordinary course of business shall not constitute a Restricted License.

"RTW Intercreditor Agreement" means that certain New York law-governed intercreditor agreement, dated as of the Tranche A Closing Date, among Parent, RTW Investments ICAV (for and on behalf of its sub-fund, RTW Fund 2) and the Collateral Agent (for the benefit of Lenders and the other Secured Parties), in form and substance consistent with the parameters of an "Applicable Intercreditor Agreement" set forth in the definition thereof in Section 1.1 of the Pre-Paid Forward Contract and otherwise satisfactory to the Collateral Agent.

"Sanctioned Person" an individual or entity that is, or is owned or controlled by individuals or entities that are: (i) the subject or target of any sanctions administered or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control ("**OFAC**"), the U.S. Department of State, the U.S. Department of Commerce, the United Nations Security Council, the European Union, the United Kingdom or other relevant sanctions authority (collectively, "**Sanctions**"); or (ii) located, organized or resident in a country or territory that is the subject of comprehensive Sanctions, including currently, Crimea, Cuba, Iran, North Korea and Syria.

"Sanctions" is defined in Section 4.18(c).

"SEC" shall mean the Securities and Exchange Commission and any analogous Governmental Authority.

"Secretary's Certificate" means, with respect to any Person, a certificate of such Person executed by its Secretary, authorized signatory or director certifying as to the various matters set forth therein.

"Section 5 of the FTC Act" means the Section 5(a) of the U.S. Federal Trade Commission Act (15 U.S.C. § 45), which prohibits unfair and deceptive acts or practices in or affecting commerce and serves as the primary basis for U.S. Federal Trade Commission authority on privacy and security.

"Secured Parties" means each Lender, each other Indemnified Person and each other holder of any Obligation of a Credit Party.

"Securities Account" means any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"Security Agreement" means the Guaranty and Security Agreement, dated as of the Tranche A Closing Date, by and among the Credit Parties and the Collateral Agent, in form and substance substantially similar to Exhibit C attached hereto or in such form or substance as the Credit Parties and the

Collateral Agent may otherwise agree.

"Sensitive Information" means, collectively, (a) any Personal Data that is subject to any Data Protection Law, (b) any information in which Parent or any of its Subsidiaries have IP Ancillary Rights or any other Intellectual Property rights (including Company IP), (c) any information with respect to which Parent or any of its Subsidiaries have contractual non-disclosure obligations, and (d) nonpublic Regulatory Submission Materials.

"SOFR" means a rate per annum equal to the secured overnight financing rate for such Business Day published by the Federal Reserve Bank of New York (or a successor administrator of the secured overnight financing rate) on the website of the Federal Reserve Bank of New York, currently at http://www.newyorkfed.org (or any successor source for the secured overnight financing rate identified as such by the administrator of the secured overnight financing rate from time to time).

"Software" means "Software", as such term is defined in the Security Agreement.

"Solvent" means, with respect to any Person as of any date of determination, that, as of such date, (a) the value of the assets (including goodwill minus disposition costs) of such Person (both at fair value and present fair saleable value) is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such Person, (b) such Person is able to generally pay all liabilities (including trade debt) of such Person as such liabilities become absolute and mature in the ordinary course of business and (c) such Person does not have unreasonably small capital after giving due consideration to the prevailing practice in the industry in which it is engaged or will be engaged. In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

"Specified Territory" means the United States, United Kingdom, Germany, France, Italy and Israel.

"SSA" means the Social Security Act of 1935, codified at Title 42, Chapter 7, of the United States Code.

"Stock Acquisition" means the purchase or other acquisition by Parent or any of its Subsidiaries of any of the Equity Interests (by merger, stock purchase or otherwise) in any other Person.

"Subordinated Debt" means any Indebtedness in the form of or otherwise constituting term debt incurred by any Credit Party or any Subsidiary thereof (including any Indebtedness incurred in connection with any Acquisition or other Investment) that: (a) is subordinated in right of payment to the Obligations at all times until all of the Obligations have been paid, performed or discharged in full and Borrower has no further right to obtain any Credit Extension hereunder pursuant to a subordination, intercreditor or other similar agreement that is in form and substance reasonably satisfactory to the Collateral Agent (which agreement shall include turnover provisions that are reasonably satisfactory to the Collateral Agent); (b) except as permitted by clause (d) below, is not subject to scheduled amortization, redemption (mandatory), sinking fund or similar payment and does not have a final maturity, in each case, before a date that is at least 120 days following the Term Loan Maturity Date; (c) does not include covenants (including financial covenants) and agreements (excluding agreements with respect to maturity, amortization, pricing and other economic terms) that, taken as a whole, are more restrictive or onerous on the Credit Parties in any material respect than the comparable covenants and agreements, taken as a whole, in the Loan Documents (as reasonably determined by a Responsible Officer of such Credit Party in good faith); (d) is not subject to repayment or prepayment, including pursuant to a put option exercisable by the holder of any such Indebtedness, prior to a date that is at least 120 days following the final maturity thereof except in the case of an event of default or change of control (or, in each case, the equivalent thereof, however described); and (e) does not provide or otherwise include provisions having the effect of providing that a default or event of default (or the equivalent thereof, however described) under or in respect of such Indebtedness shall exist, or such Indebtedness shall otherwise become due prior to its scheduled maturity or the holder or holders thereof or any trustee or agent on its or their behalf shall be permitted (with or without the giving of notice, the lapse of time or both) to cause any such Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity, in any such case upon the occurrence of a Default or Event of Default hereunder unless and until the Obligations have been declared, or have otherwise automatically become, immediately due and payable pursuant to Section 8.1(a). Notwithstanding the foregoing, Permitted Convertible Indebtedness and Indebtedness under the Pre-Paid Forward Contract and other PPFC Documents shall not constitute Subordinated Debt.

"Subsidiary" means, with respect to any Person, a corporation, partnership, limited liability company or other entity of which more than fifty percent (50.0%) of whose shares of stock or other ownership interests having ordinary voting power (other than stock or such other ownership interests having such power only by reason of the happening of a contingency) to elect a majority of the Board of Directors (or similar body, if applicable) of such corporation, partnership or other entity are at the time owned, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of a Credit Party.

"Systems" is defined in Section 4.22(a).

"Tax" means any taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges of any nature or hereafter imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"Term Loan" means each of the Tranche A Loan or the Tranche B Loan, as applicable, and "**Term Loans**" means, collectively, the Tranche A Loan and the Tranche B Loan, as the context dictates.

"Term Loan Commitment" mean each of the Tranche A Loan Commitment or the Tranche B Loan Commitment, as applicable, and "**Term Loan Commitments**" means, collectively, the Tranche A Loan Commitment and the Tranche B Loan Commitment, as the context dictates.

"Term Loan Maturity Date" means the 5th-year anniversary of the Tranche A Closing Date.

"Term Loan Note" means each of the Tranche A Note or the Tranche B Note (as applicable), and "**Term Loan Notes**" means, collectively, the Tranche A Notes and the Tranche B Notes, as the context dictates.

"Term Loan Rate" is defined in Section 2.3(a)(i).

"Term SOFR" means, for the applicable corresponding tenor, the forward-looking term rate based on SOFR that has been selected or recommended by the Relevant Governmental Body.

"Territory" means anywhere in the world.

"Third Party IP" is defined in Section 4.6(l).

"Trademarks" means (a) all trademarks, trade names, corporate names, company names, business names, fictitious business names, service marks, elements of package or trade dress of goods or services, logos and other source or business identifiers, together with the goodwill associated therewith, including all registrations and recordings thereof, and all applications in connection therewith, in the United States Patent and Trademark Office or in any similar office or agency of the United States or any state thereof or in any similar office or agency anywhere in the world in which foreign counterparts are registered or issued, and (b) all renewals thereof.

"Trading Day" means a day on which exchanges in the United States are open for the buying and selling of securities.

"Tranche A Closing Date" means the date on which the Tranche A Loan is advanced by Lenders, which, subject to the satisfaction of the conditions precedent to the Tranche A Loan set forth in Section 3.1, Section 3.5, Section 3.6 and Section 3.7, shall be ten (10) Business Days following the Effective Date.

"Tranche A Commitment" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche A Loan on the Tranche A Closing Date in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto.

"Tranche A Loan" is defined in Section 2.2(a)(i).

"Tranche A Loan Amount" means an original principal amount equal to Seventy-Five Million Dollars ($75,000,000.00).

"Tranche A Makewhole Amount" means, as of any date of prepayment of the Tranche A Loan occurring prior to the 2nd-year anniversary of the Tranche A Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 2nd-year anniversary of the Tranche A Closing Date on the amount of principal prepaid.

"Tranche A Note" means a promissory note in substantially the form attached hereto as Exhibit B-1, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Tranche A Prepayment Premium" means, with respect to any prepayment of the Tranche A Loan by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), an amount equal to the product of the amount of any principal so prepaid, multiplied by:

(a) if such prepayment occurs prior to the 3rd-year anniversary of the Tranche A Closing Date, 0.03;

(b) if such prepayment occurs on or after the 3rd-year anniversary of the Tranche A Closing Date but prior to the 4th-year anniversary of the Tranche A Closing Date, 0.02; and

(c) if such prepayment occurs on or after the 4th-year anniversary of the Tranche A Closing Date but prior to the Term Loan Maturity Date, 0.01.

For the avoidance of doubt, no Tranche A Prepayment Premium shall be due and owing for any payment of principal of the Tranche A Loan made on the Term Loan Maturity Date.

"Tranche B Closing Date" means the date on which the Tranche B Loan is advanced by Lenders, which, as indicated in the Advance Request Form for the Tranche B Loan and subject to the satisfaction of the conditions precedent to the Tranche B Loan set forth in Section 3.2, Section 3.5, Section 3.6 and Section 3.7, shall be 60 days (or such shorter period as may be agreed to by Lenders) following the delivery by Borrower to the Collateral Agent of a completed Advance Request Form for the Tranche B Loan and, in no event, later than December 31, 2022.

"Tranche B Commitment" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche B Loan on the Tranche B Closing Date in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto; provided, however, that the parties hereto agree that such commitment, and any obligations of such Lender hereunder with respect thereto, shall terminate automatically without any further action by any party hereto and be of no further force and effect if (x) any prepayment of principal amount of any Tranche A Loan is made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of any Term Loan pursuant to Section 8.1(a) on or before the Tranche B Closing Date or (y) the Tranche B Closing Date does not occur on or before December 31, 2022 (in either of which case, for purposes of this Agreement, such Lender's Tranche B Commitment equals zero).

"Tranche B Loan" is defined in Section 2.2(a)(ii).

"Tranche B Loan Amount" means an original principal amount of Twenty-Five Million Dollars ($25,000,000.00); provided, that if either of the events described clauses (x) or (y) in the proviso to the definition of Tranche B Commitment occurs, the Tranche B Loan Amount, for purposes of this Agreement, equals zero.

"Tranche B Makewhole Amount" means, as of any date of prepayment of the Tranche B Loan occurring prior to the 2nd-year anniversary of the Tranche B Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 2nd-year anniversary of the Tranche B Closing Date on the amount of principal prepaid.

"Tranche B Note" means a promissory note in substantially the form attached hereto as Exhibit B-2, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Tranche B Prepayment Premium" means, with respect to any prepayment of the Tranche B Loan by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), an amount equal to the product of the amount of any principal so prepaid, multiplied by:

(a) if such prepayment occurs prior to the 3rd-year anniversary of the Tranche A Closing Date, 0.03;

(b) if such prepayment occurs on or after the 3rd-year anniversary of the Tranche A Closing Date but prior to the 4th-year anniversary of the Tranche A Closing Date, 0.02; and

(c) if such prepayment occurs on or after the 4th-year anniversary of the Tranche A Closing Date but prior to the Term Loan Maturity Date, 0.01.

For the avoidance of doubt, no Tranche B Prepayment Premium shall be due and owing for any payment of principal of the Tranche B Loan made on the Term Loan Maturity Date.

"Transfer" is defined in Section 6.1.

"Treasury Regulations" mean those regulations promulgated pursuant to the IRC.

"TRICARE" means, collectively, a program of medical benefits covering former and active members of the uniformed services and certain of their dependents, financed and administered by the United States Departments of Defense, Health and Human Services and Transportation, and all laws applicable to such programs.

"UKBA" is defined in Section 4.18(a).

"United States" or "**U.S.**" means the United States of America, its fifty (50) states, the District of Columbia, Puerto Rico and any other jurisdiction within the United States of America.

"USD LIBOR" means the London interbank offered rate for Dollars.

"Wholly-Owned Subsidiary" means, with respect to any Person, a Subsidiary of such Person, all of the Equity Interests of which (other than directors' qualifying shares or nominee or other similar shares required pursuant to Requirements of Law) are owned by such Person or another Wholly-Owned Subsidiary of such Person. Unless the context otherwise requires, each reference to a Wholly-Owned Subsidiary herein shall be a reference to a Wholly-Owned Subsidiary of a Credit Party.

"Withdrawal Liability" means liability to a Multiemployer Plan as a result of a complete or partial withdrawal from such Multiemployer Plan, as such terms are defined in Part I of Subtitle E of Title IV of ERISA.

"Withholding Agent" is defined in Section 2.6(b).

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

UROGEN PHARMA, INC.,
as Borrower and a Credit Party

By /s/ Molly Henderson

Name: Molly Henderson

Title: Chief Financial Officer

UROGEN PHARMA LTD.,
as Parent and a Credit Party

By /s/ Molly Henderson

Name: Molly Henderson

Title: Chief Financial Officer

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BPCR LIMITED PARTNERSHIP,
as a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP,
as Lender

By: BioPharma Credit Investments V GP LLC,
its general partner

By: Pharmakon Advisors, LP,
its Investment Manager

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: CEO and Managing Member

EXHIBIT A – LOAN ADVANCE REQUEST FORM

Reference is made to that certain Loan Agreement, dated as of March 7, 2022, by and among UROGEN PHARMA, INC., a Delaware corporation ("**Borrower**"), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "**Parent**" and a Credit Party), the other Guarantors signatory thereto or otherwise party thereto from time to time, as additional Credit Parties, BIOPHARMA CREDIT PLC (in its capacity as "**Collateral Agent**"), BPCR LIMITED PARTNERSHIP (a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP (a "**Lender**"), acting by its general partner, BioPharma Credit Investments V GP LLC (the "**Loan Agreement**"); with any capitalized term not otherwise defined herein having the meaning ascribed to such term in the Loan Agreement. This Loan Advance Request is being delivered pursuant to Section 3.5 of the Loan Agreement.

The undersigned, being the duly elected and acting _____ of Borrower does hereby certify to each Lender and the Collateral Agent, solely in his/her capacity as an authorized officer of Borrower and not in his/her personal capacity, that, on [the Tranche A Closing Date] [[_____, 20__] (the "**Tranche B Closing Date**")]:

1. Borrower hereby requests a borrowing of [the Tranche A Loan] [the Tranche B Loan];

2. the representations and warranties made by the Credit Parties in Section 4 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects, unless any such representation or warranty is stated to relate to a specific earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (it being understood that any representation or warranty that is qualified as to "materiality," "Material Adverse Change," or similar language shall be true and correct in all respects on the Tranche [A][B] Closing Date or as of such earlier date, as applicable);

2. no Default or Event of Default has occurred since the [Effective Date] [Tranche A Closing Date] or is occurring as of the date hereof;

3. each of the Credit Parties is in compliance with the covenants and requirements contained in Sections 5 and 6 of the Loan Agreement;

4. all conditions referred to in Section 3 of the Loan Agreement to the making of the Tranche [A][B] Loan to be made on the Tranche [A][B] Closing Date have been satisfied (or waived in writing by the Required Lenders);

5. no Material Adverse Change has occurred since the [Effective Date] [Tranche A Closing Date];

6. the undersigned is a Responsible Officer of Borrower; and

7. the proceeds of the [Tranche A Loan] [Tranche B Loan] shall be disbursed as set forth on Attachment A hereto.

Dated: _____, 2022

[Signature page follows]

UROGEN PHARMA, INC.,
as Borrower

By_____

Name:_____

Title:_____

EXHIBIT B-1

THIS TRANCHE A NOTE HAS BEEN ISSUED WITH "ORIGINAL ISSUE DISCOUNT" (WITHIN THE MEANING OF SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED). HOLDERS OF THIS TRANCHE A NOTE SHOULD CONTACT MOLLY HENDERSON, CHIEF FINANCIAL OFFICER, UROGEN PHARMA, 400 ALEXANDER PARK DRIVE, PRINCETON, NEW JERSEY 08540 IN WRITING TO OBTAIN (1) THE ISSUE PRICE AND ISSUE DATE OF THIS TRANCHE A NOTE, (2) THE AMOUNT OF ORIGINAL ISSUE DISCOUNT ON THIS TRANCHE A NOTE AND (3) THE YIELD TO MATURITY OF THIS TRANCHE A NOTE.

SECURED TRANCHE A LOAN PROMISSORY NOTE

$37,500,000.00 Dated: March [__], 2022

FOR VALUE RECEIVED, the undersigned, UROGEN PHARMA, INC., a private limited company incorporated under the laws of England and Wales and limited by shares ("**Borrower**"), HEREBY PROMISES TO PAY to [BPCR LIMITED PARTNERSHIP] [BIOPHARMA CREDIT

INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of THIRTY-SEVEN MILLION FIVE HUNDRED THOUSAND DOLLARS AND NO CENTS ($37,000,000.00), plus interest on the aggregate unpaid principal amount of this Secured Tranche A Loan Promissory Note (this "**Tranche A Note**") at a per annum rate equal to the LIBOR Rate plus eight and one quarter percent (8.25%) per annum, and in accordance with the terms of the Loan Agreement dated as of March 7, 2022 by and among Borrower, Lender, BioPharma Credit PLC, as Collateral Agent, the other Lenders from time to time party thereto and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Borrower shall make four (4) equal quarterly payments of principal of the Tranche A Loan commencing on the first Payment Date that occurs on or immediately after the 17th calendar quarter following the Tranche A Closing Date and continuing through the Term Loan Maturity Date All unpaid principal with respect to the Tranche A Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date. Interest shall accrue on this Tranche A Note commencing on, and including, the date of this Tranche A Note, and shall accrue on this Tranche A Note, or any portion thereof, for the day on which this Tranche A Note or such portion is paid. Interest on this Tranche A Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche A Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche A Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche A Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche A Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche A Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche A Note are hereby waived.

THIS TRANCHE A NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche A Note shall be registered on a record of ownership maintained by the Collateral Agent. Notwithstanding anything else in this Tranche A Note to the contrary, the right to the principal of, and stated interest on, this Tranche A Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche A Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche A Note on the part of any other Person.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Tranche A Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

UROGEN PHARMA, INC.,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT B-2

SECURED TRANCHE B LOAN PROMISSORY NOTE

$12,500,000.00 Dated: March [__], 2022

FOR VALUE RECEIVED, the undersigned, UROGEN PHARMA, INC., a private limited company incorporated under the laws of England and Wales and limited by shares ("**Borrower**"), HEREBY PROMISES TO PAY to [BPCR LIMITED PARTNERSHIP] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of TWELVE MILLION FIVE HUNDRED THOUSAND DOLLARS AND NO CENTS ($12,500,000.00), plus interest on the aggregate unpaid principal amount of this Secured Tranche B Loan Promissory Note (this "**Tranche B Note**") at a per annum rate equal to the LIBOR Rate plus eight and one quarter (8.25%) per annum, and in accordance with the terms of the Loan Agreement dated as of March 7, 2022 by and among Borrower, Lender, BioPharma Credit PLC, as Collateral Agent, the other Lenders from time to time party thereto and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Borrower shall make four (4) equal quarterly payments of principal of the Tranche B Loan commencing on the first Payment Date that occurs during on or immediately after the 17th calendar quarter following the Tranche A Closing Date and continuing through the Term Loan Maturity Date. All unpaid principal with respect to the Tranche B Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date. Interest shall accrue on this Tranche B Note

commencing on, and including, the date of this Tranche B Note, and shall accrue on this Tranche B Note, or any portion thereof, for the day on which this Tranche B Note or such portion is paid. Interest on this Tranche B Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche B Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche B Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche B Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche B Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche B Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche B Note are hereby waived.

THIS TRANCHE B NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche B Note shall be registered on a record of ownership maintained by the Collateral Agent. Notwithstanding anything else in this Tranche B Note to the contrary, the right to the principal of, and stated interest on, this Tranche B Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche B Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche B Note on the part of any other Person.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Tranche B Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

UROGEN PHARMA, INC.,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT C

FORM OF SECURITY AGREEMENT

GUARANTY AND SECURITY AGREEMENT

Dated as of March , 2022

by

UROGEN PHARMA, INC.

(as *Borrower* and a *Grantor*),

UROGEN PHARMA LTD.

(as *Parent* and a *Grantor*),

and

EACH OTHER GRANTOR FROM TIME TO TIME PARTY HERETO

in favor of

BIOPHARMA CREDIT PLC

(as *Collateral Agent* on behalf of Lenders and the other Secured Parties)

TABLE OF CONTENTS

Page

ARTICLE 1 DEFINED TERMS 1
Section 1.1 Definitions 1
Section 1.2 Certain Other Terms 5

ARTICLE 2 GUARANTY 6
Section 2.1 Guaranty 6
Section 2.2 Limitation of Guaranty 6
Section 2.3 Authorization; Other Agreements 6
Section 2.4 Guaranty Absolute and Unconditional 7
Section 2.5 Waivers 7
Section 2.6 Reliance 8
Section 2.7 Contribution 8

ARTICLE 3 GRANT OF SECURITY INTEREST 8
Section 3.1 Collateral 8
Section 3.2 Grant of Security Interest in Collateral 9

ARTICLE 4 REPRESENTATIONS AND WARRANTIES 10
Section 4.1 Title; No Other Liens 10
Section 4.2 Perfection and Priority 10
Section 4.3 Pledged Stock 10
Section 4.4 Pledged Debt Instruments 11

ARTICLE 5 COVENANTS 11
Section 5.1 Maintenance of Perfected Security Interest; Further Documentation and Consents 12
Section 5.2 Pledged Collateral and Pledged Investment Property 13
Section 5.3 Intellectual Property 13

ARTICLE 6 REMEDIAL PROVISIONS 14
Section 6.1 Code and Other Remedies 14
Section 6.2 Accounts and Payments in Respect of General Intangibles 16
Section 6.3 Pledged Collateral 17
Section 6.4 Proceeds to be Turned over to and Held by Collateral Agent 18
Section 6.5 Sale of Pledged Collateral 18
Section 6.6 Deficiency 19
Section 6.7 Collateral Accounts 19
Section 6.8 Directions, Notices or Instructions 19

ARTICLE 7 ADDITIONAL RIGHTS OF COLLATERAL AGENT 19
Section 7.1 Collateral Agent's Appointment as Attorney-in-Fact 19
Section 7.2 Authorization to File Financing Statements 20
Section 7.3 Authority of Collateral Agent 21
Section 7.4 Duty; Obligations and Liabilities 21

ARTICLE 8 MISCELLANEOUS 21
Section 8.1 Reinstatement 21
Section 8.2 Release of Collateral and Guarantee Obligations 21
Section 8.3 Independent Obligations 22
Section 8.4 No Waiver by Course of Conduct 22
Section 8.5 Amendments in Writing 22
Section 8.6 Additional Grantors and Guarantors; Additional Pledged Collateral 22
Section 8.7 Notices 23
Section 8.8 Successors and Assigns 23
Section 8.9 Counterparts 23
Section 8.10 Severability 23
Section 8.11 Choice of Law 23
Section 8.12 Jury Trial Waiver 23
Section 8.13 Intercreditor Agreement 24
Section 8.14 Israeli Security Agreement 24

Annex 1 – Form of Pledge Amendment

Annex 2 – Form of Joinder Agreement

Annex 3 – Form of [Patent] [Trademark][Copyright] Security Agreement

Annex 4 – Form of Uncertificated Stock Control Agreement

GUARANTY AND SECURITY AGREEMENT, dated as of March , 2022, by UROGEN PHARMA, INC., a Delaware corporation ("Borrower" and a Grantor), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "Parent" and a Grantor) and each other Person that becomes a party hereto in the capacity of a Grantor hereunder pursuant to Section 8.6, in favor of BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales (as the "Collateral Agent") on behalf of Lenders and each other Secured Party.

W I T N E S S E T H:

WHEREAS, pursuant to the Loan Agreement dated as of March 7, 2022 (as the same may be amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement") by and among Borrower, the Collateral Agent and the other parties thereto, Lenders have agreed to make extensions of credit to Borrower upon the terms and subject to the conditions set forth therein;

WHEREAS, each Grantor other than Borrower agrees to guaranty, jointly and severally, the Obligations (as defined in the Loan Agreement) of Borrower;

WHEREAS, each Grantor will derive substantial direct and indirect benefits from the making of the extensions of credit under the Loan Agreement; and

WHEREAS, it is a condition precedent to the obligation of Lenders to make Term Loans to Borrower under the Loan Agreement that the Grantors shall have executed and delivered this Agreement to the Collateral Agent and each Lender for the benefit of Lenders and the other Secured Parties.

NOW, THEREFORE, in consideration of the mutual promises herein contained and for valuable consideration the receipt and sufficiency of which is hereby acknowledged and to induce each of the Collateral Agent, Lenders and the Credit Parties to enter into the Loan Agreement and to induce each Lender to make extensions of credit to Borrower thereunder, each Grantor hereunder hereby agrees with the Collateral Agent, each intending to be legally bound, as follows:

ARTICLE 1

DEFINED TERMS

Section 1.1 **Definitions**

. Capitalized terms used herein without definition are used as defined in the Loan Agreement.

(a) The following terms have the meanings given to them in the Code and terms used herein without definition that are defined in the Code have the meanings given to them in the Code (such meanings to be equally applicable to both the singular and plural forms of the terms defined): "account", "account debtor", "as-extracted collateral", "certificated security", "chattel paper", "check", "commercial tort claim", "commodity account", "commodity contract", "documents", "deposit account", "electronic chattel paper", "encumbrance", "entitlement holder", "equipment", "farm products", "financial asset", "fixture", "general intangible", "goods", "health-care-insurance receivable", "instruments", "inventory", "investment property", "letter of credit", "letter-of-credit right", "money", "proceeds", "promissory note", "record", "securities account", "security", "security entitlement", "supporting obligation", "tangible chattel paper" and "uncertificated security".

(b) The following terms shall have the following meanings:

"Agreement" means this Guaranty and Security Agreement, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Applicable IP Office" means, as applicable, the United States Patent and Trademark Office or the United States Copyright Office or any similar offices or agencies in such other jurisdictions as required by and pursuant to Section 5.12(e) of the Loan Agreement.

"Collateral" has the meaning specified in Section 3.1.

"Collateral Agent" means BioPharma Credit PLC, together with its successors and permitted assigns.

"Excluded Property" means, collectively:

(i) any "intent-to-use" application for registration of a United States Trademark for which a "Statement of Use" pursuant to Section 1(d) of the Lanham Act, 15 U.S.C. § 1051 (or any successor provision) or an "Amendment to Allege Use" pursuant to Section 1(c) of the Lanham Act, 15 U.S.C. § 1051 (or any successor provision) has not been filed with and accepted by the Applicable IP Office, solely to the extent, if any, that, and only during the period, if any, in which, the grant of a security interest therein would impair the validity or enforceability of any registration that issues from such intent-to-use United States Trademark application under Requirements of Law; provided, however, that upon filing and acceptance by the Applicable IP Office of such statement of use or amendment to allege use (as applicable), such intent-to-use application shall be considered Collateral for all purposes under the Loan Documents;

(ii) any rights or interests in any permit, lease, license, contract, instrument or other agreement held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) are prohibited by the terms thereof, but only, in each case, to the extent, and for so long as, such prohibition is not terminated or rendered unenforceable or otherwise deemed ineffective by the Code (including Sections 9-406(d), 9-407(a), 9-408(a) and 9-409 of the Code) or by any applicable Requirements of Law;

(iii) any rights or interests in any permit, lease, license, contract, instrument or other agreement held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien thereupon, and the pledge to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) require the consent, authorization, approval or waiver of any Governmental Authority or other third party (other than Borrower or an Affiliate of Borrower) and such consent, authorization, approval or waiver has not been obtained by such Grantor or Parent following their respective commercially reasonable efforts to obtain the same;

(iv) any other asset or property subject or purported to be subject to a Lien under any Collateral Document held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien thereupon, and the pledge to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) require the consent, authorization, approval or waiver of any Governmental Authority or other

third party (other than Borrower or an Affiliate of Borrower) and such consent, authorization, approval or waiver has not been obtained by such Grantor or Parent following their respective commercially reasonable efforts to obtain the same;

(v) any property or asset subject or purported to be subject to a Lien under any Collateral Document held by any Grantor that is a non-Wholly-Owned Subsidiary with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, the Operating Documents of, the joint venture agreement or shareholder agreement with respect to, or any other contract with such third party relating to such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Documents, joint venture agreement, shareholder agreement or other contract is in effect;

(vi) any asset or property subject or purported to be subject to a Lien under any Collateral Document held by any Grantor with respect to which, the cost, difficulty, burden or consequences (including adverse Tax consequences) of granting the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, a security interest therein and Lien thereupon, and pledging to the Collateral Agent thereof, in favor of and for the benefit of Lenders and the other Secured Parties, to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to Secured Parties thereby;

(vii) any rights under any Federal or state governmental license, permit, franchise or authorization to the extent that the granting of a security interest therein is specifically prohibited or restricted by any Requirements of Law;

(viii) any asset or property subject to a Permitted Lien to the extent the documents governing such Permitted Lien or the Permitted Indebtedness secured thereby validly prohibit other Liens on such assets or property, but only, in each case, to the extent, and for so long as, such prohibition is not terminated or rendered unenforceable or otherwise deemed ineffective by the Code (including Sections 9-406(d), 9-407(a), 9-408(a) and 9-409 of the Code) or by any applicable Requirements of Law;

(ix) leasehold interests in real property;

(x) fee interests in real property with a fair market value (reasonably determined in good faith by a Responsible Officer of Parent) less than $5,000,000;

(xi) Vehicles;

(xii) any letter of credit with an amount less than $500,000 and all letter-of-credit rights with respect thereto to the extent not perfected by the filing of a UCC-1 financing statement;

(xiii) commercial tort claims with a predicted value of less than $500,000 (as reasonably determined by a Responsible Officer of Parent in good faith and based upon reasonable assumptions)

(xiv) Excluded Equity Interests;

(xv) Excluded Accounts; and

(xvi) any other asset or property held by any Grantor (including any asset or property not located in the United States) with respect to which Borrower and Collateral Agent reasonably determine by mutual written agreement that the grant to Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) are specifically prohibited by Requirements of Law, but only, in each such case, to the extent, and for so long as, such prohibition is not rendered or deemed ineffective by the Code (or any other applicable Requirements of Law) notwithstanding such prohibition;

provided, however, that "Excluded Property" shall not include any proceeds, products, substitutions or replacements of Excluded Property unless such proceeds, products, substitutions or replacements would otherwise constitute Excluded Property.

"Fraudulent Transfer Laws" has the meaning set forth in Section 2.2.

"Grantor" means each of the Borrower and each other Person that becomes a party hereto in the capacity as a "Grantor" pursuant to Section 8.6, and "Grantors" means, collectively, Borrower and each other such Person.

"Guaranteed Obligations" has the meaning set forth in Section 2.1.

"Guarantor" means Parent and each other Grantor other than Borrower.

"Guaranty" means the guaranty of the Guaranteed Obligations made by Guarantors as set forth in this Agreement.

"IP License" means all express and implied grants or rights to make, have made, use, sell, reproduce, distribute, modify, or otherwise exploit any Intellectual Property in the U.S., as well as all covenants not to sue and co-existence agreements (and all related IP Ancillary Rights) relating to any Intellectual Property in the U.S.

"IP Security Agreement" means an intellectual property security agreement in the form attached hereto as Annex 3, and "IP Security Agreements" means, collectively, all such intellectual property security agreements.

"Maximum Guaranteed Amount" has the meaning set forth in Section 2.2.

"NDA" means a new drug application filed with the FDA pursuant to Section 505(b) of the U.S. Federal Food, Drug, and Cosmetic Act, along with all supplements and amendments thereto.

"Pledged Certificated Stock" means all of the Equity Interests (other than Excluded Equity Interests) in any Subsidiary evidenced by a certificate or instrument or other document of title (in each case, as defined in the Code), in each case owned by any Grantor, including a Grantor's right, title and interest resulting from its ownership of any such Equity Interests as a limited or general partner in any partnership that has issued Pledged Certificated Stock or as a member of any limited liability company that has issued Pledged Certificated Stock, and a Grantor's right, title and interest resulting from its ownership of any such Equity Interests in, to and under any Operating Document or shareholder agreement of any corporation, partnership or limited liability company to which it is a party, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including all certificated Equity Interests listed on Schedule 1 of the Security Disclosure Letter. "Pledged Certificated Stock" includes, for the avoidance of doubt, any Pledged Uncertificated Stock that subsequently becomes certificated.

"Pledged Collateral" means, collectively, the Pledged Stock and the Pledged Debt Instruments.

"Pledged Debt Instruments" means all right, title and interest of any Grantor in instruments evidencing any Indebtedness owed to such Grantor or other obligations owed to such Grantor, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including all Indebtedness described on Schedule 3 of the Security Disclosure Letter, issued by the obligors named therein. "Pledged Debt Instruments" excludes any Excluded Property.

"Pledged Investment Property" means any investment property of any Grantor, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, other than any Pledged Stock or Pledged Debt Instruments. "Pledged Investment Property" excludes any Excluded Property.

"Pledged Stock" means all Pledged Certificated Stock and all Pledged Uncertificated Stock.

"Pledged Uncertificated Stock" means all of the Equity Interests (other than Excluded Equity Interests) in any Subsidiary that is not Pledged Certificated Stock, in each case owned by any Grantor, including Grantor's right, title and interest resulting from its ownership of any such Equity Interests as a limited or general partner in any partnership not constituting Pledged Certificated Stock or as a member of any limited liability company not constituting Pledged Certificated Stock, a Grantor's right, title and interest resulting from its ownership of any such Equity Interests in, to and under any Operating Document or shareholder agreement of any partnership or limited liability company to which it is a party, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including in each case those interests set forth on Schedule 1 of the Security Disclosure Letter, to the extent such interests are not certificated.

"Secured Obligations" has the meaning set forth in Section 3.2.

"Security Disclosure Letter" means the security agreement disclosure letter, dated as of the date hereof, delivered by the Grantors to the Collateral Agent and each Lender.

"Vehicles" means rolling stock, motor vehicles, vessels, aircraft and other assets subject to certificates of title.

Section 1.2 **Certain Other Terms**

.

(a) For the purposes of and as used in this Agreement: (i) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (ii) each authorization herein shall be deemed irrevocable and coupled with an interest; and (iii) where the context requires, provisions relating to any Collateral when used in relation to a Grantor shall refer to such Grantor's Collateral or any relevant part thereof.

(b) Other Interpretive Provisions.

(i) Defined Terms. Unless otherwise specified herein or therein, all terms defined in this Agreement shall have the defined meanings when used in any certificate or other document made or delivered pursuant hereto.

(ii) This Agreement. The words "hereof", "herein", "hereunder" and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

(iii) Certain Common Terms. The words "include", "included" and "including" are not limiting and mean "including without limitation." The word "or" has the inclusive meaning represented by the phrase "and/or". The word "shall" is mandatory. The word "may" is permissive. The singular includes the plural and the plural includes the singular.

(iv) Performance; Time. Whenever any performance obligation hereunder (other than a payment obligation) shall be stated to be due or required to be satisfied on a day other than a Business Day, such performance shall be made or satisfied on the next succeeding Business Day. In the computation of periods of time from a specified date to a later specified date, the word "from" means "from and including"; the words "to" and "until" each mean "to but excluding", and the word "through" means "to and including." If any provision of this Agreement refers to any action taken or to be taken by any Person, or which such Person is prohibited from taking, such provision shall be interpreted to encompass any and all means, direct or indirect, of taking, or not taking, such action.

(v) Contracts. Except as the context otherwise requires (including to the extent otherwise expressly provided herein), references to any contract, agreement, instrument or other document, including this Agreement and the other Loan Documents, shall be deemed to include any and all amendments, supplements or modifications thereto or restatements or substitutions thereof, in each case which are in effect from time to time, but only to the extent such amendments, supplements, modifications, restatements or substitutions are not prohibited by the terms of any Loan Document.

(vi) Laws. Except as the context otherwise requires (including to the extent otherwise expressly provided herein), references to any law, statute, treaty, order, policy, rule or regulation include any amendments, supplements and successors thereto, and references to any law, statute, treaty, order, policy, rule or regulation are to be construed as including all statutory and regulatory provisions related thereto or consolidating, amending, replacing, supplementing or interpreting such law, statute, treaty, order, policy, rule or regulation.

(vii) Excluded Property. Notwithstanding anything to the contrary herein, the representations, warranties and covenants set forth herein in relation to the assets of the Grantors shall not apply to any Excluded Property.

ARTICLE 2

GUARANTY

Section 2.1 **Guaranty**

. To induce Lenders to make the Term Loans to Borrower in accordance with the terms and conditions of the Loan Agreement, each Guarantor, jointly and severally with each other Guarantor, absolutely, unconditionally and irrevocably guarantees, as primary obligor and not merely as surety, the full and punctual payment when due, whether at stated maturity or earlier, by reason of acceleration, mandatory prepayment or otherwise in accordance with any Loan Document, of all the Obligations of Borrower existing on the date hereof or hereinafter incurred or created (the "Guaranteed Obligations"). This Guaranty by each Guarantor hereunder constitutes a guaranty of payment and not of collection. Each Guarantor hereby acknowledges and agrees that the Guaranteed Obligations, at any time and from time to time, may exceed the Maximum Guaranteed Amount of such Guarantor and may exceed the aggregate of the Maximum Guaranteed Amounts of all Guarantors, in each case without discharging, limiting or otherwise affecting the obligations of any Guarantor hereunder or the rights, powers and remedies of any Secured Party hereunder or under any other Loan Document.

Section 2.2 **Limitation of Guaranty**

. Any term or provision of this Guaranty or any other Loan Document to the contrary notwithstanding, the maximum aggregate amount for which any Guarantor shall be liable hereunder (the "Maximum Guaranteed Amount") shall not exceed the maximum amount for which such Guarantor can be liable without rendering this Guaranty or any other Loan Document, as it relates to such Guarantor, subject to avoidance under (a) applicable Requirements of Law relating to fraudulent conveyance or fraudulent transfer (including the Uniform Fraudulent Conveyance Act, the Uniform Fraudulent Transfer Act and Section 548 of title 11 of the United States Code or any applicable provisions of comparable Requirements of Law) (collectively, "Fraudulent Transfer Laws") and (b) the Israeli Guarantee Law, 5727-1967. Any analysis of the provisions of this Guaranty for purposes of Fraudulent Transfer Laws shall take into account the right of contribution established in Section 2.7 below and, for purposes of such analysis, give effect to any discharge of intercompany debt as a result of any payment made under the Guaranty.

Section 2.3 **Authorization; Other Agreements**

. The Collateral Agent, on behalf of Lenders and the other Secured Parties, is hereby authorized, without notice to or demand upon any Guarantor and without discharging or otherwise affecting the obligations of any Guarantor hereunder and without incurring any liability hereunder, from time to time, to do each of the following but subject in all cases to the terms and conditions of the other Loan Documents:

(a) subject to compliance with Section 11.5 of the Loan Agreement and Section 8.5 hereof (as applicable), (i) modify, amend, supplement or otherwise change, (ii) accelerate or otherwise change the time of payment or (iii) waive or otherwise consent to noncompliance with, any Guaranteed Obligation or any Loan Document;

(b) apply to the Guaranteed Obligations any sums by whomever paid or however realized to any Guaranteed Obligation in such order as provided in the Loan Documents;

(c) refund at any time any payment received by any Secured Party in respect of any Guaranteed Obligation;

(d) in accordance with the terms of the Loan Documents: (i) sell, exchange, enforce, waive, substitute, liquidate, terminate, release, abandon, fail to perfect, subordinate, accept, substitute, surrender, exchange, affect, impair or otherwise alter or release any Collateral for any Guaranteed Obligation or any other guaranty therefor in any manner, (ii) receive, take and hold additional Collateral to secure any Guaranteed Obligation, (iii) add, release or substitute any one or more other Guarantors, makers or endorsers of any Guaranteed Obligation or any part thereof and (iv) otherwise deal in any manner with Borrower or any other Guarantor, maker or endorser of any Guaranteed Obligation or any part thereof; and

(e) subject to Section 11.1 of the Loan Agreement, settle, release, compromise, collect or otherwise liquidate the Guaranteed Obligations.

Section 2.4 **Guaranty Absolute and Unconditional**

. Each Guarantor hereby waives and agrees not to assert any defense (other than the absolute, unconditional and irrevocable payment in full of the Guaranteed Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), whether arising in connection with or in respect of any of the following clauses (a) through (f) or otherwise, and hereby agrees that its obligations under this Guaranty are irrevocable, absolute and unconditional and shall not be discharged as a result of or otherwise affected by any of the following clauses (a) through (f) (which may not be pleaded and evidence of which may not be introduced in any proceeding with respect to this Guaranty, in each case except as otherwise agreed in writing by the Collateral Agent):

(a) the invalidity or unenforceability of any obligation of Borrower or any other Guarantor under any Loan Document or any other agreement or instrument relating thereto (including any amendment, consent or waiver thereto), or any security for, or other guaranty of, any Guaranteed Obligation or any part thereof, or the lack of perfection or continuing perfection or failure of priority of any security for the Guaranteed Obligations or any part thereof;

(b) the absence of (i) any attempt to collect any Guaranteed Obligation or any part thereof from Borrower or any other Guarantor or other action to enforce the same or (ii) any action to enforce any Loan Document or any Lien thereunder;

(c) the failure by any Person to take any steps to perfect and maintain any Lien on, or to preserve any rights with respect to, any Collateral;

(d) any workout, insolvency, bankruptcy proceeding, reorganization, arrangement, liquidation or dissolution by or against Borrower, any other Guarantor or any of Borrower's other Subsidiaries or any procedure, agreement, order, stipulation, election, action or omission thereunder,

including any discharge or disallowance of, or bar or stay against collecting, any Guaranteed Obligation (or any interest thereon) in or as a result of any such proceeding;

(e) any foreclosure, whether or not through judicial sale, and any other sale or other disposition of any Collateral or any election following the occurrence of an Event of Default and during the continuance thereof by the Collateral Agent, on behalf of Lenders and any other Secured Party, to proceed separately against any Collateral in accordance with the Collateral Agent's rights and the rights of any Lender or other Secured Party under any applicable Requirements of Law; or

(f) any other defense, setoff, counterclaim or any other circumstance that might otherwise constitute a legal or equitable discharge of Borrower, any other Guarantor or any other Subsidiary of Borrower, in each case other than the absolute, unconditional and irrevocable payment in full of the Guaranteed Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted).

Section 2.5 **Waivers**

. Except, in each case, as otherwise expressly required in any of the Loan Documents, to the fullest extent permitted by Requirements of Law, each Guarantor hereby unconditionally and irrevocably waives and agrees not to assert any claim, defense, setoff or counterclaim based on diligence, promptness, presentment, requirements for any demand or notice hereunder, including any of the following: (a) any demand for payment or performance and protest and notice of protest; (b) any notice of acceptance; (c) any presentment, demand, protest or further notice or other requirements of any kind with respect to any Guaranteed Obligation (including any accrued but unpaid interest thereon) becoming immediately due and payable; and (d) any other notice in respect of any Guaranteed Obligation or any part thereof, and any defense arising by reason of any disability or other defense of Borrower or any other Guarantor. Until the absolute, unconditional and irrevocable payment in full of the Guaranteed Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), each Guarantor further unconditionally and irrevocably agrees not to (x) enforce or otherwise exercise any right of subrogation or any right of reimbursement or contribution or similar right against Borrower or any other Guarantor by reason of any Loan Document or any payment made thereunder or (y) assert any claim, defense, setoff or counterclaim it may have against any other Credit Party or set off any of its obligations to such other Credit Party against obligations of such Credit Party to such Guarantor. No obligation of any Guarantor hereunder shall be discharged other than by complete performance.

Section 2.6 **Reliance**

. Each Guarantor hereby assumes responsibility for keeping itself informed of the financial condition of Borrower, each other Guarantor and any other guarantor, maker or endorser of any Guaranteed Obligation or any part thereof, and of all other circumstances bearing upon the risk of nonpayment of any Guaranteed Obligation or any part thereof that reasonable and diligent inquiry would reveal, and each Guarantor hereby agrees that neither the Collateral Agent nor any Lender or other Secured Party shall have any duty to advise any Guarantor of information known to it regarding such condition or any such circumstances. In the event the Collateral Agent, in its sole discretion, undertakes at any time or from time to time to provide any such information to any Guarantor, such Person shall be under no obligation to (a) undertake any investigation not a part of its regular business routine, (b) disclose any information that any Lender or other Secured Party, pursuant to accepted or reasonable commercial finance or banking practices, wishes to maintain confidential or (c) make any future disclosures of such information or any other information to any Guarantor.

Section 2.7 **Contribution**

. To the extent that any Guarantor shall be required hereunder to pay any portion of any Guaranteed Obligation exceeding the greater of (a) the amount of the value actually received by such Guarantor and its Subsidiaries from the Term Loans and other Obligations and (b) the amount such Guarantor would otherwise have paid if such Guarantor had paid the aggregate amount of the Guaranteed Obligations (excluding the amount thereof repaid by Borrower) in the same proportion as such Guarantor's net worth on the date enforcement is sought hereunder bears to the aggregate net worth of all Guarantors on such date, then such Guarantor shall be reimbursed by such other Guarantors for the amount of such excess, *pro rata*, based on the respective net worth of such other Guarantors on such date.

ARTICLE 3

GRANT OF SECURITY INTEREST

Section 3.1 **Collateral**

. For the purposes of this Agreement, the following tangible and intangible assets and property now owned or at any time hereafter acquired, developed or created by a Grantor or in which a Grantor now has or at any time in the future may acquire any right, title or interest, in each case, wherever located, is collectively referred to as the "Collateral":

(a) all accounts;

(b) all as-extracted collateral;

(c) all chattel paper, including electronic chattel paper or tangible chattel paper;

(d) all checks;

(e) all deposit accounts;

(f) all documents;

(g) all encumbrances;

(h) all equipment;

(i) all fixtures;

(j) all general intangibles (including all Current Company IP Agreements, Manufacturing Agreements and any other agreements or contracts of any kind);

(k) all goods;

(l) all Intellectual Property and IP Licenses (including any IP Licenses under the Current Company IP Agreements to which a Grantor is a party and the rights of such Grantor thereunder, and all of a Grantor's right, title and interest in, to and under any Internet Domain Names and Software), including any similar or equivalent rights to those set forth in any of clauses (a) through (g) of the definition of "Intellectual Property");

(m) all instruments (including all promissory notes and similar instruments);

(n) all right, title and interest in, to and under any NDA relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale or lease, distribution, sale or lease of Product in the Territory;

(o) all inventory;

(p) all investment property (including Pledged Collateral, Pledged Investment Property, Equity Interests, securities, securities accounts and security entitlements with respect thereto and financial assets carried therein, and all commodity accounts and commodity contracts);

(q) all money (including cash and cash equivalents);

(r) all letters of credit, letter-of-credit rights and supporting obligations;

(s) all commercial tort claims with a predicted value of $500,000 or more (as reasonably determined by a Responsible Officer of Parent in good faith and based upon reasonable assumptions described on Schedule 4 of the Security Disclosure Letter);

(t) all books, records, ledger cards, files, correspondence, customer lists, blueprints, technical specifications, manuals, computer software, computer printouts, tapes, disks and other electronic storage media and related data processing software and similar items that at any time pertain to or evidence or contain information relating to any of the other property described in this Section 3.1;

(u) all property of such Grantor held by the Collateral Agent for the benefit of Lenders and any other Secured Party, including all property of every description, in the custody of or in transit to the Collateral Agent for the benefit of Lenders and any other Secured Party for any purpose, including safekeeping, collection or pledge, for the account of such Grantor or as to which such Grantor may have any right or power, including cash;

(v) all proceeds, products, accessions, rents and profits of or in respect of any of the foregoing;

(w) to the extent not otherwise included, all personal property of such Grantor, whether tangible or intangible and wherever located, and all proceeds, products, accessions, rents, issues and profits of any and all of the foregoing and all collateral security, supporting obligations and guarantees given by any Person with respect to any of the foregoing; and

(x) to the extent not otherwise included, all other properties or assets of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Collateral Document;

excluding, however, in all cases, all Excluded Property.

Section 3.2 **Grant of Security Interest in Collateral**

. Without limiting any other security interest granted to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, each Grantor, as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Obligations of such Grantor (the "Secured Obligations"), hereby pledges, hypothecates and grants to the Collateral Agent, in favor and for the benefit of Lenders and the other Secured Parties, to secure the payment and performance in full of all of the Obligations for the benefit of Lenders and the other Secured Parties, a first priority Lien (subject only to Permitted Liens) on and continuing security interest in, all of its right, title and interest in, to and under the Collateral of such Grantor, wherever located, whether now owned or hereafter acquired or arising; provided, however, notwithstanding the foregoing, no Lien or security interest is hereby granted on, and "Collateral" shall not include, any Excluded Property; provided, further, that if and when any property or asset shall cease to be Excluded Property, a first priority Lien (subject only to Permitted Liens) on and security interest in such property or asset shall be deemed granted therein and, therefore, "Collateral" shall then include any such property or asset.

ARTICLE 4

REPRESENTATIONS AND WARRANTIES

To induce each of the Collateral Agent and Lenders to enter into the Loan Documents, each Grantor, jointly and severally with each other Grantor, represents and warrants each of the following to the Collateral Agent, each Lender and the other Secured Parties:

Section 4.1 **Title; No Other Liens**

. Except for the Lien granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties pursuant to this Agreement and any other Permitted Liens under any Loan Document (including Section 4.2 hereof), such Grantor owns or otherwise has the rights it purports to have in each item of the Collateral, free and clear of any and all Liens or claims of others. Such Grantor (a) is the record and beneficial owner of the Collateral pledged by it hereunder constituting instruments or certificates and (b) except for Permitted Subsidiary Distribution Restrictions, has rights in or the power to transfer each other item of Collateral in which a Lien is granted by it hereunder, free and clear of any other Lien other than any Permitted Liens.

Section 4.2 **Perfection and Priority**

. Other than in respect of money and other Collateral subject to Section 9-311(a)(1) of the Code, the security interest granted to the Collateral Agent pursuant to this Agreement constitutes a valid and continuing first priority perfected security interest (subject, in the case of priority only, to Permitted

Liens that are expressly permitted (if at all) by the terms of the Loan Agreement or this Agreement to, or that by operation of law, have superior priority to the Lien and security interest granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties) in favor of and for the benefit of Lenders and the other Secured Parties in all Collateral, subject, for the following Collateral, to the occurrence of the following: (a) in the case of all Collateral in which a security interest may be perfected by filing a financing statement under the Code, the completion of the filings and other actions specified on Schedule 2 of the Security Disclosure Letter (which, in the case of all filings and other documents referred to on such schedule, have been duly authorized by the applicable Grantor); (b) with respect to any account over which a Control Agreement is required pursuant to Section 5.5 of the Loan Agreement, the execution of Control Agreements; (c) in the case of all United States Trademarks, Patents and Copyrights for which Code filings are insufficient to effectuate perfection, all appropriate filings having been made with the Applicable IP Office, as applicable; (d) in the case of all Pledged Certificated Stock, Pledged Debt Instruments and Pledged Investment Property, the delivery to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of such Pledged Certificated Stock, Pledged Debt Instruments and Pledged Investment Property consisting of instruments and certificates, in each case, properly endorsed for transfer to the Collateral Agent or in blank; (e) in the case of all Pledged Uncertificated Stock, the delivery to the Collateral Agent, for the benefit of the Lenders and the other Secured Parties, of an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent in the form attached as Annex 4 hereto; (f) in the case of letter-of-credit rights that are not supporting obligations of Collateral, the execution of a contractual obligation granting control to Collateral Agent, for the benefit of the Lenders and the other Secured Parties, over such letter-of-credit rights; (g) in the case of electronic chattel paper, the completion of all steps necessary to grant control to Collateral Agent, for the benefit of the Lenders and the other Secured Parties, over such electronic chattel paper; and (h) in the case of all other instruments that are not Pledged Stock, if any, the delivery thereof to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of such instruments. Such Lien on and security interest in Pledged Stock shall be prior to all other Liens on such Collateral, subject to Permitted Liens having priority over the Collateral Agent's Lien by operation of law or as and to the extent expressly permitted (if at all) by any Loan Document. Subject to Section 3.2 and this Section 4.2 above, except to the extent expressly not required pursuant to the terms of the Loan Agreement or this Agreement, all actions by each Grantor necessary or desirable under the Code to protect and perfect the first priority Lien on and security interest in the Collateral granted hereunder have been duly taken.

Section 4.3 **Pledged Stock**

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(a) The Pledged Stock issued by any Subsidiary of any Grantor pledged by such Grantor hereunder (i) consist of the number and types of Equity Interests listed on Schedule 1 of the Security Disclosure Letter (or any update thereof or supplement thereto permitted to be made pursuant to the Loan Agreement and received by the Collateral Agent in accordance with the Loan Agreement) and constitutes that percentage of the issued and outstanding equity of all classes of each issuer thereof as set forth on Schedule 1 of the Security Disclosure Letter, (ii) has been duly authorized, validly issued and is fully paid and nonassessable (other than Pledged Stock in limited liability companies and partnerships), and (iii) if and to the extent applicable, constitutes the legal, valid and binding obligation of the issuer thereof with respect thereto, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law). As of the date any Joinder Agreement or Pledge Amendment is delivered pursuant to Section 8.6, the Pledged Stock pledged by each applicable Grantor thereunder (x) is listed on the applicable schedule attached to such Joinder Agreement or Pledge Amendment, as applicable, and constitutes that percentage of the issued and outstanding equity of all classes of each issuer thereof as set forth on such schedule, (y) has been duly authorized, validly issued and is fully paid and non-assessable (other than Pledged Stock in limited liability companies and partnerships) and (z) if and to the extent applicable, constitutes the legal, valid and binding obligation of the issuer thereof with respect thereto, enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law).

(b) All Pledged Certificated Stock has been delivered to (or otherwise in accordance with the written direction of) the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a), and (ii) with respect to all Pledged Uncertificated Stock, uncertificated stock control agreements in the form attached as Annex 4 hereto have been delivered to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a).

(c) Upon the occurrence and during the continuance of an Event of Default, the Collateral Agent for the benefit of Lenders and the other Secured Parties shall be entitled to exercise all of the rights of the Grantor granting the security interest in any Pledged Stock, and a transferee or assignee of such Pledged Stock shall become a holder of such Pledged Stock to the same extent as such Grantor and, upon the transfer of the entire interest of such Grantor, such Grantor shall, by operation of law, cease to be a holder of such Pledged Stock.

Section 4.4 **Pledged Debt Instruments**

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(a) (i) All Pledged Debt Instruments constituting Indebtedness owed to such Grantor by a Subsidiary has been duly authorized, authenticated or issued and delivered by such Subsidiary, is the legal, valid and binding obligation of such Subsidiary and such Subsidiary is not in default thereunder and (ii) to the Knowledge of such Grantor, all other Pledged Debt Instruments not otherwise covered in clause (i) above constituting Indebtedness owed to such Grantor has been duly authorized, authenticated or issued and delivered by the issuer of such Indebtedness, is the legal, valid and binding obligation of such issuer and such issuer is not in default thereunder.

(b) Except as set forth on Schedule 3 of the Security Disclosure Letter (or any update thereof or supplement thereto permitted to be made pursuant to the Loan Agreement and received by the Collateral Agent in accordance with the Loan Agreement), none of the Pledged Debt Instruments constituting Indebtedness owed to such Grantor is subordinated in right of payment to any other Indebtedness or subject to the terms of an indenture (or similar agreement or instrument).

(c) All Pledged Debt Instruments constituting Indebtedness owed to such Grantor have been delivered to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a).

ARTICLE 5

COVENANTS

Each Grantor agrees with the Collateral Agent to the following, until the absolute, unconditional and irrevocable payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) and unless the

Collateral Agent, on behalf of Lenders and the other Secured Parties, otherwise consents in writing:

Section 5.1 **Maintenance of Perfected Security Interest; Further Documentation and Consents**

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(a) Except as otherwise (i) mutually agreed in writing between Borrower and the Collateral Agent not to be required under this Agreement or the other Loan Documents, (ii) mutually agreed in writing between Borrower and the Collateral Agent to be effected solely by filings of financing statements under the Code or amendments thereto to be made by the Collateral Agent or any Lender or its Related Party pursuant to Section 7.2, or (iii) as otherwise expressly provided in Section 5.14 of the Loan Agreement, such Grantor, in order to grant and maintain a security interest to the Collateral Agent pursuant to this Agreement which constitutes a valid and continuing first priority perfected security interest as described in Section 4.2 (subject only to Permitted Liens), shall promptly:

(i) after the creation or acquisition of any U.S. deposit account over which a Control Agreement is required pursuant to Section 5.5 of the Loan Agreement but prior to the movement of any cash or other funds into such account (except as may be expressly provided in Section 5.14 of the Loan Agreement), execute and deliver to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.5 of the Loan Agreement, Control Agreements in form and substance reasonably satisfactory to the Collateral Agent;

(ii) in accordance with the requirements in Section 5.3 (as applicable), with respect to any Trademarks, Patents and Copyrights or any IP Rights, execute and deliver to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, all appropriate IP Security Agreements, in form and substance reasonably satisfactory to the Collateral Agent, for the filing thereof by the Collateral Agent or its Related Party, and such Grantor hereby duly authorizes the Collateral Agent and its Related Party to file such IP Security Agreements with the Applicable IP Office;

(iii) with respect to any Pledged Certificated Stock, deliver to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Pledged Certificated Stock consisting of instruments and certificates, in each case, properly endorsed for transfer to the Collateral Agent or in blank and in form and substance reasonably satisfactory to the Collateral Agent;

(iv) with respect to any Pledged Uncertificated Stock, deliver to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent in the form attached as Annex 4 hereto (and otherwise in form and substance reasonably satisfactory to the Collateral Agent), pursuant to which, *inter alia*, such issuer agrees to comply with the Collateral Agent's instructions with respect to such Pledged Uncertificated Stock without further consent by such Grantor; and

(v) maintain the security interest created by this Agreement as a first priority perfected security interest as described in Section 4.2 (subject to Permitted Liens) and shall take reasonable efforts to warrant and defend the Collateral covered by such security interest and such priority (subject to Permitted Liens) against the claims and demands of all Persons (other than Secured Parties).

(b) Such Grantor shall furnish to the Collateral Agent at any time and from time to time statements and schedules further identifying and describing the Collateral and such other documents in connection with the Collateral as the Collateral Agent may reasonably request in writing, in all cases in reasonable detail and in form and substance reasonably satisfactory to the Collateral Agent (including in the case of any commercial tort claim constituting Collateral, for the avoidance of doubt, reasonable detail identifying the specific claims subject to the security interest granted in such commercial tort claims to the Collateral Agent pursuant to this Agreement).

(c) At any time and from time to time, upon the reasonable written request of the Collateral Agent, such Grantor shall, for the purpose of obtaining or preserving the full benefits of this Agreement and the other Collateral Documents and of the rights and powers herein and therein granted, (i) promptly and duly execute and deliver, and have recorded, such further documents, including an authorization to file (or, as applicable, the filing) of any financing statement or amendment under the Code (or other filings under similar Requirements of Law) in effect in the U.S. or any other jurisdiction with respect to the security interest created hereby and (ii) take such further action as the Collateral Agent may reasonably request in writing that is consistent with the requirements hereof and of the other Loan Documents, including executing and delivering any Control Agreements required by Section 5.5 of the Loan Agreement with respect to the Collateral Accounts, in each case of sub-clause (i) and (ii) above, subject to the terms of Section 5.12(e) of the Loan Agreement.

Section 5.2 **Pledged Collateral and Pledged Investment Property**

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(a) Delivery of Pledged Collateral and Pledged Investment Property. Without limitation to Section 1 above, such Grantor shall promptly, and no later than thirty (30) days after, acquiring any Pledged Collateral not owned on the Closing Date:

(i) deliver to the Collateral Agent, properly endorsed, in blank or otherwise in suitable form for transfer and in form and substance reasonably satisfactory to the Collateral Agent, (A) all such Pledged Stock that is Pledged Certificated Stock, (B) each Pledged Debt Instrument evidencing Indebtedness or other monetary obligations in an amount, individually or together with one or more other Pledged Debt Instruments, exceeding $500,000 (as reasonably determined by a Responsible Officer of Parent in good faith) and (C) all certificates and instruments evidencing Pledged Investment Property with a fair market value, individually or together with one or more other such certificates or instruments, exceeding $500,000 (as reasonably determined by a Responsible Officer of Parent in good faith);

(ii) subject all Collateral Accounts required to be subject to a Control Agreement pursuant to Section 5.5 of the Loan Agreement to a Control Agreement;

(iii) cause the issuer of any such Pledged Stock that is Pledged Uncertificated Stock to execute an uncertificated stock control agreement in the form attached hereto as Annex 4, pursuant to which, *inter alia*, such issuer agrees to comply with the Collateral Agent's instructions with respect to such Pledged Uncertificated Stock without further consent by such Grantor, and, for the avoidance of doubt, if any such Pledged Uncertificated Stock becomes certificated, promptly (but in any event within thirty (30) days thereof) deliver to the Collateral Agent, in suitable form for transfer and in form and substance reasonably satisfactory to the Collateral Agent, all such certificates, instruments or other similar documents (as defined in the Code).

(b) Event of Default. During the continuance of any Event of Default and in connection with the exercise of rights or remedies hereunder or under any other Loan Document, the Collateral Agent shall have the right, at any time in its discretion and without prior notice to any Grantor, to (i) transfer to or to register in its name or in the name of its nominees any Pledged Stock and (ii) exchange any certificate or instrument representing or evidencing any Pledged Stock for certificates or instruments of smaller or larger denominations.

(c) Cash Distributions with respect to Pledged Collateral and Pledged Investment Property. Except as provided in Article VI and subject to any limitations set forth in the Loan Agreement, such Grantor shall be entitled to receive all cash distributions paid in respect of the Pledged Collateral and the Pledged Investment Property.

(d) Voting Rights. Except as provided in Article VI, such Grantor shall be entitled to exercise all voting, consent and corporate, partnership, limited liability company and similar rights with respect to the Pledged Collateral and Pledged Investment Property; provided, however, that no vote shall be cast, consent, waiver or ratification given or right exercised (or failed to be exercised) or other action taken (or failed to be taken) by such Grantor in any manner that would reasonably be expected to (i) violate or be inconsistent with any of the terms of this Agreement or any other Loan Document or (ii) have the effect of materially impairing such Collateral or the position of any Secured Party or their rights or interests in such Collateral.

Section 5.3 **Intellectual Property**

. If such Grantor shall at any time after the date hereof acquire any Copyright, Trademark or Patent or any IP License that constitutes Collateral, such Grantor shall, within thirty (30) days after delivery of financial statements pursuant to Section 5.2(a) of the Loan Agreement, execute and deliver to the Collateral Agent, in form and substance reasonably acceptable to the Collateral Agent and suitable for filing in the Applicable IP Office, the IP Security Agreement(s) in the form attached hereto as Annex 3, or in any other form, as required by the Applicable IP Office or other registry in the applicable jurisdiction, in each case, in respect of any such newly-acquired Copyright(s), Trademark(s) or Patent(s) or any such newly-acquired IP Licenses (as applicable) of such Grantor registered in the Applicable IP Office.

ARTICLE 6

REMEDIAL PROVISIONS

Section 6.1 **Code and Other Remedies**

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(a) Code Remedies. During the continuance of an Event of Default, the Collateral Agent, on behalf of Lenders and the other Secured Parties, may exercise, in addition to all other rights and remedies granted to it in this Agreement, any IP Agreement, any other Loan Document or in any other instrument or agreement securing, evidencing or relating to any Secured Obligation, all rights, powers and remedies of a secured party under the Code or any other Requirements of Law or in equity.

(b) Disposition of Collateral. During the continuance of an Event of Default, without limiting the generality of the foregoing, the Collateral Agent may (personally or through its agents or attorneys), without demand of performance or other demand, presentment, protest, advertisement or notice of any kind (except any notice required by Requirements of Law referred to below) to or upon any Grantor or any other Person (all and each of which demands, defenses, advertisements and notices are hereby waived): (i) enter upon the premises where any Collateral is located, without any obligation to pay rent, through self-help, without judicial process, without first obtaining a final judgment or giving Grantor or any other Person notice or opportunity for a hearing on the Collateral Agent's or any Lender's claim or action; (ii) collect, receive, appropriate and realize upon any Collateral; (iii) store, process, repair or recondition the Collateral or otherwise prepare any Collateral for disposition in any manner to the extent the Collateral Agent deems appropriate; and (iv) sell, assign, license out, convey, transfer, grant option or options to purchase or license and deliver any Collateral (or enter into contractual obligations to do any of the foregoing), in one or more parcels at public or private sale or sales, at any exchange, broker's board or office of the Collateral Agent or any Lender or other Secured Party or elsewhere upon such terms and conditions as it may deem advisable and at such prices as it may deem best, for cash or on credit or for future delivery without assumption of any credit risk. The Collateral Agent, on behalf of Lenders and the other Secured Parties, shall have the right, upon any such public sale or sales and, to the extent permitted by the Code and other Requirements of Law, upon any such private sale or sales, to purchase or license the whole or any part of the Collateral so sold or licensed, free of any right or equity of redemption of any Grantor, which right or equity is hereby waived and released. The Collateral Agent, as representative of all Lenders and other Secured Parties, shall be entitled, for the purpose of bidding and making settlement or payment of the purchase price for all or any portion of the Collateral sold at any such sale made in accordance with the Code, to use and apply any of the Secured Obligations as a credit on account of the purchase price for any Collateral payable by the Collateral Agent on behalf of Lenders and the other Secured Parties, at such sale. If the Collateral Agent on behalf of any Lender sells any of the Collateral upon credit, Grantor will be credited only with payments actually made by purchaser and received by such Lender and applied to indebtedness of the purchaser. In the event the purchaser fails to pay for the Collateral, the Collateral Agent may resell the Collateral and Grantor shall be credited with proceeds of the sale. Neither the Collateral Agent nor any Lender shall have an obligation to marshal any of the Collateral.

(c) Management of the Collateral. Each Grantor further agrees, that, during the continuance of any Event of Default, (i) at the Collateral Agent's request, it shall assemble the Collateral and make it available to the Collateral Agent at places that the Collateral Agent shall reasonably select, whether at such Grantor's premises or elsewhere, (ii) without limiting the foregoing, the Collateral Agent also has the right to require that such Grantor store and keep any Collateral pending further action by the Collateral Agent and, while any such Collateral is so stored or kept, provide such guards and maintenance services as shall be necessary to protect the same and to preserve and maintain such Collateral in good condition, normal wear and tear excepted, (iii) until the Collateral Agent is able to sell, assign, license out, convey or transfer any Collateral, the Collateral Agent shall have the right to hold or use such Collateral to the extent that it deems appropriate for the purpose of preserving the Collateral or its value or for any other purpose deemed appropriate by the Collateral Agent and (iv) the Collateral Agent may, if it so elects, seek the appointment of a receiver or keeper to take possession of any Collateral and to enforce any of the Collateral Agent's or any Lender's remedies, with respect to such appointment without any prior written notice or hearing as to such appointment. The Collateral Agent shall not have any obligation to any Grantor to maintain or preserve the rights of any Grantor as against other Persons with respect to any Collateral while such Collateral is in the possession of the Collateral Agent.

(d) Application of Proceeds. The Collateral Agent shall apply the cash proceeds received by it in respect of any sale of, any collection from, or other realization upon all or any part of the Collateral, after deducting all reasonable costs and expenses of every kind incurred in connection therewith or incidental to the care or safekeeping of any Collateral or in any way relating to the Collateral or the rights of Lenders and the other Secured Parties, including reasonable and documented out-of-pocket attorneys' fees and disbursements, to the payment in whole or in part of the Secured Obligations, as set forth in the Loan Agreement and, if and only to the extent applicable thereunder, the RTW Intercreditor Agreement, and only after such

application and after the payment by the Collateral Agent or Lenders of any other amount required by any Requirements of Law, need the Collateral Agent or any Lender account for the surplus, if any, to any Grantor.

(e) Direct Obligation. Neither the Collateral Agent nor any Lender or other Secured Party shall be required to make any demand upon, or pursue or exhaust any right or remedy against, any Grantor or any other Person with respect to the payment of the Obligations or to pursue or exhaust any right or remedy with respect to any Collateral therefor or any direct or indirect guaranty thereof. All of the rights and remedies of the Collateral Agent and Lenders and any other Secured Party shall be cumulative, may be exercised individually or concurrently and not exclusive of any other rights or remedies provided by any Requirements of Law. To the extent it may lawfully do so, each Grantor absolutely and irrevocably waives and relinquishes the benefit and advantage of, and covenants not to assert against the Collateral Agent, Lenders or any other Secured Party, any valuation, stay, appraisement, extension, redemption or similar laws and any and all rights or defenses it may have as a surety, now or hereafter existing, arising out of the exercise by any of them of any rights or remedies hereunder. If any notice of a proposed sale (public or private) or other disposition of any Collateral shall be required by Requirements of Law, such notice shall be deemed reasonable and proper if given at least ten (10) days before such sale or other disposition.

(f) Commercially Reasonable. To the extent that applicable Requirements of Law impose duties on the Collateral Agent or any Lender or other Secured Party to exercise remedies in a commercially reasonable manner, each Grantor acknowledges and agrees that it is not commercially unreasonable for the Collateral Agent or any Lender to do any of the following:

(i) fail to incur significant costs, expenses or other liabilities reasonably deemed as such by the Collateral Agent or such Lender to prepare any Collateral for disposition or otherwise to complete raw material or work in process into finished goods or other finished products for disposition;

(ii) fail to obtain permits, licenses or other consents for access to any Collateral to sell or license or for the collection or sale or licensing of any Collateral, or, if not required by other Requirements of Law, fail to obtain permits, licenses or other consents for the collection or disposition of any Collateral;

(iii) fail to exercise remedies against account debtors or other Persons obligated on any Collateral or to remove Liens on any Collateral or to remove any adverse claims against any Collateral;

(iv) advertise dispositions of any Collateral through publications or media of general circulation, whether or not such Collateral is of a specialized nature, or to contact other Persons, whether or not in the same business as any Grantor, for expressions of interest in acquiring any such Collateral;

(v) exercise collection remedies against account debtors and other Persons obligated on any Collateral, directly or through the use of collection agencies or other collection specialists, hire one or more professional auctioneers to assist in the disposition of any Collateral, whether or not such Collateral is of a specialized nature, or, to the extent deemed appropriate by the Collateral Agent or such Lender, obtain the services of other brokers, investment bankers, consultants and other professionals to assist the Collateral Agent or such Lender in the collection or disposition of any Collateral, or utilize Internet sites that provide for the auction of assets of the types included in the Collateral or that have the reasonable capacity of doing so, or that match buyers and sellers of assets to dispose of any Collateral;

(vi) dispose of assets in wholesale rather than retail markets;

(vii) disclaim warranties, such as title, merchantability, possession, non-infringement or quiet enjoyment; or

(viii) purchase insurance or credit enhancements to insure the Collateral Agent or any Lender or other Secured Party against risks of loss, collection or disposition of any Collateral or to provide to the Collateral Agent and Lenders a guaranteed return from the collection or disposition of any Collateral.

(g) IP Licenses. To the extent permitted, and only for the purpose of enabling the Collateral Agent to exercise rights and remedies under this Section 6.1 or Section 8.1 of the Loan Agreement during the continuance of an Event of Default (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral) at such time as the Collateral Agent on behalf of Lenders and the other Secured Parties shall be lawfully entitled to exercise such rights and remedies, each Grantor hereby grants to the Collateral Agent: (i) an irrevocable, non-exclusive, assignable, royalty-free license or other right to use (and for its agents or representatives to use) in the Territory (exercisable without payment of royalty or other compensation to such Grantor), including the right to sublicense, use and practice, any and all Intellectual Property now owned or held or hereafter acquired or held by such Grantor and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; and (ii) an irrevocable license (without payment of rent or other compensation to such Grantor) to use, operate and occupy all real property owned, operated, leased, subleased or otherwise occupied by such Grantor; provided that, in each case of sub-clauses (i) and (ii) above, such license and sublicenses with respect to Trademarks will be subject to the maintenance of quality standards with respect to the goods and services on which such Trademarks are used sufficient to preserve the validity of such Trademarks; provided, further, that nothing in this clause (g) shall require a Grantor to grant any license that (x) violates the express terms of any license agreement between a Grantor and a third party governing such Grantor's use of such Intellectual Property or (y) is prohibited by applicable Requirement of Law.

Each Grantor acknowledges that the purpose of this Section 6.1 is to provide a non-exhaustive list of actions or omissions that are commercially reasonable when exercising remedies against any Collateral and that other actions or omissions by the Collateral Agent, Lenders or any other Secured Party shall not be deemed commercially unreasonable solely on account of not being indicated in this Section 6.1. Without limitation upon the foregoing, except as expressly provided in this Section 6.1, nothing contained in this Section 6.1 shall be construed to grant any rights to any Grantor or to impose any duties on the Collateral Agent or any Lender or other Secured Party that would not have been granted or imposed by this Agreement or by applicable Requirements of Law in the absence of this Section 6.1.

Section 6.2 **Accounts and Payments in Respect of General Intangibles**

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(a) In addition to, and not in substitution for, any similar requirement in the Loan Agreement, if required by the Collateral Agent at any time during the continuance of an Event of Default, any payment of accounts or payment in respect of general intangibles relating to the Collateral, when collected by any Grantor, shall promptly (and, in any event, within two (2) Business Days of such collection) be deposited by such Grantor in the exact

form received (unless the Collateral Agent otherwise agrees in writing), duly indorsed by such Grantor to the Collateral Agent for the benefit of Lenders and the other Secured Parties, segregated from other funds of such Grantor (unless the Collateral Agent otherwise agrees in writing) in a Collateral Account, subject to withdrawal by the Collateral Agent as provided in Section 6.4. Until so turned over, such payment shall be held by such Grantor in trust for the Collateral Agent for the benefit of Lenders and the other Secured Parties, segregated from other funds of such Grantor. Each such deposit of proceeds of accounts and payments in respect of general intangibles relating to the Collateral shall, upon the Collateral Agent's request, be accompanied by a report identifying in reasonable detail the nature and source of the payments included in the deposit.

(b) At any time during the continuance of an Event of Default, in each case to the extent not prohibited under Section 8.1 of the Loan Agreement:

(i) each Grantor shall, upon the Collateral Agent's request, assemble and hold for the benefit of Lenders and the other Secured Parties all original and other documents evidencing, and relating to, the contractual obligations and transactions that gave rise to any account or any payment in respect of general intangibles, including all IP Licenses, original orders, invoices and shipping receipts and notify account debtors that the accounts or general intangibles have been collaterally assigned to the Collateral Agent for the benefit of Lenders and the other Secured Parties and that payments in respect thereof shall be made directly to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct; and

(ii) each Grantor shall take all actions, deliver all documents and provide all information necessary or reasonably requested by the Collateral Agent to ensure any Internet Domain Name is registered.

(c) Anything herein to the contrary notwithstanding, each Grantor shall remain liable under each account and each payment in respect of general intangibles included in the Collateral to observe and perform all the conditions and obligations to be observed and performed by it thereunder, all in accordance with the terms of any agreement giving rise thereto. Neither the Collateral Agent nor any Lender or other Secured Party shall have any obligation or liability under any agreement giving rise to an account or a payment in respect of a general intangible included in the Collateral by reason of or arising out of any Loan Document or the receipt by the Collateral Agent or any Lender or other Secured Party of any payment relating thereto, nor shall the Collateral Agent nor any Lender or other Secured Party be obligated in any manner to perform any obligation of any Grantor under or pursuant to any agreement giving rise to an account or a payment in respect of a general intangible included in the Collateral, to make any payment, to make any inquiry as to the nature or the sufficiency of any payment received by it or as to the sufficiency of any performance by any party thereunder, to present or file any claim, to take any action to enforce any performance or to collect the payment of any amounts that may have been assigned to it or to which it may be entitled at any time or times.

Section 6.3 **Pledged Collateral**

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(a) Voting Rights. During the continuance of an Event of Default, upon written notice from the Collateral Agent to the relevant Grantor(s), all rights of each Grantor to exercise or refrain from exercising the voting and other consensual rights which it would otherwise be entitled to exercise pursuant hereto shall cease and all such rights shall thereupon become vested in the Collateral Agent or a nominee on behalf of Lenders or the other Secured Parties, who shall thereupon have the sole right to exercise such voting and other consensual rights, including the right to exercise (i) any voting, consent, corporate and other right pertaining to the Pledged Collateral at any meeting of shareholders, partners or members, as the case may be, of the relevant issuer or issuers of Pledged Collateral or otherwise, and (ii) any right of conversion, exchange and subscription and any other right, privilege or option pertaining to the Pledged Collateral as if it were the absolute owner thereof (including the right to exchange at its discretion any Pledged Collateral upon the merger, amalgamation, consolidation, reorganization, recapitalization or other fundamental change in the corporate or equivalent structure of any issuer of Pledged Collateral, the right to deposit and deliver any Pledged Collateral with any committee, depositary, transfer agent, registrar or other designated agency upon such terms and conditions as the Collateral Agent (or such nominee) on behalf of Lenders or the other Secured Parties may determine), all without liability except to account for property actually received by it; provided, however, that the Collateral Agent (or such nominee) shall have no duty to any Grantor to exercise any such right, privilege or option and shall not be responsible for any failure to do so or delay in so doing; provided, further, that the failure of the Collateral Agent (or such nominee) to delivery such notice shall not limit, affect or diminish any right of the Collateral Agent or the Lenders hereunder.

(b) Proxies. During the continuance of an Event of Default, in order to permit the Collateral Agent on behalf of Lenders and the other Secured Parties to exercise the voting and other consensual rights that it may be entitled to exercise pursuant hereto and to receive all dividends and other distributions that it may be entitled to receive hereunder, (i) each Grantor shall promptly execute and deliver (or cause to be executed and delivered) to the Collateral Agent all such proxies, dividend payment orders and other instruments as the Collateral Agent may from time to time reasonably request in writing and (ii) without limiting the effect of clause (i) above, such Grantor hereby grants to the Collateral Agent for the benefit of Lenders and the other Secured Parties an irrevocable proxy to vote all or any part of the Pledged Collateral and to exercise all other rights, powers, privileges and remedies to which a holder of the Pledged Collateral would be entitled (including giving or withholding written consents of shareholders, partners or members, as the case may be, calling special meetings of shareholders, partners or members, as the case may be, and voting at such meetings), which proxy shall be effective, automatically and without the necessity of any action (including any transfer of any Pledged Collateral on the record books of the issuer thereof) by any other Person (including the issuer of such Pledged Collateral or any officer or agent thereof) during the continuance of an Event of Default and which proxy shall only terminate upon (A) the cure of any and all Events of Default or (B) the absolute, unconditional and irrevocable payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted).

(c) Authorization of Issuers. Each Grantor hereby expressly and irrevocably authorizes and instructs, without any further instructions from such Grantor, each issuer of any Pledged Collateral pledged hereunder by such Grantor to, and each Grantor that is an issuer of Pledged Collateral so pledged hereunder hereby agrees to: (i) comply with any instruction received by it from the Collateral Agent in writing that states that an Event of Default is continuing and is otherwise in accordance with the terms of this Agreement, and each Grantor agrees that such issuer shall be fully protected from liabilities to such Grantor in so complying; and (ii) during the continuance of such Event of Default, unless otherwise permitted hereby or by the Loan Agreement, pay any dividend or make any other payment with respect to the Pledged Collateral directly to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct.

Section 6.4 **Proceeds to be Turned over to and Held by Collateral Agent**

. Unless otherwise expressly provided in the Loan Agreement or this Agreement, during the continuance of an Event of Default and, upon written notice by the Collateral Agent to the relevant Grantor or Grantors, all proceeds of any Collateral received by any Grantor hereunder in cash or Cash Equivalents shall be held by such Grantor in trust for Lenders and the other Secured Parties, segregated from other funds of such Grantor (unless the

Collateral Agent otherwise agrees in writing), and shall, promptly upon receipt by any Grantor, be turned over to the Collateral Agent for the benefit of Lenders and the other Secured Parties in the exact form received (unless the Collateral Agent otherwise agrees in writing), with any necessary endorsement. All such proceeds of Collateral and any other proceeds of any Collateral received by the Collateral Agent in cash or Cash Equivalents shall be held by the Collateral Agent for the benefit of itself and the other Secured Parties in a Collateral Account. All proceeds being held by the Collateral Agent in a Collateral Account (or by such Grantor in trust for Lenders and the other Secured Parties) shall continue to be held as collateral security for the Secured Obligations and shall not constitute payment thereof until applied as provided in the Loan Agreement.

Section 6.5 **Sale of Pledged Collateral**

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(a) Each Grantor recognizes that the Collateral Agent may be unable to effect a public sale of any Pledged Collateral by reason of certain prohibitions contained in the Securities Act and applicable state or foreign securities laws or otherwise or may determine that a public sale is impracticable, not desirable or not commercially reasonable and, accordingly, may resort to one or more private sales thereof to a restricted group of purchasers that shall be obliged to agree, among other things, to acquire such securities for their own account for investment and not with a view to the distribution or resale thereof. Each Grantor acknowledges and agrees that any such private sale may result in prices and other terms less favorable than if such sale were a public sale and, notwithstanding such circumstances, agrees that any such private sale shall be deemed to have been made in a commercially reasonable manner. The Collateral Agent shall be under no obligation to delay a sale of any Pledged Collateral for the period of time necessary to permit the issuer thereof to register such securities for public sale under the Securities Act or under applicable state securities laws even if such issuer would agree to do so.

(b) Each Grantor agrees to use commercially reasonable efforts to do or cause to be done all such other acts as may be reasonably necessary to make such sale or sales of any portion of the Pledged Collateral pursuant to Section 6.1, this Section 6.5 and Section 8.1 of the Loan Agreement valid and binding and in compliance with all applicable Requirements of Law. Each Grantor further agrees that a breach of any covenant contained herein will cause irreparable injury to the Collateral Agent, Lenders and the other Secured Parties, that the Collateral Agent, Lenders and the other Secured Parties have no adequate remedy at law in respect of such breach and, as a consequence, that each and every covenant contained herein shall be specifically enforceable against such Grantor, and such Grantor hereby waives and agrees not to assert any defense against an action for specific performance of such covenants except for a defense that no Event of Default has occurred and is continuing under the Loan Agreement or a defense of unconditional payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted). Each Grantor waives any and all rights of contribution or subrogation upon the sale or disposition of all or any portion of the Pledged Collateral by the Collateral Agent on behalf of Lenders and the other Secured Parties.

Section 6.6 **Deficiency**

. Each Grantor shall remain liable for any deficiency if the proceeds of any sale or other disposition of any Collateral are insufficient to pay the Secured Obligations and the reasonable and documented fees and disbursements of any attorney employed by the Collateral Agent or any Lender to collect such deficiency.

Section 6.7 **Collateral Accounts**

. If any Event of Default shall have occurred and be continuing, the Collateral Agent may apply the balance from any Collateral Account of a Grantor or instruct the bank at which any Collateral Account is maintained to pay the balance of any Collateral Account to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct, to be applied to the Secured Obligations in accordance with the terms hereof.

Section 6.8 **Directions, Notices or Instructions**

. Neither the Collateral Agent nor any Lender or any Related Party thereof or any other Secured Party shall take any action under or issue any directions, notice or instructions pursuant to any Control Agreement or similar agreement or any acknowledgement from a landlord or third party bailee with respect to any Collateral Access Agreement unless an Event of Default has occurred and is continuing.

ARTICLE 7

ADDITIONAL RIGHTS OF COLLATERAL AGENT

Section 7.1 **Collateral Agent's Appointment as Attorney-in-Fact**

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(a) Each Grantor hereby irrevocably constitutes and appoints the Collateral Agent and any Related Party thereof, with full power of substitution, as its true and lawful attorney-in-fact with full irrevocable power and authority in the place and stead of such Grantor and in the name of such Grantor or in its own name, for the purpose of carrying out the terms of the Loan Documents, to take any appropriate action and to execute any document or instrument that may be necessary or desirable to accomplish the purposes of the Loan Documents, in each case during the continuance of an Event of Default, and, without limiting the generality of the foregoing, each Grantor hereby gives the Collateral Agent and its Related Party the power and right, on behalf of such Grantor, without notice to or assent by such Grantor, to do any of the following when an Event of Default shall be continuing:

(i) in the name of such Grantor, in its own name or otherwise, take possession of and indorse and collect any check, draft, note, acceptance or other instrument for the payment of moneys due under any account or general intangible or with respect to any other Collateral and file any claim or take any other action or proceeding in any court of law or equity or otherwise deemed appropriate by the Collateral Agent for the purpose of collecting any such moneys due under any account or general intangible or with respect to any other Collateral whenever payable;

(ii) in the case of any Intellectual Property (including any IP Ancillary Rights) or any IP Licenses included in the Collateral, execute, deliver and have recorded any document that the Collateral Agent may request to evidence, effect, publicize or record the Collateral Agent's security interest, in favor of and for the benefit of Lenders and the other Secured Parties, in such Intellectual Property or IP Licenses and the goodwill and general intangibles of such Grantor relating thereto or represented thereby and the Collateral Agent's (on behalf of Lenders and the other Secured Parties) rights and remedies with respect thereto;

(iii) pay or discharge taxes and Liens levied or placed on or threatened against any Collateral, effect any repair or obtain or pay any insurance called for by the terms of the Loan Agreement (including all or any part of the premiums therefor and the costs thereof);

(iv) execute, in connection with any sale provided for in Section 6.1 or 6.5, any document to effect or otherwise necessary or appropriate in relation to evidence the sale of any Collateral; or

(v) (A) direct any party liable for any payment under any Collateral to make payment of any moneys due or to become due thereunder directly to the Collateral Agent or as the Collateral Agent shall direct, (B) ask or demand for, and collect and receive payment of and receipt for, any moneys, claims and other amounts due or to become due at any time in respect of or arising out of any Collateral, (C) commence and prosecute any suit, action or proceeding at law or in equity in any court of competent jurisdiction to collect any Collateral and to enforce any other right in respect of any Collateral, (D) defend any actions, suits, proceedings, audits, claims, demands, orders or disputes brought against such Grantor with respect to any Collateral, (E) settle, compromise or adjust any such actions, suits, proceedings, audits, claims, demands, orders or disputes and, in connection therewith, give such discharges or releases as the Collateral Agent may deem appropriate, (F) assign or license any Intellectual Property included in the Collateral on such terms and conditions and in such manner as the Collateral Agent shall in its sole discretion determine, including the execution and filing of any document necessary to effectuate or record such assignment or license and (G) generally, sell, assign, license, convey, transfer or grant a Lien on, make any contractual obligation with respect to and otherwise deal with, any Collateral as fully and completely as though the Collateral Agent on behalf of Lenders and the other Secured Parties were the absolute owner thereof for all purposes and do, at the Collateral Agent's option, at any time or from time to time, all acts and things that the Collateral Agent deems necessary to protect, preserve or realize upon any Collateral and the Collateral Agent's, in favor of and for the benefit of Lenders and the other Secured Parties, security interests therein and to effect the intent of the Loan Documents, all as fully and effectively as such Grantor might do.

(vi) If any Grantor fails to perform or comply with any contractual obligation contained herein, the Collateral Agent, at its option, but without any obligation so to do, may perform or comply, or otherwise cause performance or compliance, with such contractual obligation.

(b) In accordance with, and without limiting the generality of, Section 2.4 of the Loan Agreement, each Grantor agrees to promptly pay or reimburse the Lender Expenses and any other reasonable and documented out-of-pocket expenses of the Collateral Agent and any Lender and other Secured Party incurred in connection with the taking of any actions pursuant to or as otherwise contemplated by this Section 7.1, together with, solely in the event any Grantor fails to pay any of the Obligations when due or upon the commencement and during the continuance of an Insolvency Proceeding of the Borrower or, at the election of the Required Lenders, upon the occurrence and during the continuance of any other Event of Default, interest thereon at the Default Rate from the date any such expenses were paid by the Collateral Agent or any Lender through the date such expenses are reimbursed by the relevant Grantor.

(c) Each Grantor hereby ratifies all that said attorneys shall lawfully do or cause to be done by virtue of this Section 7.1. All powers, authorizations and agencies contained in this Agreement are coupled with an interest and are irrevocable until the absolute, unconditional and irrevocable payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted), this Agreement is terminated and the security interests created hereby are released

Section 7.2 **Authorization to File Financing Statements**

. Each Grantor authorizes the Collateral Agent and its Related Party, at any time and from time to time, without notice to any Grantor, to file or record financing statements and other filing or recording documents or instruments with respect to any Collateral, and amendments thereto, in each case in such form, in such jurisdictions and in such offices as the Collateral Agent reasonably determines appropriate to perfect or protect the security interests of the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, under this Agreement or any other Loan Document (and the Collateral Agent's and each Lender's and each other Secured Party's rights in respect thereof), and such financing statements, documents and instruments, and amendments thereto, may describe the Collateral covered thereby as "all assets of the debtor" or words of similar effect and may include a notice that any disposition of the Collateral, by any Grantor or other Person, shall be deemed to violate the rights of the Collateral Agent and Lenders and other Secured Parties under the Code (or other Requirements of Law in the applicable jurisdiction) to the extent not permitted under this Agreement or any other Loan Document. Save as otherwise required by Requirements of Law, a photographic or other reproduction of this Agreement shall be sufficient as a financing statement or other filing or recording document or instrument for filing or recording in any jurisdiction. Notwithstanding anything to the contrary herein or in the Loan Agreement, Lender Expenses shall not include, and the Collateral Agent and Lenders shall be solely responsible for, any filing fees or other expenses incurred by the Collateral Agent or any Lender in connection with any filings, recordings or other actions taken in jurisdictions other than the United States, Israel and, with respect to any Grantor that is not a Domestic Subsidiary, the jurisdiction of such Grantor, and, upon the occurrence and during the continuance of an Event of Default, any such other jurisdiction pursuant to Section 5.12(e) of the Loan Agreement.

Section 7.3 **Authority of Collateral Agent**

. Each Grantor acknowledges that, as between the Collateral Agent and the Grantors, the Collateral Agent shall be conclusively presumed to be acting as agent for each Lender and all of the other Secured Parties with full and valid authority so to act or refrain from acting, and no Grantor shall be under any obligation or entitlement to make any inquiry respecting such authority.

Section 7.4 **Duty; Obligations and Liabilities**

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(a) Duty of Collateral Agent. The Collateral Agent's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in its possession shall be to deal with it in the same manner as it deals with similar property for its own account, but in no event in less than a commercially reasonable manner. The powers conferred on the Collateral Agent hereunder are solely to protect each Lender's and the other Secured Parties' interest in the Collateral and shall not impose any duty upon the Collateral Agent to exercise any such powers. The Collateral Agent shall be accountable only for amounts that it receives as a result of the exercise of such powers, and neither it nor any of its Related Parties shall be responsible to any Grantor for any act or failure to act hereunder, except for its or their own gross negligence, bad faith or willful misconduct as finally determined by a court of competent jurisdiction. In addition, the Collateral Agent shall not be liable or responsible for any loss or damage to any Collateral, or for any diminution in the value thereof, by reason of the act or omission of any warehousemen, carrier, forwarding agency, consignee or other bailee if such Person has been selected by the Collateral Agent in good faith.

(b) Obligations and Liabilities with respect to Collateral. Neither the Collateral Agent nor Lenders or any other Secured Parties nor any of their respective Related Parties shall be liable for failure to demand, collect or realize upon any Collateral or for any delay in doing so or shall be under any obligation to sell or otherwise dispose of any Collateral upon the request of any Grantor or any other Person or to take any other action whatsoever with regard to any Collateral.

ARTICLE 8

MISCELLANEOUS

Section 8.1 **Reinstatement**

. Each Grantor agrees that, if any payment made by any Credit Party or other Person and applied to the Secured Obligations is at any time annulled, avoided, set aside, rescinded, invalidated, declared to be fraudulent or preferential or otherwise required to be refunded or repaid, or the proceeds of any Collateral are required to be returned by any Secured Party to such Credit Party, its estate, trustee, receiver or any other party, including any Grantor, under any bankruptcy law, state or federal law, common law or equitable cause, in each case as finally determined by a court of competent jurisdiction, then, to the extent of such payment or repayment, any Lien or other Collateral securing such liability shall be and remain in full force and effect, as fully as if such payment had never been made. If, prior to any of the foregoing, (a) any Lien or other Collateral securing such Grantor's liability hereunder shall have been released or terminated by virtue of the foregoing or (b) any provision of the Guaranty hereunder shall have been terminated, cancelled or surrendered, such Lien, other Collateral or provision shall be reinstated in full force and effect and such prior release, termination, cancellation or surrender shall not diminish, release, discharge, impair or otherwise affect the obligations of such Grantor in respect of any Lien or other Collateral securing such obligation or the amount of such payment.

Section 8.2 **Release of Collateral and Guarantee Obligations**

.

(a) When all Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted) have been absolutely, unconditionally and irrevocably paid in full, the Collateral shall be automatically released from the Lien created hereby and this Agreement and all obligations (other than those expressly stated to survive such termination) of each Lender and any other Secured Party and each Grantor and Guarantor hereunder shall automatically terminate, all without delivery of any instrument or performance of any act by any party (except as required hereunder), and all rights of the Collateral Agent, Lenders and any other Secured Parties to the Collateral shall automatically revert to the Grantors. Upon the sale, transfer or other disposition of any Collateral to any Person (other than a Credit Party) that is permitted under the Loan Documents or to which Required Lenders have otherwise consented (including the sale, transfer or other disposition of Pledged Stock of a Grantor to any Person (other than a Credit Party)), such Collateral shall be automatically released from the Lien created hereby. In connection with any Permitted License and any other licensing of Intellectual Property permitted pursuant to the Loan Agreement, the Collateral Agent, on behalf of the Lenders and Secured Parties, shall enter into customary non-disturbance and similar agreements, in each case in form and substance reasonably satisfactory to the Collateral Agent and the other party or parties thereto.

(b) In connection with any termination or release pursuant to this Section 8.2, the Collateral Agent shall, and to the extent required, each Secured Party hereby authorizes the Collateral Agent to, promptly execute and deliver to any Grantor all instruments, documents and agreements which such Grantor shall reasonably request in writing to evidence and confirm such termination or release (including termination statements under the Code and customary payoff letters), and will duly assign, transfer and deliver to such Grantor (or its designee), such of the Collateral that may be in the possession of the Collateral Agent, all without further consent or joinder of the Collateral Agent or any Lender or other Secured Party.

(c) Any termination or release pursuant to this Section 8.2 is subject to reinstatement as provided in Section 8.1.

(d) Upon the release of the Liens on any Collateral or of a Grantor from all of its obligations as a Credit Party under the Loan Agreement and as a Grantor hereunder, any representation, warranty or covenant contained in any Loan Document relating to any such Collateral or such Grantor, as applicable, shall no longer be deemed to be made.

(e) In accordance with, and without limiting the generality of, Section 2.4 of the Loan Agreement, each Grantor agrees to pay or reimburse promptly the Lender Expenses and any other reasonable and documented out-of-pocket expenses of the Collateral Agent and any Lender and other Secured Party incurred in connection with the taking of any actions pursuant to or as otherwise contemplated by this Section 8.2.

Section 8.3 **Independent Obligations**

. The obligations of each Grantor hereunder are independent of and separate from the Secured Obligations and the Guaranteed Obligations. Upon any Event of Default and during the continuance thereof, the Collateral Agent for the benefit of Lenders and the other Secured Parties may, at its sole election, proceed directly and at once, without notice, against any Grantor and any Collateral to collect and recover the full amount of any Secured Obligation or Guaranteed Obligation then due, without first proceeding against any other Grantor, any other Credit Party or any other Collateral and without first joining any other Grantor or any other Credit Party in any proceeding.

Section 8.4 **No Waiver by Course of Conduct**

. Neither the Collateral Agent nor any Secured Party shall by any act (except by a written instrument pursuant to Section 8.5), delay, indulgence, omission or otherwise be deemed to have waived any right or remedy hereunder or to have acquiesced in any Default or Event of Default. No failure to exercise, nor any delay in exercising, on the part of the Collateral Agent or any Secured Party, any right, power or privilege hereunder shall operate as a waiver thereof. No single or partial exercise of any right, power or privilege hereunder shall preclude any other or further exercise thereof or the exercise of any other right, power or privilege. A waiver by the Collateral Agent or any Secured Party of any right or remedy hereunder on any one occasion shall not be construed as a bar to any right or remedy that the Collateral Agent or any Secured Party would otherwise have on any future occasion.

Section 8.5 **Amendments in Writing**

. None of the terms or provisions of this Agreement may be waived, amended, supplemented or otherwise modified except in accordance with Section 11.5 of the Loan Agreement; provided, however, that annexes to this Agreement may be supplemented (but no existing provisions may be modified

and no Collateral may be released) through Pledge Amendments and Joinder Agreements, in substantially the form of Annex 1 and Annex 2 attached hereto, respectively, in each case, duly executed by the Collateral Agent and each Grantor directly affected thereby.

Section 8.6 **Additional Grantors and Guarantors; Additional Pledged Collateral**

.

(a) Joinder Agreements. If, at the option of Parent pursuant to Section 5.12 of the Loan Agreement or as otherwise required pursuant to Section 5.12 or Section 5.13 of the Loan Agreement, Parent shall cause any Subsidiary (other than an Excluded Subsidiary, unless Parent has elected to join such Excluded Subsidiary pursuant to Section 5.12 of the Loan Agreement) that is not a Grantor and Guarantor hereunder on the Closing Date to become a Grantor and Guarantor hereunder, such Subsidiary shall execute and deliver to the Collateral Agent a Joinder Agreement substantially in the form of Annex 2 attached hereto and shall thereafter for all purposes be a party hereto and have the same rights, benefits and obligations as a Grantor and Guarantor party hereto on the Closing Date.

(b) Pledge Amendments. To the extent any Pledged Collateral has not been delivered as of the Closing Date, each relevant Grantor shall, promptly after such Pledged Collateral is acquired, deliver a pledge amendment duly executed by such Grantor in substantially the form of Annex 1 attached hereto (each, a "Pledge Amendment"). Such Grantor authorizes the Collateral Agent to attach each Pledge Amendment to this Agreement.

Section 8.7 **Notices**

. All notices, requests and demands hereunder to or upon the Collateral Agent or any other party hereto shall be effected in the manner provided for in Section 9 of the Loan Agreement; provided, however, that any such notice, request or demand to or upon any Grantor hereunder shall be addressed to Borrower's notice address set forth in Section 9 of the Loan Agreement.

Section 8.8 **Successors and Assigns**

. This Agreement shall be binding upon the successors and assigns of each Grantor and shall inure to the benefit of the Collateral Agent and each Secured Party and their respective successors and assigns; provided, however, that no Grantor may assign, transfer or delegate any of its rights or obligations under this Agreement without the prior written consent of the Collateral Agent.

Section 8.9 **Counterparts**

. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or by electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Section 8.10 **Severability**

. Any provision of this Agreement being held illegal, invalid or unenforceable in any jurisdiction shall not affect any part of such provision not held illegal, invalid or unenforceable, any other provision of this Agreement or any part of such provision in any other jurisdiction.

Section 8.11 **Choice of Law**

. THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION), AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HERETO AND THERETO, SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT.

Section 8.12 **Jury Trial Waiver**

. TO THE FULLEST EXTENT PERMITTED BY REQUIREMENTS OF LAW, EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ITS RIGHT TO A JURY TRIAL IN ANY CLAIM, SUIT, ACTION OR PROCEEDING WITH RESPECT TO, OR DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH, THIS AGREEMENT, ANY OTHER LOAN DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREIN AND THEREIN OR RELATED HERETO OR THERETO (WHETHER FOUNDED IN CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO OTHER PARTY AND NO RELATED PARTY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.2 AND (C) HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

THE TERMS OF SECTION 10 OF THE LOAN AGREEMENT ARE INCORPORATED HEREIN BY REFERENCE, *MUTATIS MUTANDIS*, AS IF SET FORTH IN FULL HEREIN AND THE PARTIES HERETO AGREE TO SUCH TERMS AND TO BE BOUND BY SUCH TERMS.

Section 8.13 **Intercreditor Agreement**

. NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, THE LIEN AND SECURITY INTEREST GRANTED TO THE COLLATERAL AGENT PURSUANT TO OR IN CONNECTION WITH THIS AGREEMENT, THE TERMS OF THIS AGREEMENT, AND THE EXERCISE OF ANY RIGHT OR REMEDY BY THE COLLATERAL AGENT HEREUNDER ARE SUBJECT TO THE PROVISIONS OF THE INTERCREDITOR AGREEMENT DATED AS OF MARCH 16, 2022 (AS MAY BE AMENDED, RESTATED, AMENDED AND RESTATED, SUPPLEMENTED OR OTHERWISE MODIFIED FROM TIME TO TIME, THE "INTERCREDITOR AGREEMENT") BY AND BETWEEN BIOPHARMA CREDIT PLC, AS COLLATERAL AGENT UNDER THE LOAN AGREEMENT AND RTW INVESTMENTS ICAV, FOR AND ON

BEHALF OF RTW FUND 2, AS PAYER UNDER THE PRE-PAID FORWARD CONTRACT (AS DEFINED THEREIN) AND ACKNOWLEDGED AND AGREED BY UROGEN PHARMA, INC., AS BORROWER UNDER THE LOAN AGREEMENT, AND UROGEN PHARMA LTD., AS THE COUNTERPARTY UNDER THE PRE-PAID FORWARD CONTRACT AND PARENT AND A CREDIT PARTY UNDER THE LOAN AGREEMENT. IN THE EVENT OF ANY CONFLICT BETWEEN THE TERMS OF THE INTERCREDITOR AGREEMENT AND THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT, THE TERMS OF THE INTERCREDITOR AGREEMENT SHALL CONTROL.

Section 8.14 **Israeli Security Agreement**

. For the avoidance of doubt, it is hereby clarified that this Agreement is in addition to the Israeli Security Agreement (and in no manner in lieu thereof or replacement thereto), and each of this Agreement and the Israeli Security Agreement shall independently serve as aforesaid to secure the Secured Obligations in their entirety. Without derogating from the generality of the foregoing or from any other right of the Collateral Agent, the Collateral Agent shall have the right to act on this Agreement or on the Israeli Security Agreement, or on both, in each case in connection with the liens and security interests created by each (including, with respect to any and all assets, properties and rights subject to each of this Agreement and the Israeli Security Agreement); and no action or omission relating to any such liens and security interests shall prevent or stop the Collateral Agent from invoking such other liens and security interests, at the same time or subsequently.

[Signature Pages Follow]

IN WITNESS WHEREOF, each of the undersigned has caused this Guaranty and Security Agreement to be duly executed and delivered as of the date first above written.

UROGEN PHARMA, INC.,
as Borrower and a Grantor

By_____

Name:_____

Title:_____

UROGEN PHARMA LTD.,
as Parent and a Grantor

By_____

Name:_____

Title:_____

ACCEPTED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,

as Collateral Agent

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 1
TO GUARANTY AND SECURITY AGREEMENT

FORM OF PLEDGE AMENDMENT

This Pledge Amendment, dated as of _____, 20__, is delivered pursuant to Section 8.6 of the Guaranty and Security Agreement, dated as of March 16, 2022, by UROGEN PHARMA, INC., as Borrower, the undersigned Grantor and the other Persons from time to time party thereto as Grantors in favor of BIOPHARMA CREDIT PLC, as Collateral Agent on behalf of Lenders and each of the other Secured Parties (as such agreement may be amended, restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"). Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

The undersigned hereby agrees that this Pledge Amendment may be attached to the Guaranty and Security Agreement and that the Pledged Collateral listed on Annex 1-A to this Pledge Amendment shall be and become part of the Collateral referred to in the Guaranty and Security Agreement and shall secure all Secured Obligations of the undersigned.

[GRANTOR]

By: _____
Name:
Title:

Annex 1-A

PLEDGED STOCK

ISSUER	CLASS	CERTIFICATE NO(S).	PAR VALUE	NUMBER OF SHARES, UNITS OR INTERESTS

PLEDGED DEBT INSTRUMENTS

COMMERCIAL TORT CLAIMS

ACKNOWLEDGED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 2
TO
GUARANTY AND SECURITY AGREEMENT

FORM OF JOINDER AGREEMENT

This JOINDER AGREEMENT, dated as of _____ __, 20__, is delivered pursuant to Section 8.6 of the Guaranty and Security Agreement, dated as of March 16, 2022, by and among UROGEN PHARMA, INC. ("Borrower") and the other Persons from time to time party thereto as Grantors, in favor of BIOPHARMA CREDIT PLC (together with its successors and permitted assigns, the "Collateral Agent") on behalf of Lenders and each of the other Secured Parties, (as such agreement may be amended, restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"). Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

By executing and delivering this Joinder Agreement, the undersigned, as provided in Section 8.6 of the Guaranty and Security Agreement, (a) hereby becomes a party to the Guaranty and Security Agreement as a "Grantor" and "Guarantor" thereunder with the same force and effect as if originally named as a Grantor and Guarantor therein and, without limiting the generality of the foregoing, hereby assumes all obligations and liabilities of a Grantor and a Guarantor thereunder and (b) as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Secured Obligations of the undersigned, hereby pledges and hypothecates to the Collateral Agent for the benefit of Lenders and the other Secured Parties, and grants to the Collateral Agent for the benefit of Lenders and the other Secured Parties, a lien on and security interest in, all of its right, title and interest in, to and under the Collateral of the undersigned. The undersigned hereby agrees to be bound as a Grantor and a Guarantor for the purposes of the Guaranty and Security Agreement.

In connection with this Joinder Agreement, the undersigned has delivered to the Collateral Agent a completed Perfection Certificate duly executed by the undersigned. The information set forth in Annex 1-A is hereby added to the information set forth in Schedules 1 and 3 to the Security Disclosure Letter. By acknowledging and agreeing to this Joinder Agreement, the undersigned hereby agrees that this Joinder Agreement may be attached to the Guaranty and Security Agreement, the Perfection Certificate delivered herewith by the undersigned shall constitute a "Perfection Certificate" referred to in Section 4.6 of the Loan Agreement and that the Pledged Collateral listed on Annex 1-A to this Joinder Agreement shall be and become part of the Collateral referred to in the Guaranty and Security Agreement and shall secure all Secured Obligations of the undersigned.

The undersigned hereby represents and warrants that each of the representations and warranties contained in Article IV of the Guaranty and Security Agreement applicable to it is true and correct on and as the date hereof as if made on and as of such date.

In witness whereof, the undersigned has caused this Joinder Agreement to be duly executed and delivered as of the date first above written.

[Additional Grantor]

By: _____
Name:
Title:

ACKNOWLEDGED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 3
TO
GUARANTY AND SECURITY AGREEMENT

FORM OF [COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT

THIS [COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT, dated as of _____, 20__, is made by _____ ("Grantor"), in favor of BIOPHARMA CREDIT PLC (together with its successors and permitted assigns, the "Collateral Agent") on behalf of Lenders and the other Secured Parties (as defined in the Loan Agreement referred to below).

W I T N E S E T H:

WHEREAS, pursuant to the Loan Agreement, dated as of March 7, 2022 (as the same may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement"), by and among UROGEN PHARMA, INC., a Delaware corporation ("Borrower"), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "Parent" and a Credit Party), the other parties thereto from time to time, as additional Credit Parties, BIOPHARMA CREDIT PLC, as Collateral Agent, BPCR LIMITED PARTNERSHIP, (as a "Lender") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership acting by its general partner, BioPharma Credit Investments V GP LLC (as a "Lender"), each Lender has agreed to make extensions of credit to Borrower upon the terms and subject to the conditions set forth therein;

WHEREAS, Grantor [(other than Borrower)] has agreed, pursuant to a Guaranty and Security Agreement dated as of March 16, 2022 in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties (as such agreement may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"), to guarantee the Obligations (as defined in the Loan Agreement) of Borrower; and

WHEREAS, Grantor is party to the Guaranty and Security Agreement pursuant to which Grantor is required to execute and deliver this [Copyright] [Patent] [Trademark] Security Agreement;

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree, intending to be legally bound, as follows:

Section 1. Defined Terms. Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

Section 2. Grant of Security Interest in [Copyright] [Trademark] [Patent] Collateral. Grantor, as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Secured Obligations, hereby mortgages, pledges and hypothecates to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, and grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a Lien on and security interest in, all of its right, title and interest in, to and under the following Collateral of Grantor, in each case, solely to the extent constituting Collateral (and excluding any Excluded Property) (the "[Copyright] [Patent] [Trademark] Collateral"):

(a) [all of its Copyrights and all IP Licenses and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Copyright, including, without limitation, those referred to on Schedule 1 hereto;

(b) all renewals, reversions and extensions of the foregoing; and

(c) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

or

(a) [all of its Patents and all IP License and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Patent, including,

without limitation, those referred to on Schedule 1 hereto;

(b) all reissues, reexaminations, continuations, continuations-in-part, divisionals, substitutes, renewals and any patent term extension or adjustment (including any supplementary protection certificate) of the foregoing, and any patent issued with respect to any of the foregoing, and any confirmation patent or registration patent or patent of addition based on any such patent; and

(c) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

or

(d) [all of its Trademarks and all IP Licenses and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Trademark, including, without limitation, those referred to on Schedule 1 hereto, but excluding any "intent-to-use" application for registration of a United States Trademark for which a "Statement of Use" pursuant to Section 1(d) of the Lanham Act, 15 U.S.C. § 1051 (or any successor provision) or an "Amendment to Allege Use" pursuant to Section 1(c) of the Lanham Act, 15 U.S.C. § 1051 (or any successor provision) has not been filed with and accepted by the Applicable IP Office (but only excluding such intent-to-use application until such statement of use or amendment to allege use (as applicable) is filed with and accepted by the Applicable IP Office);

(e) all renewals and extensions of the foregoing;

(f) all goodwill of the business connected with the use of, and symbolized by, each such Trademark; and

(g) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

Section 3. Guaranty and Security Agreement. The security interest granted pursuant to this [Copyright] [Patent] [Trademark] Security Agreement is granted in conjunction with the security interest granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties, pursuant to the Guaranty and Security Agreement and Grantor hereby acknowledges and agrees that the obligations, rights and remedies of Grantor and of the Collateral Agent on behalf of Lenders and the other Secured Parties with respect to the security interest in the [Copyright] [Patent] [Trademark] Collateral made and granted hereby are more fully set forth in the Guaranty and Security Agreement, the terms and provisions of which are incorporated by reference herein as if fully set forth herein.

Section 4. Grantor Remains Liable. Grantor hereby agrees that, anything herein to the contrary notwithstanding, Grantor shall assume full and complete responsibility for the prosecution, defense, enforcement or any other reasonably necessary actions in connection with their [Copyrights] [Patents] [Trademarks] and IP Licenses subject to a security interest hereunder.

Section 5. Counterparts. This [Copyright] [Patent] [Trademark] Security Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this [Copyright] [Patent] [Trademark] Security Agreement by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Section 6. Governing Law. THIS [COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HERETO SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN [COPYRIGHT] [PATENT] [TRADEMARK] COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT.

THE TERMS OF SECTION 10 OF THE LOAN AGREEMENT ARE INCORPORATED HEREIN BY REFERENCE, *MUTATIS MUTANDIS*, AS IF SET FORTH IN FULL HEREIN AND THE PARTIES HERETO AGREE TO SUCH TERMS AND TO BE BOUND BY SUCH TERMS.

Section 7. Termination. Upon the absolute, unconditional and irrevocable payment in full of the Secured Obligations in accordance with the provisions of the Loan Agreement and the expiration or termination of the Term Loan Commitments, the security interest in the [Copyright] [Patent] [Trademark] Collateral granted hereby shall automatically terminate, without delivery of any instrument or performance of any act by any party, and all rights to the [Copyright] [Patent] [Trademark] Collateral shall automatically revert to Grantors or any other Person entitled thereto. At such time, the Collateral Agent authorizes the filing by such Grantor of an appropriate termination hereof.

Section 8. Intercreditor Agreement. Notwithstanding anything herein to the contrary, the security interest granted pursuant to this [Copyright] [Patent] [Trademark] Security Agreement, the terms of this [Copyright] [Patent] [Trademark] Security Agreement and the exercise of any right or remedy hereunder are subject to the provisions of the Intercreditor Agreement, dated as of March 16, 2022, by and between the Collateral Agent, RTW Investments ICAV (for and on behalf of RTW Fund 2) and acknowledged and agreed to by Grantor and Borrower (as may be amended, restated, amended and restated, supplemented or otherwise modified from time to time).

IN WITNESS WHEREOF, Grantor has caused this [Copyright] [Patent] [Trademark] Security Agreement to be executed and delivered by its duly authorized officer as of the date first set forth above.

Very truly yours,

[GRANTOR]
as Grantor

By: _____
Name:
Title:

ACCEPTED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,

its Investment Manager

By: Pharmakon Management I, LLC,

its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

SCHEDULE I
TO
[COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT

[Copyright] [Patent] [Trademark] Registrations

1. REGISTERED [COPYRIGHTS] [PATENTS] [TRADEMARKS]

[Include Registration Number and Date]

2. [COPYRIGHT] [PATENT] [TRADEMARK] APPLICATIONS

[Include Application Number and Date]

3. [IP LICENSES

[Include complete legal description of agreement (name of agreement, parties and date)]

ANNEX 4
TO
GUARANTY AND SECURITY AGREEMENT
FORM OF UNCERTIFICATED STOCK CONTROL AGREEMENT

This UNCERTIFICATED STOCK CONTROL AGREEMENT (this "**Agreement**"), dated as of _____ __, 20__, is made by and among [APPLICABLE GRANTOR], a [JURISDICTION OF ORGANIZATION] [ENTITY TYPE] (the "**Grantor**"), BIOPHARMA CREDIT PLC, a public limited company organized under the laws of England and Wales, as collateral agent on behalf of the Secured Parties (together with its successors and permitted assigns, the "**Collateral Agent**"), and [APPLICABLE INTEREST ISSUING COMPANY], a [JURISDICTION OF ORGANIZATION] [ENTITY TYPE] (the "**Issuer**"). All capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Security Agreement (as defined below) or the Loan Agreement (as defined below), as applicable.

WHEREAS, UROGEN PHARMA, INC., a Delaware corporation ("**Borrower**"), the Collateral Agent and the Lenders have entered into that certain Loan Agreement, dated as of March 7, 2022 (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**");

WHEREAS, the Grantor is the registered holder of [DESCRIBE PLEDGED UNCERTIFICATED STOCK] issued by the Issuer (the "**Pledged Stock**");

WHEREAS, pursuant to the Guaranty and Security Agreement, dated as of March 16, 2022, by and among the Grantor, the Collateral Agent and the other parties thereto (as amended, amended and restated, supplemented or otherwise modified from time to time, the "**Security Agreement**"), the Grantor has granted a continuing Lien on and security interest (the "**Security Interest**") in, all of its right, title and interest in, to and under the Pledged Stock (other than Excluded Equity Interests), whether now existing or hereafter arising or acquired; and

WHEREAS, it is a condition precedent to the making and maintaining of the Term Loans by Lenders under the Loan Agreement that the parties hereto execute and deliver this Agreement in order to perfect a first priority Security Interest in the Pledged Stock.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree, intending to be legally bound, as follows:

1. The Issuer confirms that:

(h) The Pledged Stock is Equity Interests that are not represented by certificates;

(i) The Issuer is the issuer of the Pledged Stock and the Grantor is registered on the books and records of the Issuer as the registered holder of the Pledged Stock; and

(j) The Security Interest in the Pledged Stock is registered on the books and records of the Issuer.

2. The Grantor hereby irrevocably agrees that, for so long as this Agreement remains in effect, the Collateral Agent, for the benefit of Lenders and the other Secured Parties, shall have exclusive control of the Pledged Stock. In furtherance of such agreement, the Grantor hereby irrevocably authorizes and directs the Issuer, and the Issuer hereby agrees:

(k) Subject to the provisions of Section 3 hereof, to comply with any and all written instructions delivered to the Issuer which directs that the transfer of any or all of the Pledged Stock to the Collateral Agent be registered on the books and records of the Issuer in the name of the Collateral Agent as the holder thereof, for the benefit of Lenders and the other Secured Parties, without further consent by the Grantor or any other Person; and

(l) Subject to the provisions of Section 3 hereof, not to comply with any instructions relating to any or all of the Pledged Stock originated by any Person other than the Collateral Agent, on behalf of Lenders and the other Secured Parties, or a court of competent jurisdiction. In the event of any conflict between any instruction originated by the Collateral Agent and any instruction originated by any other Person, the Issuer shall comply only with the instruction originated by the Collateral Agent.

3. In addition to, and not in lieu of, the obligation of the Issuer to honor instructions as agreed in Section 2 hereof, the Issuer and the Collateral Agent hereby agree as follows:

(m) Subject to the rights of the Grantor described herein, the Issuer agrees that, from and after the date hereof, the Pledged Stock shall be under the exclusive dominion and control of the Collateral Agent;

(n) So long as the Issuer has not received a written notice from the Collateral Agent that it is exercising exclusive control over the Pledged Stock (a "**Notice of Exclusive Control**"), the Issuer may comply with instructions of the Grantor concerning the Pledged Stock, which Notice of Exclusive Control shall only be given by the Collateral Agent following the occurrence and during the continuance of an Event of Default. After the Issuer receives a Notice of Exclusive Control from the Collateral Agent, the Issuer will not accept any instructions concerning the Pledged Stock from any Person other than the Collateral Agent, unless otherwise ordered by a court of competent jurisdiction; and

(o) Until the Issuer receives a Notice of Exclusive Control, the Grantor shall be entitled to direct the Issuer with respect to voting the Pledged Stock.

4. This Agreement shall not subject the Issuer to any obligation or liability except as expressly set forth herein and under any Requirements of Law. In particular, the Issuer need not investigate whether the Collateral Agent is entitled under the Security Agreement or otherwise to give an instruction or Notice of Exclusive Control.

5. The Issuer hereby represents, warrants and covenants with the Collateral Agent that:

(p) This Agreement has been duly authorized, executed and delivered by the Issuer and constitutes a legal, valid and binding obligation of the Issuer enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law);

(q) The Issuer has not entered into, and until termination of this Agreement will not enter into, any agreement with any other Person relating to the Pledged Stock pursuant to which it has agreed, or will agree, to comply with instructions provided by such Person. The Issuer has not entered into any other agreement with the Grantor purporting to limit or condition the obligation of the Issuer to comply with instructions as agreed in Section 3 hereof;

(r) Except for the claims and interests of the Collateral Agent, on behalf of Lenders and the other Secured Parties, and the Grantor in the Pledged Stock, the Issuer does not know of any claim to, or interest in, the Pledged Stock (except to the extent constituting Permitted Liens). If any Person asserts any Lien or adverse claim (including any writ, garnishment, judgment, attachment, execution or similar process) against the Pledged Stock (other than Permitted Liens), the Issuer will promptly notify the Collateral Agent and the Grantor thereof;

(s) There is no agreement (except this Agreement) between the Issuer and the Grantor or among the Issuer, the Grantor and any third Person with respect to the Pledged Stock [except for [IDENTIFY RELEVANT AGREEMENTS] (the "**Existing Agreements**")]. In the event of any conflict between this Agreement (or any portion hereof) and any other such agreement (including any Existing Agreement) with respect to the Pledged Stock, whether now existing or hereafter entered into, the terms of this Agreement shall prevail; and

(t) The granting by the Grantor of the Security Interest in the Pledged Stock to the Collateral Agent for the benefit of Lenders and the other Secured Parties does not violate the Operating Documents or any other agreement governing the Issuer or the Pledged Stock.

6. This Agreement shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective successors and assigns.

7. Each notice, request or other communication to a party hereto under this Agreement shall be in writing, will be sent to such party's address set forth under its name below or to such other address as such party may notify the other parties hereto and will be effective on receipt.

8. No amendment or modification of this Agreement or waiver of any right hereunder shall be binding on any party hereto unless it is in writing and is signed by all the parties hereto.

9. The rights and powers granted herein to the Collateral Agent (a) have been granted in order to perfect the Security Interest in the Pledged Stock, (b) are powers coupled with an interest and (c) will not be affected by any bankruptcy of the Grantor or any lapse in time. The obligations of the Issuer hereunder shall continue in effect until the Collateral Agent has notified the Issuer in writing that the Security Interest in the Pledged Stock has been terminated pursuant to the Security Agreement.

10. This Agreement shall be governed by and construed in accordance with the laws of the [ISSUER'S JURISDICTION OF ORGANIZATION], WITHOUT REGARD TO ANY PRINCIPLES OF CONFLICTS OF LAW THAT COULD REQUIRE THE APPLICATION OF THE LAW OF ANY OTHER JURISDICTION, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN [ISSUER'S JURISDICTION OF ORGANIZATION] SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN THE PLEDGED STOCK, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL APPLY TO THAT EXTENT].

11. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

12. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

[Signature Page Follows]IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

[GRANTOR]
By:
Name:
Title:

Address for Notices:

[ISSUER]
By:
Name:
Title:

Address for Notices:

BIOPHARMA CREDIT PLC,
a public limited company

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By_____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

Address for Notices:

BIOPHARMA CREDIT PLC
c/o Beaufort House
51 New North Road

Exeter EX4 4EP
United Kingdom
Attention: Company Secretary
Telephone: +44 01 392 477 500
Facsimile: +44 01 392 498 288

Email: biopharmacreditplc@linkgroup.co.uk

with copies (which shall not constitute notice) to:

Pharmakon Advisors LP

110 East 59th Street, #3300

New York, NY 10022

Attn: Pedro Gonzalez de Cosio

Phone: +1 (212) 883-2296

Fax: +1 (917) 210-4048

Email: Pharmakon@PharmakonAdvisors.com

and

Akin Gump Strauss Hauer & Feld LLP

One Bryant Park

New York, NY 10036-6745

Attn: Geoffrey E. Secol

Phone: (212) 872-8081

Fax: (212) 872-1002

Email: gsecol@akingump.com

EXHIBIT D

COMMITMENTS; NOTICE ADDRESSES

Lender	Commitments	Notice Address
BPCR LimitedPartnership	Tranche A Commitment: $37,500,000.00	BPCR LIMITED PARTNERSHIP c/o Beaufort House

	Tranche B Commitment: $12,500,000.00	51 New North Road Exeter EX4 4EP United Kingdom Attn: Company Secretary Tel: +44 01 392 477 500 Fax: +44 01 392 498 288 Email: biopharmacreditplc@linkgroup.co.uk with copies (which shall not constitute notice) to: PHARMAKON ADVISORS LP 110 East 59th Street, #3300 New York, NY 10022 Attn: Pedro Gonzalez de Cosio Phone: +1 (212) 883-2296 Fax: +1 (917) 210-4048 Email: Pharmakon@PharmakonAdvisors.com and AKIN GUMP STRAUSS HAUER & FELD LLP One Bryant Park New York, NY 10036-6745 Attn: Geoffrey E. Secol Phone: (212) 872-8081 Fax: (212) 872-1002 Email: gsecol@akingump.com
BioPharma Credit Investments V (Master) LP	Tranche A Commitment: $37,500,000.00 Tranche B Commitment: $12,500,000.00	BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP c/o BioPharma Credit Investments V GP LLC c/o Walkers Corporate Limited 190 Elgin Avenue, George Town, Grand Cayman KY1-9008 Attn: Pedro Gonzalez de Cosio with copies (which shall not constitute notice) to: PHARMAKON ADVISORS LP 110 East 59th Street, #3300 New York, NY 10022 Attn: Pedro Gonzalez de Cosio Phone: +1 (212) 883-2296 Fax: +1 (917) 210-4048 Email: Pharmakon@PharmakonAdvisors.com and AKIN GUMP STRAUSS HAUER & FELD LLP One Bryant Park New York, NY 10036-6745 Attn: Geoffrey E. Secol Phone: (212) 872-8081 Fax: (212) 872-1002 Email: gsecol@akingump.com

EXHIBIT E

COMPLIANCE CERTIFICATE

TO: BIOPHARMA CREDIT PLC

FROM: UROGEN PHARMA LTD.

The undersigned authorized officer of UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621, hereby certifies, solely in his/her capacity as a Responsible Officer of UroGen Pharma Ltd. and not in his/her personal capacity, that in accordance with the terms and conditions of the Loan Agreement (the "**Loan Agreement**"; capitalized terms used, but not defined herein having the meanings given them in the Loan Agreement) dated as of March 7, 2022 by and among UROGEN PHARMA, INC. (as "**Borrower**"), UroGen Pharma Ltd. (as "**Parent**" and a Guarantor), the other Guarantors from time to time party thereto, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales with company number 10443190 (as the "**Collateral Agent**") and the Lenders:

(i) The Credit Parties are in complete compliance for the period ending _____ with all required covenants except as noted below;

(ii) No Default or Event of Default has occurred and is continuing, except as noted below;

(iii) Each Credit Party and each of its Subsidiaries has timely filed all U.S. federal income Tax returns and other material Tax returns and reports (or extensions thereof) of each Credit Party and each of its Subsidiaries required to be filed by any of them and such returns and reports are correct in all material respects, and has timely paid all material Taxes owed which are due and payable by such Credit Party or Subsidiary or upon their respective properties, assets, income, businesses and franchises, except as otherwise permitted pursuant to the terms of Section 4.10 or Section 5.3 of the Loan Agreement; and

(iv) No Liens have been levied or claims made against any Credit Party or any of its Subsidiaries relating to unpaid employee payroll or benefits of which (a) such Credit Party has not previously provided written notification to the Collateral Agent or (b) which do not constitute Permitted Liens.

Attached are the required documents, if any, supporting our certification(s). The undersigned Responsible Officer on behalf of Parent further certifies that the attached financial statements (which shall not be attached if such financial statements are deemed delivered by filing with the SEC on Form 10-Q or 10-

K as applicable) fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Parent and its Subsidiaries as of applicable the dates and for the applicable periods in accordance with Applicable Accounting Standards consistently applied.

Date: _____

[signature page follows]

UROGEN PHARMA LTD.,
as Parent

By_____

Name: _____

Title: _____

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Complies		
1)	Annual Financial Statements	90 days after year end	Yes	No	N/A
2)	Quarterly Financial Statements	45 days after quarter end	Yes	No	N/A
3)	Other Information after an Event of Default	5 Business Days after request	Yes	No	N/A
4)	Legal Action Notice	Promptly	Yes	No	N/A
5)	Notice of Default, etc.	Promptly (within 5 Business Days) after knowledge	Yes	No	N/A

Deposit and Securities Accounts ***(Please list all accounts and indicate each Excluded Account with an asterisk (*); attach separate sheet if additional space needed)***

	Bank	Account Number	New Account?		Acct Control Agmt in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No
5)			Yes	No	Yes	No
6)			Yes	No	Yes	No

Other Matters

Have there been any changes in management since the last Compliance Certificate? Yes No

Have there been any prohibited Transfers? Yes No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

_____

_____

_____

_____

LENDER USE ONLY

Compliance Status Yes

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[●]", HAS BEEN OMITTED BECAUSE UROGEN PHARMA LTD. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) IS THE TYPE OF INFOMRATION UROGEN PHARMA LTD. CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE AND CONFIDENTIAL

Manufacturing & Supply Agreement

Between:

1) UroGen Pharma Ltd. and

2) Cenexi-Laboratoires Thissen s.a.

Table of Contents

Article1: Definitions 4

Article 2: Subject matter of Agreement 6

Article 3: Scope of Agreement 7

Article 4: Customer-Supplied Materials, Starting Material and Packaging Material 8

Article 5: Delivery and Storage of Customer-Supplied Materials, Starting Material and Packaging Material / Storage of Contract Products 10

Article 6: Manufacturing Directions, Instructions, Protocols and Reports 11

Article 7: Quality Control, Testing Procedure, Reports, Retention of Samples 13

Article 8: Release and Shipment of Contract Products 14

Article 9: Defective Contract Products 15

Article 10: Warranty provisions 16

Article 11: Hold Harmless and Liability 17

Article 12: Orders and Forecasting for Contract Products 19

Article 13: Prices 21

Article 14: Obligation to Inform 22

Article 15: Reimbursement of tooling costs (third party fees) 23

Article 16: Confidentiality 24

Article 17: Intellectual Property 26

Article 18: Term 26

Article 19: Miscellaneous 28

Article 20: Governing Law 30

Article 21: Dispute Resolution 30

Article 22: Assignment 31

Exhibit 1 Contract Products 32

Exhibit 2 Contacts 33

Exhibit 3 Starting Material and Customer-Supplied Materials 34

Exhibit 4 Packaging Material 35

Exhibit 5 Product Specifications 36

Exhibit 6 Transport Packaging and Shipping Requirements 37

Exhibit 7 Prices 38

Exhibit 8 Price revision 39

Manufacturing & Supply Agreement

This Manufacturing & Supply Agreement (hereinafter referred to as the "Agreement") is made on April 24, 2020 (hereinafter referred to as the "Effective Date") by and between:

UroGen Pharma Ltd., a company organized and existing under the laws of the State of Israel having an address at 9 HaTaasia St., Ra'anana 4365007, Israel, and hereinafter referred to as "Customer"

and

Cenexi-Laboratoires Thissen s.a., a company incorporated in Belgium, having its registered office at 2-4-6, Rue de la Papyrée, B-1420 Braine-l'Alleud, also acting hereunder on behalf of its Affiliates, and hereinafter referred to as "Manufacturer"

WHEREAS

1. Customer is a pharmaceutical company specialized in the commercialization of specialty products in a number of therapeutic areas, and has an affiliate with a USA marketing and sales organization;

2. Customer has developed the Contract Product and has filed a New Drug Application for the Contract Product (not including Bulk Product) in the USA. Customer is interested in having the Contract Products (as hereinafter defined) manufactured, packaged and inspected by Manufacturer for the US market and for other potential markets as the case may be;

3. Manufacturer is a company specialized in the manufacture of pharmaceutical products and has facilities for the production and testing of specific pharmaceutical and oncology products;

4. Manufacturer is willing to manufacture, package and inspect the Contract Products for Customer; and

5. Manufacturer will be a manufacturer of the Contract Products and Customer will purchase the Contract Products from Manufacturer per the terms outlined in this agreement.

NOW, THEREFORE, in consideration of the above, Customer and Manufacturer (hereinafter referred together as the "Parties" and separately as a "Party") agree as follows:

Article1: Definitions

As used in this Agreement the following terms shall have the following meanings:

- Affiliate: shall mean a company controlling, controlled by or under common control with the relevant Party, where the control means the direct or indirect power to exercise more than half the voting rights of the relevant company, the power to appoint more than half the members of its supervisory board, board of management or bodies representing legally the company or the rights to manage its affairs.

- Agreement: shall mean this manufacturing and supply agreement and any subsequent written amendment executed by the Parties.

- Binding Forecast means [●]

- Cancellation Fees: means the fees payable, if any, by Customer for Customer's cancellation of [●]

.

Customer for cancellation of scheduled production of a Firm Order	Cancellation Fee Payable (% of Total Batch Cost)
> = [●] days	[●]
[●] days	[●]
[●] days	[●]

- cGMP: shall mean current European and US FDA Good Manufacturing Practices.

- Contract Products: shall mean Customer's products as listed in Exhibit 1 hereto.

- Customer-Supplied Materials: shall mean the RTGel (as defined below) and the active pharmaceutical ingredient described in Exhibit 3 attached hereto ("API"), and any other materials that will be provided to Manufacturer by or on behalf of Customer for use in manufacturing the Contract Products, as set forth in Exhibit 3 or otherwise agreed upon in writing by the Parties.

- Defect: shall mean any aberration from the then current (i) Product Specifications, or

(ii) packaging requirements for the Contract Products, or any other failure to conform

to the warranties in Article 10.1. "Defective" shall have a correlative meaning. For clarity a Defect includes a Hidden Defect.

- Forecast: shall have the meaning in Article 12.1.

- GDP: shall mean Good Distribution Practices.

- Hidden Defect: shall mean (a) with respect to Contract Product, any Defect that would not have been discovered through visual inspection as required under the Quality Agreement within the [●] period referenced in Article 9.1 or which otherwise breaches Manufacturer's warranties set forth in this Agreement (such as, but not limited to, defects that can be determined only through testing) and (b) with respect to Customer-Supplied Materials, any defect that causes the Customer-Supplied Material to fail to conform to the applicable specifications for such Customer-Supplied Material at the time of delivery by Customer under this Agreement, that would not have been discovered through visual inspection and testing as required under Article 4.7 of this Agreement and the Quality Agreement.

- ICH guidelines: shall mean the guidelines published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

- Investigation Report: shall mean a report, prepared by Manufacturer in accordance with cGMP and Manufacturer's SOPs, on the circumstances of either a defect/deviation/complaint including without limitation explanations on the cause for such defect/deviation/complaint, the batches affected by the defect/deviation/complaint and possible measures to maintain or re-establish the appropriate quality of the Contract Products.

- Manufacturing Batch Record: A Manufacturing Batch Record (MBR) is a detailed, step- by-step description of the entire production process for a specific drug. The MBR explains exactly how the product is produced, indicating specific types and quantities of components and raw materials, processing parameters, in-process quality controls, environmental controls, etc. An executed MBR documents the production events, quality charts, environmental monitoring records and inspection reports for the entire production process for a specific batch.

- Manufacturing Deviation Report: shall mean a report prepared by Manufacturer if a deviation from the conditions laid down in the manufacturing instruction has appeared.

- Marketing Authorization: shall mean the approval issued by the relevant authority to sell the Contract Products in a country, including, in the US, the NDA as approved by the FDA.

- NDA: New Drug Application is the regulatory dossier that must be filed with the US Food and Drug Administration ("FDA") requesting formal approval to manufacture, package, distribute, market and sell Contract Product in the United States of America and its affiliate territories.

- Packaging Material: shall mean any material, other than Customer-Supplied Material, employed in the packaging of the Contract Products.

- Prices: shall mean the prices to be paid by Customer to Manufacturer for the manufacturing of the Contract Products as provided in Exhibit 7 hereto.

- Primary Packaging Material: shall mean Packaging Material which is in direct contact with the drug product components of the Contract Products.

- Product Specifications: shall mean the specifications of the Contract Products and all components thereof, including the specifications for the vials of mitomycin sterile lyophilized powder, as provided in Exhibit 5 hereto, as the same may be amended from time to time by mutual written agreement of Customer and Manufacturer.

- Quality Agreement: shall mean the agreement to be signed separately by the Parties, detailing the pharmaceutical responsibilities of each Party related to the Contract Products and all components thereof including, among others, Starting Material and Packaging Material, manufacturing directions, instructions, protocols, reports, quality control, testing, release and shipment of Contract Products.

- Registration Dossier: shall mean the NDA when referring to the US and the US FDA, or the equivalent registration dossier for other territories prepared by Customer for the purpose of obtaining a Marketing Authorization.

- RTGel: shall mean Customer's proprietary formulated gel in a vial that will be provided to Manufacturer by a third party on behalf of Customer for inclusion in the final Contract Product package (as specified in the MBR).

- Secondary Packaging Material: shall mean Packaging Material which is not in direct contact with the drug product components of the Contract Products.

- Starting Material: shall mean any substance, other than Customer-Supplied Material, used in the manufacturing of the Contract Products.

- Testing Deviation Report: shall mean a report prepared by Manufacturer in accordance with cGMP and Manufacturer's SOPs if a deviation from the nominal value (also known as Out of Specification, or OOS) as laid down in the testing instruction has appeared.

- Testing Protocol: shall mean formal documents signed by both Parties that typically outline testing requirements, activities, resources, documentation and schedules to be completed with respect to Contract Products. The Parties will agree in writing on the form of test plan prior to any test of the Contract Products or any component thereof.

- Validation Activities: shall mean the activities as described in Exhibit 7 hereto.

- Variation: shall mean a variation to the terms of a Marketing Authorisation.

Article 2: Subject matter of Agreement

2.1 During the Term of this Agreement, Manufacturer shall manufacture, package, test, store and inspect for Customer the Contract Products listed in Exhibit 1 to this Agreement.

2.2 The provisions of this Agreement apply to all orders for the manufacturing of Contract Products under this Agreement after the Effective Date and before termination of this Agreement.

Article 3: Scope of Agreement

3.1 The Manufacturer assures that it has a manufacturing authorization under national law, is in good standing with the US FDA, and is fully compliant with cGMP in accordance with the Quality Agreement for the manufacturing, packaging and inspection/testing of the Contract Products. The Manufacturer undertakes to provide Customer with a certified copy of such manufacturing authorization. The Manufacturer is obliged to immediately inform the Customer about any restriction to the manufacturing authorization for the Contract Products and any change in circumstances concerning such manufacturing authorization. Any changes in the place of manufacture of the Contract Products, including changes made under the existing manufacturing authorization, are subject to prior written agreement of Customer.

3.2 Customer owns or controls all rights regarding the manufacturing directions for Contract Products including any additions and improvements thereto. Customer shall have the right to use the Contract Products for any lawful purpose, including commercialization under the applicable Marketing Authorization and conducting post-marketing studies or other clinical development. Manufacturer possesses the necessary technical know-how to manufacture the Contract Products according to the manufacturing directions as well as the operation of appropriate manufacturing equipment.

3.3 The Manufacturer shall comply with the current recognized pharmaceutical rules and the relevant statutory provisions including without limitation cGMP regulations. Furthermore, in the manufacture of the Contract Products, Manufacturer will comply with the instructions as agreed upon in written form with the Customer and all other applicable laws, rules, regulations and guidelines.

3.4 Customer and Manufacturer appoint the qualified and responsible persons as listed in Exhibit 2 as contact persons for all pharmaceutical, technical and logistical questions. Written notice of any changes and alterations must be given immediately.

3.5 With respect to the Contract Products, Customer has the right to inspect, during normal working hours and subject to [●] (in emergency cases [●] prior notice, those parts of Manufacturer's facilities that are involved in manufacturing, packaging, controlling, testing and storage of the Contract Products, and to see Manufacturer's batch documentation and other reports, notes, data, records, results and information relating to the Contract Products. This right for inspection includes the participation of members of governmental authorities. If Manufacturer's efforts in connection with an inspection by Customer related to the Contract Products exceed [●] every year (or [●] per calendar year in the case of the

initial product readiness audit by FDA), Customer shall compensate such efforts of Manufacturer at the rate of [●]. Notwithstanding the foregoing, in addition to the two auditors per audit, Customer shall be entitled to have one passive trainee observe Customer's auditors without any additional cost. Customer shall be entitled to perform an additional [●] audit in accordance with this Section 3.5 at no additional cost to Customer in the event the audit relates to manufacturing process scale up for Contract Products or a material manufacturing process change for Contract Products.

3.6 The manufacturing and testing of the Contract Products have to comply with the information contained in the Registration Dossier. Customer will make available the corresponding parts of the Registration Dossier at Manufacturer's disposal. The manufacturing instructions and testing instructions prepared by Manufacturer according to the manufacturing directions and testing directions are property of Customer. All originals and copies of the manufacturing instructions and testing instructions will be handed over by Manufacturer to Customer immediately after the termination of this Agreement. Manufacturer undertakes to keep the entire documentation including the manufacturing instructions and test instructions up to date and to implement and document any changes to such instructions agreed upon by the Parties in writing during the Term of this Agreement.

3.7 A detailed description of the pharmaceutical responsibilities of each Party is set forth in the Quality Agreement, which shall be amended by the Parties as soon as practicable to apply to the Contract Products, and which shall become part of this Agreement and may not be terminated separately. The Parties agree that Customer's Affiliates may perform on behalf of Customer the pharmaceutical responsibilities of Customer under the Quality Agreement. In case of discrepancies between this Agreement and the Quality Agreement, the provisions of this Agreement shall prevail, except for technical and quality responsibility issues, for which the Quality Agreement shall prevail over this Agreement.

Article 4: Customer-Supplied Materials, Starting Material and Packaging Material

4.1 The respective pharmaceutical responsibilities of Customer and Manufacturer for the Customer-Supplied Materials, the Starting Material and

the Packaging Material shall be set forth in the Quality Agreement.

4.2 Customer-Supplied Materials will be provided by Customer [●].

4.3 Any change of the specification, the manufacturing process and/or the supplier of Starting Material and/or Packaging Material requires prior mutual written consent of the Parties, and may require submission to and approval of the prevailing regulatory authority prior to implementation. Customer will have the right, with the written consent

of Manufacturer, to change of the specifications, the manufacturing process and/or the supplier of any Customer-Supplied Materials.

4.4 Manufacturer will source Starting Material in relation to the Forecast in reasonable amounts based on a minimum stock level of [●] relating to the current Forecast provided by Customer and is entitled to source Starting Material in relation to the Forecast in reasonable amounts based on a maximum stock level of [●] relating to the current Forecast provided by Customer (in case of Starting materials with a critical lead time special arrangements to be taken).

4.5 The Manufacturer is entitled to source Packaging Material in relation to the Forecast based on the following rules:

Average Stock Volumes (based on current Forecasts)

	Contract Products	Contract Products	Contract Products
Material	[●]	[●]	[●]
Primary Packaging Material	[●]	[●]	[●]
Secondary Packaging Material	[●]	[●]	[●]

In the event of a packaging or artwork change that results in unused Packaging Materials, Customer shall not be responsible for paying for any unused Packaging Materials ordered by Manufacturer in excess of the amounts set forth above.

4.6 Manufacturer is responsible for the proper inspection of the quality of the Starting Material and Packaging Material which it provides. The respective material shall be inspected by Manufacturer for quality and identity and released in accordance with the Quality Agreement.

4.7 The Customer-Supplied Materials shall be inspected, handled, stored, tested and released by Manufacturer according to the Quality Agreement, if not otherwise agreed in writing between the Parties. In any event, Manufacturer shall examine that the containers, closures and seals are intact, and that the labelling of the containers is consistent with the delivery note. Manufacturer will check and verify the relevant quality control documentation and Customer-Supplied Materials for the quality, identity and

physical integrity of each shipment and will notify Customer if any Customer-Supplied Materials have any visible defects.

4.8 Only Starting Material, Packaging Material and Customer-Supplied Materials properly released and with adequate shelf life may be used by Manufacturer as specified in Exhibit 5 and the Quality Agreement.

4.9 In the event Customer changes the requirements for the Starting Material, the Product Specifications, the packaging of the Contract Products or the like, and as a result of such Customer-required changes such materials become obsolete or useless and cannot be used in the normal course of Manufacturer's business, Customer shall [●] any dedicated material sourced by Manufacturer according to Articles 4.4 and 4.5 which become obsolete and cannot be used in the normal course of Manufacturer's business, and as applicable, Customer shall [●] for work in progress or finished products, if any, which become obsolete and cannot be sold due to such Customer-required changes.

4.10 In the event Customer changes the requirements of packaging materials and as a result of such Customer-required changes the fee to be paid by Manufacturer to the supplier of Packaging Materials for these changes is increased, such increased fee will be charged to [●]. In the event the [●] by Manufacturer to the supplier of Packaging Materials is [●] as a result of Customer-required changes, the [●] will be [●], or will be [●].

Article 5: Delivery and Storage of Customer-Supplied Materials, Starting Material and Packaging Material / Storage of Contract Products

5.1 Customer is responsible for the timely delivery, [●] before the anticipated manufacturing start date, of such Starting and/or Packaging Material of Customer-Supplied Materials, including the relevant quality control documents. Manufacturer will inform Customer without delay after receipt of Customer's order for Contract Products about the required amount of such Customer-Supplied Materials. Customer-Supplied Materials shall be delivered to Manufacturer's site [●].

Customer is responsible to ensure (a) a minimum of [●] of API (based on the then current Forecast) is delivered to Manufacturer [●] before the anticipated manufacturing date requiring such API and (b) a minimum of [●] RTGel - (based on the then current Forecast) is delivered to Manufacturer.

Customer-Supplied Material will remain the property of Customer and Customer is responsible for proper insurance coverage of such Customer-Supplied Materials stored at Manufacturer's facility; provided, however, Manufacturer shall handle and store all

Customer-Supplied Materials in accordance with the Quality Agreement and the terms of this Agreement and shall be responsible for any losses, damage, theft, or other impairment of the Customer-Supplied Materials arising from or in connection with Manufacturer's failure to comply with or breach of the Quality Agreement or this Agreement.

5.2 Manufacturer is obliged to observe the diligence Manufacturer usually employs in its own affairs with respect to the storage of Customer-Supplied Materials. Unless otherwise indicated, Manufacturer will observe the FIFO (first in – first out) principle. Manufacturer shall handle all Customer-Supplied Materials in accordance with specifications for such materials as set forth in the Quality Agreement or provided in writing by Customer, and in compliance with all applicable terms of the Quality Agreement and all applicable laws, rules and regulations.

5.3 Manufacturer shall store all Customer-Supplied Materials, Starting Material, Packaging Material and Contract Products under the storage conditions specified in the Registration Dossier, the Marketing Authorization, the Quality Agreement, applicable specifications, including the Product Specifications, and all applicable laws, rules and regulations, including ICH guidelines. Containers must be labelled in compliance with the Registration Dossier and the Marketing Authorization and the respective GDP, national, US, European, and international laws, rules and regulations, as applicable.

5.4 Manufacturer will ensure that all Customer-Supplied Materials, Starting Material and Primary Packaging Material as well as Contract Product is kept in quarantine until released or rejected, as applicable, by the competent person of Manufacturer.

5.5 In the case the final Contract Products are not picked-up [●] after both release and availability of the final Contract Products for loading at the [●] location for transport by Customer's carrier, storage costs will be charged to the customer [●]. In the case the final Contract Products are not picked-up [●] after both release and availability of the final Contract Products for loading at the [●] location for transport by Customer's carrier, storage costs will instead be charged to the customer at the rate of [●]. For clarity, storage costs shall not be charged to the extent the Parties dispute in good faith whether such Contract Products have met the conditions set forth in the Quality Agreement required for release of Contract Products. Customer shall provide Manufacturer with export records relating to the export of the final Contract Products outside of the European Union.

Article 6: Manufacturing Directions, Instructions, Protocols and Reports

6.1 The Contract Products shall be manufactured and packaged according to the Product Specifications as contained in the Quality Agreement and Exhibit 5, the manufacturing and packaging instructions (as set out in Article 6.2 below), and as specified in the Registration Dossier, Marketing Authorization, and the Batch Manufacturing Record.

6.2 Based on the manufacturing directions contained in the Registration Dossier and Marketing Authorization, Manufacturer will draft the corresponding manufacturing instructions, which will have to be released by Customer in written form. The manufacturing instructions will also include the required in-process controls.

6.3 Manufacturer will prepare an executed Manufacturing Batch Record on every production batch according to the requirements of the cGMP regulations.

6.4 If amendments become necessary, the manufacturing instruction and/or MBR have to be replaced by a new amended version of the document and to be signed by both Parties. The respective new version enters into force upon signature by both Parties for all not yet manufactured Contract Products. Manufacturer will be [●].

6.5 If quality parameters, or parameters defined in the Registration Dossier and/or Marketing Authorization regarding the manufacturing process are modified, they must be validated (as applicable) before implementation. Manufacturer will inform Customer of the intended validation and provide Customer with a validation plan, to which Customer has to agree in writing. After validation, Manufacturer will inform Customer about the results of the validation in writing.

6.6 Manufacturer is obliged to use as auxiliary materials and utilities getting in direct contact with the Contract Products only such materials and utilities which are pharmaceutically safe and which are in accordance with the requirements of the Registration Dossier and Marketing Authorization. Customer has to agree on any material changes regarding such materials and utilities beforehand in writing.

6.7 If a relevant major deviation from the conditions laid down in the manufacturing instruction has appeared, Manufacturer will inform and provide relevant information/data to Customer as soon as practicable and without delay, but in any event within [●] of the first observation of the deviation, about the deviating data ("Manufacturing Deviation Report"). In such case, Customer and Manufacturer commit themselves to agree upon the necessary measures to be taken and Manufacturer will promptly take such measures. Major deviation management will be done according to Quality Agreement.

Manufacturer will make a report inclusive of relevant data on the circumstances of such deviation ("Investigation Report"), including without limitation explanations on the cause for such deviation, the batches affected by the deviation and possible measures to maintain or re-establish the appropriate quality of the Contract Products.

Manufacturer will submit the Manufacturing Deviation Report and Investigation Report for Customer's approval. The costs for such Investigation Report will be borne by the Manufacturer, except if the deviation was caused by any Customer-Supplied Material

that, at the time of delivery to Manufacturer by or on behalf of Customer, failed to conform to the applicable specifications for such Customer-Supplied Material (excluding any Hidden Defect in the Customer Supplied Material).

6.8 For every Contract Product, Manufacturer will store the complete documentation according to Articles 6.3 and 6.7 for [●] after manufacturing of such Contract Product batch. Thereafter, Manufacturer will ask Customer's instruction before destroying any documentation related to the Contract Product.

Article 7: Quality Control, Testing Procedure, Reports, Retention of Samples

7.1 Manufacturer will carry out quality control measures and tests, and will retain samples, as applicable, in each case as specified in the Quality Agreement.

7.2 Based on the testing directions contained in the Registration Dossier, Manufacturer will draft the corresponding testing instructions to be approved by Customer in written form. Manufacturer will carry out tests in accordance with such testing instructions. If Manufacturer is not able to carry out the testing methods laid down in the testing instructions, Manufacturer and Customer will discuss and agree upon alternative methods, such methods being subject to approval by Customer in writing.

7.3 Manufacturer confirms Customer the proper testing of each batch, and the conformity of such testing with the testing instructions and provides Customer with the corresponding documentation as agreed in the Quality Agreement. Upon request of Customer, Manufacturer will present the complete original testing documentation and submit copies of such documentation.

7.4 If amendments become necessary, the testing instruction and/or master Testing Protocol have to be replaced by a new amended version of the document signed by both Parties. The respective new version enters into force upon signature by both Parties for all not yet tested Contract Products.

7.5 If testing instructions are modified, they have to be validated before implementation according to the respective ICH guidelines. Manufacturer will inform Customer of the intended validation and provide Customer with a validation plan, to which Customer has to agree in writing. After validation, Manufacturer will inform Customer about the results of the validation in writing prior to implementation.

7.6 If a deviation from the nominal value as laid down in the testing instruction has appeared, Manufacturer will inform Customer without delay and consistent with process that is outlined in the Quality Agreement about the data which deviate ("Testing Deviation Report"). In such case, Customer and Manufacturer commit themselves to agree upon the necessary measures to be taken and Manufacturer will promptly take such measures.

Manufacturer will make a report inclusive of relevant data on the circumstances of such deviation ("Investigation Report"), including without limitation explanations on the cause for such deviation, the batches affected by the deviation and possible measures to maintain or re-establish the appropriate quality of the Contract Products.

Manufacturer will submit the Investigation Report for Customer's approval. The costs for such Investigation Report will be borne by Manufacturer, except if the deviation was caused by any Customer-Supplied Material that, at the time of delivery to Manufacturer by or on behalf of Customer, failed to conform to the applicable specifications for such Customer-Supplied Material (excluding any Hidden Defect in the Customer Supplied Material).

7.7 Manufacturer will store the complete documentation according to Article 7.6 and a sufficient number of retained samples of both Customer Supplied Material & Starting Material for [●] after reception and finished Contract Products for [●] after manufacturing or for any longer time periods as are required by applicable laws, rules or regulations in the United States and, upon written notice from Company, such other countries or jurisdictions where Contract Products have obtained regulatory approval or are otherwise being marketed, distributed or sold. Place of storage and quantity of retained samples are agreed upon between the Parties. In any case, the quantity of retained samples must be sufficient for two complete release and shelf-life testings.

7.8 Prior to launch of the Product by Customer, Manufacturer will provide the minimum requirements identified by Applicable Law (including DSCSA regulations) related to serialization, including proper labelling of Customer's [●], plus testing and maintenance of data sharing/communication with Customer's serialization partners. During the term of the Agreement, Manufacturer will support any regulatory updates, such as aggregation, by implementing and testing with Customer and Customer's partners any required process changes or modifications in advance of regulatory required implementation date**.**

Article 8: Release and Shipment of Contract Products

8.1 Manufacturer will proceed with all controls imposed by the regulatory and pharmaceutical laws applicable as per the Marketing Authorization(s), Registration Dossier and Product Specifications at each stage of the Manufacturing process (including packaging process) of the Contract Products in such a way as to ensure compliance of the batches with the requirements of the Marketing Authorization(s), Registration Dossier and all applicable laws, rules and regulations, including cGMP.

8.2 Manufacturer will package the Contract Products according to the requirements as listed in the Quality Agreement, such requirements referring to, inter-alia, the selection

of the packaging containers for transportation, the labelling of such packaging containers and the destination to which the Contract Products shall be sent. In addition, Manufacturer will provide to Customer or its designee all relevant shipment documents such as packaging lists, etc., as applicable and as described in the Exhibit 6.

8.3 Manufacturer shall deliver the Contract Products [●] from Manufacturer's site in Braine L'Alleud, Belgium. The transfer of the risk and of title to the Contract Products takes place [●].

8.4 Manufacturer shall give at least [●] notice period before the estimated delivery date on which the Contract Products will be available for loading at the [●] location to allow Customer or its designee to take physical possession of the Contract Products.

Article 9: Defective Contract Products

9.1 Defects in the outer appearance of the Contract Products and missing quantities of Contract Products have to be notified by Customer or, on behalf of Customer, by the recipient of Contract Products (as designated by Customer), in each case [●] after receipt of the Contract Products. Hidden Defects in Contract Products shall be notified to Manufacturer within [●] after discovery of the Hidden Defect by Customer.

9.2 Manufacturer shall provide technical clarification and internal investigation of Defects. Manufacturer shall answer any pertinent question of Customer concerning existing or presumed Defects without delay, but not more than [●] after receipt of such question, and shall supply Customer with the relevant and complete documentation in case of any such Defects as soon as practicable and without delay, but in any event within [●] after commencing investigation of the Defects. The same shall apply in case any governmental authorities ask for such documentation. In this case, Manufacturer will provide responses to the relevant questions to Customer and Customer will provide the answers to the relevant governmental authorities. If Manufacturer receives Defect complaints concerning a Contract Product directly from a third party, Manufacturer will inform Customer thereof and will forward such complaints to Customer without undue delay. In such case, Customer and Manufacturer will provide each other mutual support in clarifying the cause for the Defect, if any. As far as direct contact with such third parties is concerned, third party complaints regarding Contract Products will exclusively be dealt with by Customer.

9.3 If an analysis performed by Customer shows that Contract Products do not comply with the then current Product Specifications and are not in compliance with other related documentation or if Customer notifies Manufacturer of any Defect or Hidden Defect in

the Customer Product pursuant to Article 9.1, and Manufacturer does not agree with such test result or notification, the Parties herewith agree on a further analysis to be performed by a specialized laboratory of international reputation acceptable to both Parties. Such analysis shall be considered as final and binding upon both Parties. The costs for the laboratory analysis will be borne by the Party responsible for the Defect (see Article 10.2). If the Contract Products are found by the laboratory to have no Defects, the costs [●]. When Manufacturer agrees or if the laboratory finds that Contract Product is Defective and that Manufacturer is responsible for the Defect as provided in Article 10.2 ("Manufacturer Defective Manufacturing"), then Article 9.4 shall apply.

9.4 Defective Product.

9.4.1 If Customer rejects Contract Products under Article 9 and the non-conformance is determined to have arisen from Manufacturer Defective Manufacturing, and Customer has not previously paid for the Defective Contract Product, Manufacturer will replace the Defective Contract Product and all materials required for the manufacture of the replacement Contract Products, and Customer shall be liable to pay Manufacturer's invoice price for such replacement Contract Product but shall not be liable to pay Manufacturer's invoice price for the Defective Contract Product and Manufacturer shall use [●] to manufacture and deliver such conforming Contract Products as soon as possible (but in any event such manufacturing shall be completed within [●] after the rejection.

9.4.2 If Customer rejects Contract Products under Article 9 and the non-conformance is determined to have arisen from Manufacturer Defective Manufacturing and Customer has previously paid for the Defective Contract Products, Manufacturer will promptly, at Customer' election, either: (i) refund all amounts paid by Customer to Manufacturer for the Defective Contract Products; or (ii) replace the Defective Contract Products and all materials required for the manufacture of the replacement Contract Products with conforming Contract Products without Customer being liable for Manufacturer's invoice price for such replacement Contract Product and Manufacturer shall use [●] to manufacture and deliver such conforming Contract Products as soon as possible (but in any event such manufacturing shall be completed within [●]) after Customer's election of this subsection (ii).

Article 10: Warranty provisions

10.1 Manufacturer warrants that (i) it will produce the Contract Products in full compliance with cGMP, GDP, the Registration Dossier, Marketing Authorization and all other applicable laws, rules and regulations, including those applicable to the then applicable and prevailing regulatory authority at its production premises and production processes for the Contract Products, (ii) at the time the Contract Products are loaded on to the means of transport with Customer's carrier at the [●] location, the Contract Products

will conform to all Product Specifications, will not be adulterated or misbranded and (iii) at the time of release in accordance with the Quality Agreement, Contract Products will have remaining shelf life of at least the required shelf life set forth in the Quality Agreement. Furthermore Manufacturer warrants that it will produce and analyse the Contract Products according to the registered methods and specifications and Manufacturer warrants that it will maintain throughout the Term all necessary governmental permissions, authorizations and the like required to manufacture and supply the Contract Products hereunder.

10.2 Manufacturer is responsible for all Defects of the Contract Products, except solely for

(i) Defects already inherent in or deriving from Customer-Supplied Materials provided that such Customer-Supplied Materials, at the time of delivery to Manufacturer, failed to conform to the applicable specifications for such Customer-Supplied Materials and/or (ii) Defects that arose as a result of Manufacturer's strict adherence to Customer's written instructions or requirements and (iii) Latent Defects in the Customer-Supplied Materials.

10.3 In case of Defect of Contract Products, whether due to Manufacturer Defective Manufacturing or otherwise, Manufacturer is required to

a) rework, reprocess or recover the affected batch(es) of Contract Products; but however, only if authorized by Customer in writing; or

b) replace the Defective Contract Products with Contract Products of appropriate quality; or

c) if applicable, comply with Article 9.4.

In case the Defect of Contract Products falls within the responsibility of Manufacturer as provided in Article 10.2, Manufacturer will perform its obligations under this Article 10.3(a) or (b) free of charge.

In case the Defect of Contract Products falls within the responsibility of Customer as described in Article 10.2(i) or (ii), Customer shall fully compensate Manufacturer for the performance of its obligation under this Article 10.3(a) or (b).

10.4 Customer's warranty claims fall under the statute of limitations [●] after expiry of shelf life of the respective Contract Products.

Article 11: Hold Harmless and Liability

11.1 Manufacturer shall indemnify, defend and hold harmless Customer, its Affiliates, officers, directors, agents, and employees, against any and all claims and damages of a third party arising out of personal injury or property damage that are due to

Manufacturer's or its Affiliate's or their subcontractor's, agent's, representative's or designee's negligence or willful misconduct or breach of this Agreement, including breach of the warranties in Article 10.1 and breach of the obligation to supply Contract Product by the delivery date specified in each Firm Order.

11.2 Customer shall indemnify, defend and hold harmless Manufacturer, its Affiliates, officers, directors, agents, and employees against any and all claims and damages of a third party arising out of personal injury or property damage that are due to handling, storing, distribution, use or sale by Customer of Contract Products, or claims by customers concerning alleged defects or misrepresentation in respect of Contract Products, except to the extent that such claims and damages result from the negligence or wilful misconduct or breaches of this Agreement by Manufacturer, or its Affiliates or their subcontractors, agents, representatives or designees.

11.3 The liability of each Party to the other Party shall be limited to direct and immediate damages and neither Party shall be liable to the other Party for indirect or consequential damages, including loss of profits, revenue or contracts, loss of business opportunity, increase in overhead expenses or reduction of anticipated savings, even if such losses and/or increases are foreseeable; provided, however, this limitation shall not apply to damages resulting from breaches by a Party of its confidentiality and non-use obligations under Article 16, or from a Party's fraud, gross negligence or willful misconduct and this limitation will not apply to third party claims that are indemnifiable under Section 11.1 or 11.2.

11.4 Except for the Parties' indemnification obligations related to third party claims under Sections 11.1 and 11.2, each Party's maximum liability to the other Party with respect to any claim under or in relation to this Agreement shall be equal to [●]. Each Party's maximum liability to the other Party with respect to any claim under or in relation to this Agreement with respect to the Parties' indemnification obligations related to third party claims under Sections 11.1 and 11.2 shall be equal to [●]. Nothing in this Agreement shall operate as to exclude or in any way limit liability for fraud or to the extent resulting from gross negligence or willful misconduct or for any other liability that may not be limited as a matter of applicable law.

11.5 Either Party undertakes to hold and maintain for the Term of this Agreement torts liability insurance in an amount adequate to cover its possible liability under this Agreement. At a minimum, Manufacturer shall hold and maintain throughout the Term general liability insurance coverage in the amount of at least [●] million per occurrence and [●] million in the aggregate.

Article 12: Orders and Forecasting for Contract Products

12.1

a. Purchase Orders: Customer will place purchase orders for Contract Products within [●] of the start of each month with a minimum leadtime of [●]. As an exception, Customer may place purchase orders for Contract Products with a leadtime that is less than [●] and Manufacturer will use its [●] to accept and fulfill such orders. After receipt of any purchase order by Manufacturer, Manufacturer will send an order acceptance to Customer within [●] after receipt of such order. Manufacturer shall accept each purchase order that complies with the minimum leadtime of [●] and shall use [●] to accept any other purchase order. Once accepted by Manufacturer, each purchase order shall become firm and binding on the Parties and shall be deemed a "Firm Order". Unless the Parties agree to a shorter leadtime, Contract Product will be scheduled for delivery the [●] after such Firm Order was submitted.

b Forecast: To allow a continuous and economical production, commencing on execution of this Agreement and no later than [●] thereafter, Customer will provide to Manufacturer in writing a rolling estimate of Customer's orders for Contract Product for the following [●] (each, a "Forecast"). Each Forecast will be broken down by [●].

- From [●].
- From [●].
- From [●].

Notwithstanding the foregoing, the Parties hereby agree that the forecast outside of the first [●] months (covering the binding forecast) is both nonbinding and only an estimate.

Customer agrees to use [●] to give notice to Manufacturer if Customer becomes aware of a significant increase or decrease to anticipated orders of Contract Product from the amounts set forth in the Forecast, and Manufacturer will use [●] to give notice to Customer in the event that its open manufacturing capacity that can be made available to Customer in response to a Forecast will significantly decrease during the Forecast period.

12.2 Manufacturer shall be obligated to manufacture and have available for pick-up at the [●] location the quantities of Contract Products in each Firm Order on the delivery date specified in each Firm Order, and Customer or its designee is required to pick-up the ordered amount of Contract Products on the delivery date specified in each Firm Order.

12.3 Should Manufacturer not be able to meet the delivery date as specified in the relevant Firm Order, Manufacturer will inform Customer accordingly without delay and shall propose alternative solutions and the following shall apply:

12.3.1 Subject to Article 12.3.2 below, if Manufacturer is unable to deliver the quantity of Contract Product ordered under a Firm Order within [●] of the delivery date specified in such Firm Order (provided that such delivery date complies with the provisions of Section 12.1) due to an act or omission by Manufacturer ("Late Delivery") then Customer will receive a credit from Manufacturer for such Late Delivery that will be applied against [●]. The credit will be [●] of Contract Product subject to such Late Delivery. If not rectified by [●] of the delivery date specified in the Firm Order, the credit shall [●].

12.3.2. For clarity, a Late Delivery will not include any delay in shipment of Contract Products caused by events outside of Manufacturer's reasonable control, such as (i) a Force Majeure Event, and (ii) the suspension of production by either Party following a report of nonconformity.

12.3.3 In the event Manufacturer is responsible for any OTD (on time delivery) indicator below [●] during any rolling [●] period, Customer will have the right to terminate this Agreement immediately. Upon such termination Manufacturer will be responsible for continuing to provide Contract Products until such time that Customer has qualified, secured and received regulatory authority approval for sourcing Contract Product from another manufacturer, and Manufacturer will also fully assist Customer in sharing of pertinent information and technology transfer to such other manufacturer.

12.4 Customer shall advise Manufacturer immediately in writing of all information at its disposal which might alter the Forecast.

12.5 Cancellation Fees shall be payable, if any, by Customer in the event of cancellation of scheduled production of a Firm Order.

12.6 Customer shall have the right to designate a portion of the Contract Products ordered pursuant to any Firm Order to be delivered in accordance with Article 12.2 as Bulk Product (as defined on Exhibit 1). Customer shall notify Manufacturer when issuing the purchase order of the applicable Finished Product (as defined in Exhibit 1) has commenced whether it would like any portion of the Contract Products ordered pursuant to such Firm Order to be delivered as Bulk Product.

12.7 Upon any delivery of Finished Product, Manufacturer shall deliver any leftover portion of the batch of Bulk Product that was not packaged into Finished Product as well as any leftover RTGel provided by Customer for such order that was not packaged into Finished Product.

Article 13: Prices

13.1 The Prices for manufacturing of Contract Products are set forth in Exhibit 7 (all prices are VAT excluded). The Prices include [●]. Upon delivery of the Finished Product, Manufacturer shall invoice Customer for the applicable Bulk Product batch fee set forth on Exhibit 7 together with the Finished Product packaging price set forth on Exhibit 7 for each unit of the Finished Product delivered. Notwithstanding the foregoing, in the event any portion of Contract Product is delivered as Bulk Product in accordance with Article 12.6, Manufacturer shall invoice Customer as follows (a) upon delivery of the Bulk Product, [●] and (b) upon delivery of the Finished Product, Manufacturer shall invoice Customer [●].

13.2 Payment for Contract Products will be made by Customer within [●] after release of Contract Product, delivery to Customer or its designee at the [●] location and receipt of an undisputed invoice. If Customer is more than [●] late in paying any undisputed payment for Contract Products pursuant to this Section 13.2, Customer shall be charged and pay a [●] late payment penalty. If Customer is more than [●] late in paying any undisputed payment for Contract Products pursuant to this Section 13.2, instead of the late payment in the foregoing sentence, Customer shall be charged and pay a [●] late payment penalty.

13.3 Subject to the then applicable MBR and Manufacturing instructions, on the first January of each year following the 2nd anniversary of the date of initial commercial launch of Contract Product, prices will change according to the rules described in Exhibit 8.

13.4 Manufacturer is entitled to claim an adjustment of the Prices in case of [●]. In any case, any modification or adjustment of the Prices will take place only after a good faith negotiation and mutual agreement of the Parties.

13.5 Customer and Manufacturer are entitled to claim an adjustment of Prices in the case of:

13.5.1. [●], or

13.5.2. [●], or

13.5.3. [●].

In such case, the Parties will negotiate in good faith and the adjustment of Prices will take place only after mutual agreement of the Parties.

Article 14: Obligation to Inform

14.1 The Parties to this Agreement will inform each other without delay about batch recalls and complaints relating to Contract Products and/or any Starting Material and/or any Packaging Material as well as about any circumstance concerning their contractual relationship, problems and/or new technical and scientific information relating to Contract Products. Upon receiving any notice of or any discovery that Contract Product should be recalled or subject to corrective action, Manufacturer shall cease deliveries of such Contract Product to Customer until a decision has been made by Customer whether a recall or some other corrective action is necessary. The decision to initiate a recall or to take other corrective action, if any, shall be made and implemented solely by Customer. Manufacturer will, [●], cooperate and provide timely

assistance in connection with a recall or correction, as may be reasonably requested by Customer, within the terms of the Quality Agreement and subject to applicable laws, rules and regulations. To the extent that a recall or other corrective action results from or arises out of Manufacturer's failure to comply with this Agreement or the Quality Agreement, including Manufacturer's manufacture of Defective Contract Product, then the provisions of Section 10.3 shall apply and Manufacturer shall [●], within the limits set forth in Section 11.4.

14.2 Should any unforeseen circumstance lead to difficulties in performing and executing this Agreement, each Party shall immediately inform the other Party, orally and in written form about this circumstance, especially in case of technical difficulties.

14.3 The same shall apply in case of difficulties in procuring Starting Material. The Parties will in such a case use their [●] to resolve this situation. Any deviation from any relevant regulation, instruction etc. shall only be effective after the mutual written consent of the Parties.

14.4 Manufacturer agrees to inform Customer of any governmental authority audit, inquiry, communication or inspection, which directly or indirectly affects the production of the Contract Products, promptly upon learning of the same, but in any event within such time period as may be specified in the Quality Agreement. In the event of any review, audit or inspection by any governmental authority which directly involves any Contracts Products ("Product-Related Inspection"), Manufacturer shall provide Customer with immediate notice thereof. Manufacturer shall use [●] to ensure that Customer will have the right to be present at any Product-Related Inspection and Manufacturer shall provide Customer with the results of such Product-Related Inspection. In the event of any written observations (or other written communication) by a governmental authority which directly or indirectly involves or may affect any Contract Products or the manufacture thereof, Manufacturer will inform Customer and provide Customer with copies of all related documentation promptly, but in any event within such time period as may be specified in the Quality Agreement, and Customer will have the opportunity to provide assistance to Manufacturer in responding to any such governmental authority communication. Without limiting the foregoing, Manufacturer shall provide Customer the opportunity to review and provide input to any proposed written response by Manufacturer to any Product-Related Inspection and, if Customer elects to provide input to the response to a Product-Related Inspection, Customer will provide such input as promptly as practicable (or, if applicable, within any time period specified in the Quality Agreement) and Manufacturer shall incorporate all reasonable comments from Customer.

Article 15: Reimbursement of tooling costs (third party fees)

15.1 In the event Customer changes the lay-outs of packaging materials, and as a result of such Customer changes the fee to be paid by Manufacturer to the supplier of packaging materials is increased, such increased fee for these changes will be charged to [●].

Article 16: Confidentiality

16.1 Each Party (the "Receiving Party") undertakes to keep confidential any and all information, whether patented or not, regardless the support and the form, received from the other Party (the "Disclosing Party") relating to the Contract Products or the manufacture thereof (hereinafter referred to as the "Confidential Information"). The Receiving Party shall treat all Confidential Information of the Disclosing Party with utmost confidence using the same degree of care that the Receiving Party uses to protect its own Confidential Information and in any event not less than a [●]. The Receiving Party specifically shall: (a) not use Confidential Information of the Disclosing Party for any purpose other than to perform the Receiving Party's obligations or exercise the Receiving Party's rights under this Agreement; (b) not disclose Confidential Information of the Disclosing Party except (i) to its Affiliates, and to those officers, directors, employees, contractors, agents and other representatives of the Receiving Party and its Affiliates ("Permitted Agents") who have a need to know such Confidential Information for the purposes described in clause (a) and who have been made aware of this Agreement and are themselves bound by obligations of confidentiality similar to the provisions hereof, or (ii) with the prior written consent of the Disclosing Party; and (c) take all appropriate measures, including such measures as the Disclosing Party may reasonably request, to safeguard the Confidential Information of the Disclosing Party from loss, misappropriation, destruction, theft or disclosure to unauthorized persons.The Receiving Party shall not be entitled to use the Confidential Information of the Disclosing Party after termination of this Agreement without the written consent of the Disclosing Party. Manufacturing instructions, testing instructions, Customer IP (as defined in Article 17), and Customer- Supplied Materials and all data, documents and information related to Customer- Supplied Materials shall at all times be considered as being Confidential Information of Customer and notwithstanding anything to the contrary, Customer shall be the Disclosing Party and Manufacturer shall be the Receiving Party of all of such Confidential Information for all purposes of this Agreement.

The restrictions herein contained shall not extend to Confidential Information which the Receiving Party shows

a) was, prior to the time of disclosure by the Disclosing Party, already known to the Receiving Party and not directly or indirectly received from the Disclosing Party as can be substantiated by written records; provided that this exception shall not apply to Customer IP which shall remain the Confidential Information of Customer; or

b) was generally available to the public prior to the time of disclosure by the Disclosing Party; or

c) has become, through no act or failure to act on the part of the Receiving Party or any of its Affiliates or Permitted Agents, public information or generally available to the public; or

d) has been furnished - without any restriction on the Receiving Party's disclosure of such information - by a third party who has not directly or indirectly received it from the Disclosing Party and which Party was legally entitled to do so.

16.2 If the Receiving Party is required by final court order to disclose any Confidential Information of the Disclosing Party, the Receiving Party will provide the Disclosing Party with immediate written notice of such requirement or obligation (together with a copy of any relevant court order) to enable the Disclosing Party to seek appropriate protective relief and/or to take steps to resist or narrow the scope of any required disclosure. The Receiving Party will cooperate with the Disclosing Party with respect to such matters and will in any event disclose only such Confidential Information of the Disclosing Party that it is legally compelled to disclose and will ensure that all such Confidential Information so disclosed is accorded confidential treatment in terms of this Agreement. The Receiving Party will notify the Disclosing Party in writing of the means, content and timing of such disclosure prior to such disclosure being made. If prior notification is precluded by law or regulation or where enforcement action by the applicable authority precludes prior notification, the Receiving Party will notify the Disclosing Party as soon as reasonably practicable. Any mandatory disclosure hereunder will be limited to the extent necessary by the legal requirement.

16.3 Immediately upon termination or expiration of this Agreement, the Receiving Party will return to the Disclosing Party any and all tangible media or other medium containing the Disclosing Party's Confidential Information which was provided to the Receiving Party pursuant to the terms hereof. The Receiving Party will expunge all Confidential Information from its digital, electronic, or other mediums, and will destroy any notes, compilations, studies and all other materials prepared by the Receiving Party, based in whole or in part on the Confidential Information provided by the Disclosing Party, provided that the Receiving Party shall be entitled to keep one copy each of such files as are necessary to comply with existing internal data retention policies for data security or disaster recovery purposes, pursuant to which policies, such copies are automatically created in a temporary archive electronic backup system. The Receiving Party shall issue to the Disclosing Party a certificate signed by the Receiving Party's legal counsel and the possessors of the signatory rights of the Receiving Party confirming said destruction of the Confidential Information (the "Certificate"). The Certificate shall include an acknowledgment of the Receiving Party that it has no rights of use in or to the Confidential Information after the expiration date.

16.4 Without prejudice to any other rights and remedies the Disclosing Party may have, the Receiving Party acknowledges and agrees that damages alone may not be an adequate remedy for any breach of the provisions of this Agreement by the Receiving Party or its Affiliates or Permitted Agents and accordingly, the Receiving Party agrees

that the Disclosing Party may be entitled, in addition to all legal remedies, without proof of special damage, to seek the remedies of injunction, specific performance and other equitable relief that may be available against a threatened or continuing breach, with the requirement of the placement of a bond waived by the Receiving Party.

16.5 The Parties agree that, as between the Parties and their Affiliates and the exchange of Confidential Information between and among them, this Agreement supersedes the Three-Way Nondisclosure Agreement among Customer, Manufacturer's Affiliate, Phixen S.A.S, and SGS North America Inc. dated 16 December 2018; provided, that all information shared by the Parties or their Affiliates pursuant to such Nondisclosure Agreement shall be deemed Confidential Information under this Agreement, and the use and disclosure thereof shall be governed by the terms of this Article 16.

16.6 This Article 16 of this Agreement shall survive the termination of this Agreement for a period of [●].

Article 17: Intellectual Property

17.1 Any information, data, results, inventions and improvements deriving from Manufacturer's services and operations hereunder, whether patentable or not, (collectively, "Customer IP") shall be the exclusive property of the Customer, which as their exclusive owner shall be entitled to exploit such Customer IP as it will deem appropriate and to file patent applications at is sole discretion in any country on a worldwide basis. Manufacturer shall promptly disclose to Customer any Customer IP made, conceived, learned or reduced to practice by Manufacturer during the Term, and Manufacturer hereby assigns to Customer any and all right, title and interest in and to any Customer IP. At Customer's request, Manufacturer shall provide to Customer reasonable assistance in recording, perfecting and maintaining Customer's rights, title and interest throughout the world in Customer IP, including executing and delivering any assignments requested by Customer. If and to the extent any Customer IP that is made, conceived, learned or reduced to practice by Manufacturer includes operational improvements to Manufacturer's pre-existing manufacturing technology that are generally applicable to other manufacturing projects of Manufacturer and are not specific to the Contract Products, or to any Customer-Supplied Materials or other Confidential Information of Customer, Customer hereby grants to Manufacturer a non- exclusive, perpetual, worldwide license, with the right to sublicense to its affiliates only, under such generally applicable improvements solely to perform manufacturing projects for third parties.

Article 18: Term

18.1 The Agreement will be effective as of the signature by the Parties and shall remain in full force and effect during five (5) years from the first commercial production of the Contract Product for the US market, and thereafter be extended for consecutive 24 (twenty-four) month periods (the initial period and any consecutive period together referred to as "Term"), unless the Agreement is terminated by one of the Parties with 18 (eighteen) months prior written notice before the expiry of the initial term or any consecutive period.

18.2 This Agreement may be terminated early in accordance with the following:

a) Either Party may terminate this Agreement by giving notice in writing to the other Party, which notice shall be effective upon receipt by the other Party, should the other Party become insolvent, make an arrangement for the benefit of creditors, go into liquidation or receivership.

b) Should an event of force majeure as provided in Article 19.2 continue for more than 3 (three) months and there is no viable plan in place to remedy the effects of such force majeure within a reasonable time frame, the Party that is unaffected by the force majeure may terminate this Agreement by giving notice in writing to the other Party that is affected by the force majeure, which notice shall be effective upon receipt by the other (affected) Party.

c) Either Party may terminate this Agreement by giving written notice to the other, which notice shall be effective upon receipt by the other Party, if any necessary governmental permission, authorization or the like in respect of Manufacturer is withdrawn, suspended or restricted, resulting in permanent limitation or exclusion of Manufacturer's capability to manufacture the Contract Products.

d) Customer is entitled to terminate this Agreement with written notice effective upon receipt by Manufacturer, if the sale and/or distribution of the Contract Products is no longer permitted by the official authorities in any country where Contract Products are distributed, or if the Contract Products are withdrawn from the market or the Marketing Authorization is revoked or modified (termination right only in favor of Customer).

e) Customer is entitled to terminate this Agreement with written notice of termination effective upon receipt by Manufacturer in the event Manufacturer breaches any article herein, including but not limited to Article 12.3 herein, and fails to cure such breach within thirty (30) days of written notice of such breach from Customer.

f) Customer and Manufacturer are entitled to terminate this Agreement for any reason or no reason with 24 (twenty-four) months prior written notice to the other. In the event Manufacturer provides written notice of termination pursuant to this Section 18.2(f), Manufacturer shall use [●] to assist Customer in building Contract Product inventory prior to the effective date of termination.

18.3 If Manufacturer is in the process of manufacturing Contract Products for Customer on the day this Agreement expires or is terminated, Manufacturer shall proceed as follows:

a) If not notified differently by Customer, all amounts of Contract Products which are in the process of being manufactured according to the Customer's orders shall be carried through until completion in accordance with the terms of this Agreement and the Quality Agreement, and the Contract Products resulting there from shall be delivered to Customer by Manufacturer and shall be paid for by Customer in accordance with the terms hereof.

b) If this Agreement is terminated pursuant to Article 18.2(d), Manufacturer will immediately cease manufacture when so notified by Customer. In this case, Manufacturer will be paid for the Contract Products manufactured until receipt of such notification by Customer.

18.4 In addition, upon termination of this Agreement, Manufacturer shall deliver to Customer all unused Starting Material, Packaging Materials and other materials, whether raw materials, packaging supplies or other which are in good condition, within shelf life and reasonable in terms of quantity and dedicated to the manufacture of the Contract Products, and Manufacturer shall deliver to Customer all Customer-Supplied Materials. Alternatively, Customer may request that such materials etc. be destroyed. The costs of such material, whether delivered to Customer or destroyed by Manufacturer at Customer's request, shall be reimbursed to Manufacturer by Customer.

18.5 Termination of this Agreement shall not extinguish the rights of either Party that accrue prior to expiration or termination or release either Party from any accrued obligations that extend beyond termination or expiration, including the obligation to deliver or to make payment of all amounts then or thereafter due and payable. In addition, the following provisions shall survive any expiration or early termination of this Agreement: Articles 1, 6.8, 7.1, 7.3, 7.7, 9, 10.1, 10.2, 10.4, 10.4, 11.1, 11.2, 11.3, 11.4, 16, 17.1, 18.3, 18.4, 18.5, 19.1, 19.3, 19.4, 19.5, 19.8, 19.9, 20, 21 and 22.

Article 19: Miscellaneous

19.1 Interpretation of Agreement

In this Agreement

a) Reference to "this Agreement" or to any other agreement or document referred to in this Agreement shall mean this Agreement or such other agreement or document as amended, varied, supplemented or modified from time to time and shall include the Exhibits.

b) Reference to Articles and Exhibits are references to Articles and Exhibits of and to this Agreement, unless otherwise stated.

c) Words denoting the singular shall include the plural and vice versa; words denoting either gender shall include a reference to both genders.

d) The heading and sub-headings are inserted for convenience only and shall not affect the construction of this Agreement or any Article thereof.

e) Each and all of the Exhibits shall constitute an integral part of this Agreement.

f) The words "include," "includes" or "including" shall be construed as incorporating the phrase "but not limited to" or "without limitation" and shall mean including without limiting the generality of any description preceding or following such words.

19.2 Force Majeure. In the event that a Party's performance of this Agreement or of any of its obligations hereunder, other than payment of money as herein provided, is prevented by reasons of any cause not within the control of such Party, and which could not by reasonable diligence have been avoided by such Party, the Party so affected, upon giving prompt written notice to the other Party as to the nature and probable duration of such event, shall be excused from such performance to the extent and only for the duration of such prevention, provided that the Party so affected shall use its [●] to avoid or remove such cause of non-performance and shall fulfil and continue performance hereunder with the utmost dispatch whenever and to the extent such cause or causes are removed.

19.3 Severability. Should one of the provisions of this Agreement become or prove to be null and void this will be without effect on the validity of the Agreement as a whole. Both Parties will, however, endeavour to replace the void provision by a valid one which in its economic effect complies most with the void provision. The same shall apply *mutatis mutandis* in case this Agreement contains any gaps.

19.4 Waiver. If any Party should at any time refrain from enforcing its rights arising from a breach or default by the other Party of any of the provisions of this Agreement, such waiver shall not be construed as a continuing waiver regarding that breach or default or other breaches or defaults of the same or other provisions of this Agreement.

19.5 Entire Agreement. The terms and conditions herein contained constitute the entire Agreement between the Parties with respect to the subject matter hereof. No modification or amendment of this Agreement shall be binding upon any Party hereto unless in writing and signed by duly authorized officers of the respective Party. Exhibits 1 to 8 of this Agreement form an integral part of this Agreement.

19.6 Consents. Whenever a Party's consent is required under this Agreement (such as, e.g. for a release, agreements to or approvals of documents or of changes, or similar) such consent may be refused for valid reasons only and the consent shall be declared without delay.

19.7 Customer Affiliates. The Parties agree that Customer's Affiliates may perform on behalf of Customer any responsibilities of Customer under this Agreement and Customer's Affiliates may exercise any of Customer's rights under this Agreement.

19.8 Counterparts. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

19.9 Relationship of Parties. Neither Party is, nor will be deemed to be an employee, agent, or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party will have the authority to speak for, represent, or obligate the other Party in any way without prior written authority from the other Party. Customer shall not be prohibited from obtaining supply of Contract Products from any third party or from manufacturing Contract Products on its own.

Article 20: Governing Law

The Agreement will be governed by the laws of Swiss law. The United Nations Convention on Contracts for the International Sale of Goods shall not apply.

Article 21: Dispute Resolution

All disputes, controversy or claim arising out of or in connection with this Agreement including the validity, invalidity, breach or termination thereof, shall be settled by arbitration in accordance with the International Arbitration Rules of the International Chamber of Commerce in force on the date when the Notice of Arbitration is submitted in accordance with these Rules. The seat of the arbitration shall be in [●]. The arbitral proceedings shall be conducted in English before a panel of three (3) arbitrators. Each Party will promptly appoint one arbitrator and the third arbitrator will be appointed promptly by agreement of the two arbitrators appointed by the Parties. Notwithstanding the foregoing, in the event of an actual or threatened breach of this Agreement or in the event of potential irreparable harm, the aggrieved Party may, without waiving any remedy under this Agreement, seek provisional equitable relief (including restraining orders, specific performance, or other injunctive relief) from any court having jurisdiction over the Parties and the subject matter of the issue, without first submitting to arbitration hereunder. In addition, any claim for injunction, specific performance or other equitable relief pursuant to Article 16.4 shall

not be subject to arbitration and, instead, the aggrieved Party may initiate litigation in any court of competent jurisdiction.

Article 22: Assignment

Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Party, except that a Party may assign this Agreement without such consent to its Affiliate or its successor in interest by way of merger, acquisition, or sale of all or substantially all of its assets to which this Agreement relates. Any purported assignment in violation of this Article 22 will be null and void and of no force or effect.

IN WITNESS WHEREOF, Customer and Manufacturer have executed this Agreement as of the Effective Date set forth above.

UroGen Pharma Ltd.	**Cenexi Laboratoires Thissen S.A.**
Place: Israel	Place: Brussels
/s/ Keren Stotzky	/s/ Christophe Allard
Name: Keren Stotzky	Name: Christophe Allard
Title: VP Manufacturing & Supply Chain	Title: General Manager

Amendment #1 to Manufacturing and Supply Agreement

This Amendment #1 to the Manufacturing & Supply Agreement ("Amendment #1"), effective this 2nd day of March, 2022 ("Amendment #1 Effective Date"), is by and between **UroGen Pharma Ltd.**, a company organized and existing under the laws of the State of Israel having an address at 9 HaTaasia St., Ra'anana 4365007, Israel ("Customer") and **Cenexi-Laboratoires Thissen S.A.**, a company incorporated in Belgium, having its registered office at 2-4-6, Rue de la Papyrée, B-1420 Braine-l'Alleud, also acting hereunder on behalf of its Affiliates ("Manufacturer").

WHEREAS, Customer and Manufacturer entered into a certain Manufacturing and Supply Agreement dated April 24, 2020 (the "Agreement") regarding the manufacturing by Manufacturer and the purchase by Customer of UGN-101; and

WHEREAS, Customer and Manufacturer mutually agree to amend the Agreement as set forth in this Amendment #1.

NOW THEREFORE, in consideration of the above, and for good and valuable consideration the receipt and sufficiency of which the parties acknowledge, Customer and Manufacturer agree to amend the Agreement as follows:

1. The following defined terms are added to Article 1 of the Agreement:

   - Customer Equipment: shall mean the equipment specified on Exhibit 3 attached hereto.

   - Positive FDA Decision: shall mean a Marketing Authorization from the FDA for a Contract Product.
   - Negative FDA Decision: shall mean a communication from the FDA that an NDA for a Contract Product, following its submission by Customer and acceptance and review by the FDA, is not approvable in its present form. For clarity, a Negative FDA Decision includes a "Complete Response Letter" from the FDA, as defined in 21 CFR Section 314.110(a).
   - Negative Phase 3 Study Data: shall mean data from a Phase 3 Study of a Contract Product in development that, in the reasonable determination of Customer, provides insufficient evidence of safety and effectiveness for such Contract Product to support the filing of an application to the relevant authority for a Marketing Authorization (e.g., the filing of an NDA to the FDA).

2. The following new Section 4.11 is hereby added to the Agreement immediately following Section 4.10:

   4.11 Customer shall at all times retain ownership of the Customer Equipment. Manufacturer shall ensure that all Customer Equipment is properly stored and maintained. Manufacturer will be responsible for installing, cleaning and maintaining all Customer Equipment, as needed to manufacture the amounts of Contract Product ordered by Customer under this Agreement. Manufacturer will use the Customer Equipment exclusively for the manufacture of Contract

   Product under this Agreement and for no other purpose without prior consent by Customer. Upon termination or expiration of this Agreement, Manufacturer shall deliver all Customer Equipment to Customer or its designee at Customer's risk, cost and expense and in accordance with shipping instructions provided by Customer.

3. The first sentence of Section 12.1(a) of the Agreement is hereby deleted in its entirety and replaced with the following:

   Customer will place purchase orders for Contract Products within [●] of the start of the month with a minimum leadtime of [●] for Finished Product and [●] for Bulk Product.

4. The following new Section 12.1(c) is hereby added to the Agreement immediately following Section 12.1(b):

   c. Minimum Annual Quantity Forecasts and Minimum Annual Quantity Commitments: Starting as defined in Exhibit 7 and continuing during the Term, Customer shall provide to Manufacturer a rolling forecast setting forth its forecasted minimum annual quantity for each Contract Product for the upcoming calendar period as defined in Exhibit 7 (each, an "MAQ Forecast").

   Manufacturer shall [●] fulfill purchase orders for (and shall accept purchase orders submitted by Customer in accordance with the MAQ) Forecasts defined and agreed on in Exhibit 7 and to manufacture at least its Minimum Annual Quantity of each Contract Product in each calendar year, which, for clarity, shall require [●]. Without limiting any of Manufacturer's other duties, representations and warranties under the Agreement including those set forth in Article 9 (Defective Contract Products) and Article 10 (Warranty Provisions), this commitment shall be deemed meet even in the event of a defective batch. As used herein, "Anticipated Yield" shall mean [●] of the theoretical yield for such Contract Product for the [●] following the Amendment #1 Effective Date, or [●], whichever is sooner. In the event of a significant change in this yield during this timeframe, the Parties shall discuss in good faith the yield and the allocated capacity for the Contract Products. Following [●], the Parties will review in good faith the Anticipated Yield for the remaining calendar years of the Term.

   In the event that, on a Contract Product-by-Contract Product basis in any given calendar year during the Term, Customer submits to Manufacturer purchase orders for such Contract Product with specified delivery dates in such calendar year that in the aggregate are fewer than its applicable MAQ commitment for such Contract Product in such calendar year, then, except to the extent such failure to meet the MAQ is directly attributable to Manufacturer and subject to the

   remainder of this Section 12.1(c), Customer shall be obligated to compensate Manufacturer for an amount equal to [●].

   Customer shall have the capacity, following prior written approval by Manufacturer, which cannot be unreasonably withheld, to transfer a portion of its MAQ for a given Contract Product in a particular calendar year to another Contract Product or any other further strength of a Contract Product for the same calendar year.

In the event Customer identifies that it will likely not be able to meet its MAQ for a given Contract Product in a particular calendar year during the Term (the "MAQ Shortfall Calendar Year", then in the event Customer provides Manufacturer with written notice thereof (the "MAQ Shortfall Notice"), Manufacturer shall use diligent efforts to refill the manufacturing capacity at the facility in the MAQ Shortfall Calendar Year and in the event Manufacturer is able to refill all or any portion of the manufacturing capacity, then the MAQ Shortfall Payment shall be [●]. For sake of clarity, Customer shall notify Manufacturer of the precise adjustment that needs to be done on the MAQ for a Contract Product in the MAQ Shortfall Calendar Year, and shall Manufacturer be able to refill the manufacturing capacity, Manufacturer shall no longer be liable for its MAQ commitment for that Contract Product in the MAQ Shortfall Calendar Year. However, Manufacturer will use diligent efforts to provide manufacturing capacity in the event Customer, following its delivery of a MAQ Shortfall Notice, submits timely purchase orders to Manufacturer to meet Customer's MAQ for a Contract Product in the MAQ Shortfall Calendar Year.

5. The following two sentences are hereby added at the end of Section 12.2 of the Agreement:

With respect to any Firm Order for a number of units of Contract Product, any timely delivery of Contract Product under such Firm Order that is within plus or minus [●] of the quantity of Contract Product ordered in such Firm Order (the "Allowable Variance") shall be deemed to fulfill Manufacturer's obligation to deliver the quantity of Contract Product in such Firm Order. In the event Manufacturer anticipates that the quantity of Contract Product under any such Firm Order will be outside of the Allowable Variance, then Manufacturer shall promptly notify Customer thereof and the Parties shall discuss in good faith how to address such variance.

6. Section 13.1 of the Agreement is hereby deleted in its entirety and replaced with the following:

The Prices for manufacturing of Contract Products are set forth in Exhibit 7 (all prices are VAT excluded). The Prices include [●]. Upon the release (in accordance with the Quality Agreement) of any Bulk Product batch manufactured by Manufacturer for use in Finished Products or for delivery to Customer as Bulk Product, in each case, ordered by Customer pursuant to any Firm Order, Manufacturer shall invoice Customer for the applicable Bulk Product batch fee set forth on Exhibit 7. Upon the delivery of the Finished Product, Manufacturer shall invoice Customer for the Finished Product packaging price set forth on Exhibit 7 for each unit of the Finished Product delivered.

7. The first sentence of Section 13.2 of the Agreement is hereby deleted in its entirety and replaced with the following:

Payment for the Bulk Product batch fee will be made by Customer within [●] after (a) release of the Bulk Product, (b) solely to the extent the Bulk Product is ordered by Customer for delivery as Bulk Product pursuant to a Firm Order, delivery to Customer or its designee at the [●] location and (c) receipt of an undisputed invoice. Payment of the Finished Product packaging fee will be made by Customer within [●] after release of Finished Product, delivery to Customer or its designee at [●] location and receipt of an undisputed invoice. For sake of clarity, Finished Product shall be subject to two different orders: one order for Bulk Product and a second order for packaging (Finished Product).

8. The phrase "during five (5) years from the first commercial production of the Contract Product for the US market" in Section 18.1 of the Agreement is hereby deleted and replaced with "for a period of five (5) years from the Amendment #1 Effective Date".

9. Section 18.2(d) of the Agreement is hereby deleted in its entirety and replaced with the following:

Customer is entitled to terminate this Agreement on a Contract Product-by-Contract Product basis with written notice effective upon receipt by Manufacturer, if (i) Customer has received a Negative FDA Decision for a Contract Product, (ii) Customer reasonably elects to discontinue the development of such Contract Product following receipt of Negative Phase 3 Study Data for such Contract;(iii) if the sale and/or distribution of such Contract Product is no longer permitted by the official authorities or is materially adversely affected by the acts of any official authority, in each case, in any country where such Contract Product is sold or distributed, or (iv) if such Contract Product is withdrawn from the market or the Marketing Authorization is revoked or modified by the relevant authority (termination right only in favor of Customer)

10. Article 23: Environment, Safety and Governance shall be added to the Agreement and state the following:

Each party is in compliance with and shall continue to comply with all applicable laws as required by applicable law for its performance under the Agreement, which include without limitation, applicable environmental and health and animal safety laws. Accordingly, each party will (i) perform under this Agreement in a safe and ethical manner (including the storage, handling and disposal of any hazardous materials and the treatment of animals); and (ii) notify the other if such party is not in compliance with such applicable laws and such non-compliance poses a significant threat to the environment or the health, safety or welfare of animals.

11. Exhibit 1 of the Agreement is deleted in its entirety and replaced with Exhibit 1 to this Amendment #1.

12. Exhibit 3 of the Agreement is deleted in its entirety and replaced with Exhibit 3 to this Amendment #1.

13. Exhibit 7 of the Agreement is deleted in its entirety and replaced with Exhibit 7 to this Amendment #1.

14. A new Exhibit 9 to the Agreement (Preliminary Term Sheet Governing [●] and Dedication of [●]) is attached as Exhibit 9 to this Amendment #1.

15. Except as amended above, all other terms and conditions of the Agreement shall remain the same and in full force and effect. Capitalized terms used herein which are not defined shall have the respective meanings ascribed to them in the Agreement. The Agreement as modified by this Amendment #1, constitute the entire agreement between the Parties with respect to the subject matter hereof. All references to the term "Agreement" in the Agreement shall be deemed to include all of the terms and conditions of this Amendment #1.

16. This Amendment #1 may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Amendment #1.

[Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, Customer and Manufacturer have executed this Amendment #1 as of the Amendment #1 Effective Date set forth above

UroGen Pharma Ltd.	**Cenexi Laboratoires Thissen S.A.**
Place: Israel	Place: Brussels
/s/ Keren Stotzky	/s/ Christophe Durand
Name: Keren Stotzky	Name: Christophe Durand
Title: VP Manufacturing & Supply Chain	Title: President

Exhibit 31.1

CERTIFICATION 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

I, Elizabeth Barrett, certify that:

1. I have reviewed this quarterly report on Form 10-Q of UroGen Pharma, Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2022

By: /s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Don Kim, certify that:

1. I have reviewed this quarterly report on Form 10-Q of UroGen Pharma, Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2022

By: /s/ Don Kim

Don Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of UroGen Pharma, Ltd. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Elizabeth Barrett, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 10, 2022

By: /s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of UroGen Pharma, Ltd. (the "Company") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Molly Henderson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 10, 2022

By: /s/ Don Kim

Don Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)