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 September 30, 2024

OR

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

For the transition period from to

Commission file number: 001-38079

UROGEN PHARMA LTD.
(Exact Name of Registrant as Specified in its Charter)

Israel	**98-1460746**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification 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 November 1, 2024, the registrant had 42,199,414 ordinary shares, par value NIS 0.01 per share, outstanding.

UroGen Pharma Ltd.
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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)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 124,916	$ 95,002
Marketable securities	124,659	41,966
Restricted cash	1,073	821
Accounts receivable, net	22,802	15,443
Inventories	7,594	5,673
Prepaid expenses and other current assets	14,053	10,281
Total current assets	295,097	169,186
Non-current assets:		
Property and equipment, net	608	689
Restricted deposit	175	225
Right of use assets	1,052	1,671
Marketable securities	4,641	4,502
Other non-current assets	370	2,038
Total Assets	$ 301,943	$ 178,311
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,685	$ 16,538
Employee related accrued expenses	9,029	10,814
Other current liabilities	4,073	3,860
Total current liabilities:	32,787	31,212
Non-current liabilities:		
Prepaid forward obligation	118,526	109,722
Long-term debt	121,709	98,551
Long-term lease liabilities	212	844
Uncertain tax positions liability	3,194	3,194
Total Liabilities	276,428	243,523
Commitments and Contingencies (Note 18)		
Shareholders' Equity (Deficit):		
Ordinary shares, NIS 0.01 par value, 100,000,000 shares authorized at September 30, 2024 and December 31, 2023; 42,190,815 and 32,490,119 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	115	89
Additional paid-in capital	793,874	614,035
Accumulated deficit	(768,710)	(679,348)
Accumulated other comprehensive income	236	12
Total Shareholders' Equity (Deficit)	25,515	(65,212)
Total Liabilities and Shareholders' Equity (Deficit)	$ 301,943	$ 178,311

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 September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	$ 25,204	$ 20,852	$ 65,833	$ 59,183
Cost of revenue	2,453	2,367	6,410	7,075
Gross profit	22,751	18,485	59,423	52,108
Operating expenses:				
Research and development expenses	11,355	10,230	42,251	34,312
Selling, general and administrative expenses	28,941	21,755	86,296	68,723
Operating loss	(17,545)	(13,500)	(69,124)	(50,927)
Financing on prepaid forward obligation	(5,915)	(5,479)	(17,348)	(16,047)
Interest expense on long-term debt	(2,721)	(3,815)	(8,629)	(11,129)
Interest and other income, net	2,599	906	5,922	1,941
Loss before income taxes	(23,582)	(21,888)	(89,179)	(76,162)
Income tax expense	(91)	9	(183)	(66)
Net Loss	$ (23,673)	$ (21,879)	$ (89,362)	$ (76,228)
Statements of Comprehensive Loss				
Net loss	$ (23,673)	$ (21,879)	$ (89,362)	$ (76,228)
Other comprehensive income (loss)				
Unrealized gain (loss) on investments	267	20	224	(27)
Comprehensive Loss	$ (23,406)	$ (21,859)	$ (89,138)	$ (76,255)
Net loss per ordinary share - basic and diluted	$ (0.55)	$ (0.68)	$ (2.36)	$ (2.89)
Weighted average number of shares outstanding used in computation of basic and diluted loss per ordinary share	43,100,237	32,298,182	37,797,492	26,358,719

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

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

	Ordinary Shares					
	Number of Shares	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total
Balance as of July 1, 2024	41,169,954	$ 112	$ 775,270	$ (745,037)	$ (31)	$ 30,314
Changes During the Three Months Ended September 30, 2024						
Exercise of options into ordinary shares	99,433	—	115			115
Share-based compensation			3,489			3,489
Issuance of ordinary shares, net of issuance costs	921,428	3	15,000			15,003
Other comprehensive income					267	267
Net loss				(23,673)		(23,673)
Balance as of September 30, 2024	42,190,815	$ 115	$ 793,874	$ (768,710)	$ 236	$ 25,515
Balance as of July 1, 2023	23,498,617	$ 64	$ 493,109	$ (631,453)	(154)	$ (138,434)
Changes During the Three Months Ended September 30, 2023						
Exercise of options into ordinary shares	55,781	—	18			18
Share-based compensation			2,224			2,224
Issuance of pre-funded warrants, net of issuance costs			48,700			48,700
Issuance of ordinary shares, net of issuance costs	7,300,380	20	67,338			67,358
Other comprehensive income					20	20
Net loss				(21,879)		(21,879)
Balance as of September 30, 2023	30,854,778	$ 84	$ 611,389	$ (653,332)	$ (134)	$ (41,993)

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

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

	Ordinary Shares					
	Number of Shares	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive income (loss)	Total
Balance as of January 1, 2024	32,490,119	$ 89	$ 614,035	$ (679,348)	$ 12	$ (65,212)
Changes During the Nine Months Ended September 30, 2024						
Exercise of options into ordinary shares	378,800	1	249			250
Share-based compensation			9,805			9,805
Issuance of pre-funded warrants, net of issuance costs			18,641			18,641
Issuance of ordinary shares, net of issuance costs	9,321,896	25	151,144			151,169
Other comprehensive income					224	224
Net loss				(89,362)		(89,362)
Balance as of September 30, 2024	42,190,815	$ 115	$ 793,874	$ (768,710)	$ 236	$ 25,515
Balance as of January 1, 2023	23,129,953	$ 63	$ 487,787	$ (577,104)	$ (107)	$ (89,361)
Changes During the Nine Months Ended September 30, 2023						
Exercise of options into ordinary shares	424,445	1	832			833
Share-based compensation			6,732			6,732
Issuance of pre-funded warrants, net of issuance costs			48,700			48,700
Issuance of ordinary shares, net of issuance costs	7,300,380	20	67,338			67,358
Other comprehensive loss					(27)	(27)
Net loss				(76,228)		(76,228)
Balance as of September 30, 2023	30,854,778	$ 84	$ 611,389	$ (653,332)	$ (134)	$ (41,993)

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)

	Nine Months Ended September 30,	
	2024	**2023**
Cash Flows From Operating Activities		
Net loss	$ (89,362)	$ (76,228)
Adjustment to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	261	612
Accrued financing on prepaid forward obligation	9,013	8,714
(Accretion) on marketable securities	(1,555)	(622)
Share-based compensation	9,805	6,732
Amortization of discount on long-term debt	(1,330)	981
Amortization of right of use assets	619	669
Changes in operating assets and liabilities:		
Inventory	(1,921)	(677)
Accounts receivable, net	(7,359)	(143)
Prepaid expenses and other current assets	(3,772)	(4,937)
Other non-current assets	1,668	690
Accounts payable and accrued expenses	3,147	1,700
Employee related accrued expenses	(1,785)	(105)
Lease liabilities	(626)	(766)
Restricted deposit	50	—
Net cash used in operating activities	(83,147)	(63,380)
Cash Flows From Investing Activities		
Purchases of marketable securities	(118,794)	(35,009)
Maturities of marketable securities	37,740	45,538
Purchases of property and equipment	(180)	(138)
Net cash (used in) provided by investing activities	(81,234)	10,391
Cash Flows From Financing Activities		
Proceeds from exercise of options into ordinary shares	250	833
Proceeds from issuance of long-term debt	24,488	—
Proceeds from pre-funded warrant issuance, net of issuance costs	18,641	48,700
Proceeds from ordinary shares issuance, net of issuance costs	151,169	67,358
Net cash provided by financing activities	194,548	116,891
Increase (Decrease) in Cash and Cash Equivalents	30,167	63,902
Cash, Cash Equivalents and Restricted Cash at Beginning of Period	95,822	56,220
Cash, Cash Equivalents and Restricted Cash at End of Period	$ 125,989	$ 120,122
Supplemental Disclosures of Non-Cash Activities		
Right of use assets obtained in exchange for new operating lease liabilities	$ —	$ 122

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, advancing UGN-102 through regulatory approval, and raising capital to support and expand these activities.

On April 15, 2020, the U.S. Food and Drug Administration ("FDA") granted expedited approval for *Jelmyto*, a first-in-class treatment indicated for adults with low-grade upper tract urothelial cancer. *Jelmyto* consists of mitomycin, an established chemotherapy, and sterile hydrogel, using 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.

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

Note 2 – Basis of Presentation

The 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 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, 2023, as filed with the U.S. Securities and Exchange Commission ("SEC") on March 14, 2024.

The Company has experienced net losses since its inception and has an accumulated deficit of $768.7 million and $679.3 million as of September 30, 2024 and December 31, 2023, respectively. The Company expects to incur losses and have negative net cash flows from operating activities as it executes on its strategy including engaging in further research and development activities, particularly conducting non-clinical studies and clinical trials. The success of the Company depends on the ability to successfully commercialize its technologies to support its operations and strategic plan.

In accordance with the accounting guidance related to the presentation of financial statements, management evaluates whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for the next 12 months from the date the financial statements are issued. The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, and do not include any adjustments relating to the carrying amounts and classification of assets and liabilities that may be necessary should the Company be unable to continue as a going concern. The Company's ability to continue as a going concern is expected to be impacted by its ability to raise additional capital to fund its operations, produce cash inflows from *Jelmyto* product sales and advance UGN-102 through regulatory approval.

Based on the Company's cash, cash equivalents and marketable securities as of September 30, 2024, together with management's cash flow projections, the Company believes that it has sufficient cash and cash equivalents to fund its operations beyond one year from the issuance of these condensed consolidated financial statements. The Company may need to raise additional capital in the future. There can be no assurances that the Company will be able to secure such additional financing on terms that are satisfactory to the Company, in an amount sufficient to meet the Company's needs, or at all. In the event the Company is not successful in obtaining sufficient funding, this could force the Company to delay, limit, or reduce the Company's product development, commercialization efforts or other operations.

Note 3 – Significant Accounting Policies

Principles of Consolidation

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

Cash and cash equivalents and marketable securities totaled $254.2 million as of September 30, 2024. The Company accounts for its investments, which include cash equivalents and marketable securities, as available-for-sale in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, "Investments — Debt and Equity Securities". Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported in other comprehensive income/loss within shareholders' equity. Realized gains and losses are recorded as a component of interest and other income, net. The cost of securities sold is based on the specific-identification method.

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

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

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

Concentration of Credit Risk

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

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

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

Income Taxes

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

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. After concluding that a particular filing position can be recognized (i.e., has a more-likely-than-not chance of being sustained), ASC 740-10-30-7 requires that the amount of benefit recognized be measured using a methodology based on the concept of cumulative probability. Under this methodology, the amount of benefit recorded represents the largest amount of tax benefit that is greater than 50% likely to be realized upon settlement with a taxing authority that has full knowledge of all relevant information. See Note 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 (the "RTW Transaction") with RTW Investments ("RTW") in which the Company received funds to support the launch of *Jelmyto* and the development of UGN-102 in return for tiered, future cash payments based on net sales of *Jelmyto* and, subject to FDA approval, UGN-102, UGN-103 and UGN-104. The net proceeds received under the RTW Transaction were recognized as a long-term liability. The Company recognizes the current cash payable amounts under the arrangement within other current liabilities on the condensed consolidated balance sheets. The subsequent measurement for the liability follows the accounting principles defined in ASC Topic 835-30, "Imputation of Interest". See Note 9 for further discussion related to the prepaid forward obligation.

Long-Term Debt

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

Leases

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

The Company accounts for leases in accordance with ASC Topic 842, "Leases". The Company determines if an arrangement is a lease at inception. Right-of-use ("ROU") assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term as of the commencement date. Operating lease ROU assets are presented as 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 arrangements with third-party national specialty distributors. Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customer, chargebacks relating to differences between the wholesale acquisition cost and the contracted price offered to the end consumer, chargebacks relating to 340b drug pricing programs and other government sponsored programs, Medicaid drug rebate programs, the Company's copay assistance program, and Medicare refunds for discarded drug, which are estimated based on the Company's historical experience.

Research and Development Expenses

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

Selling, General and Administrative Expenses

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

Share-Based Compensation

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

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

Pre-funded Warrants

The Company's outstanding pre-funded warrants are accounted for as a freestanding equity-linked financial instrument that meets the criteria for equity classification under ASC 480, “Distinguishing Liabilities from Equity,” and ASC 815, “Derivatives and Hedging.” Accordingly, the Company classifies the pre-funded warrants as a component of permanent shareholders’ equity within additional paid-in capital and records them at the applicable issuance date using a relative fair value allocation method. The Company valued the pre-funded warrants at the applicable issuance date, concluding that their sales price approximated their fair value, and allocated the net sales proceeds from the applicable equity transaction proportionately to the ordinary shares and pre-funded warrants.

Net Loss per Ordinary Share

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

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

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

Recently Adopted or Issued Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which provides guidance to improve the disclosures about a public entity’s reportable segments and address requests from investors for additional, more detailed information about a reportable segment’s expenses. Public entities must adopt the new guidance for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The amendments in this ASU must be applied on a retrospective basis to all prior periods presented in the financial statements and early adoption is permitted. The Company is currently assessing the disclosures which will be required under the new guidance and does not believe the adoption of ASU 2023-07 will have any material impact on its consolidated financial statements.

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

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

SEC Climate Disclosures

In March 2024, the SEC issued its final climate disclosure rule, which requires certain disclosures relating to emissions and other climate-related topics. For smaller reporting companies, disclosure requirements will begin phasing in for fiscal years beginning on or after January 1,

2027. Subsequently, in April 2024, the SEC issued an order staying implementation of the SEC Climate Disclosure Rules pending the resolution of certain challenges. The Company is currently evaluating the impact these rules will have on its consolidated financial statements and related disclosures.

Note 4 – Other Financial Information

Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Accounts payable	$ 5,556	$ 6,514
Accrued sales reserves	7,695	4,391
Accrued clinical expenses	1,094	1,246
Accrued research and development expenses	693	1,049
Accrued selling, general and administrative expenses	2,763	2,752
Accrued other expenses	1,884	586
Total accounts payable and accrued expenses	$ 19,685	$ 16,538

Interest and Other Income, Net

Interest and other income, net consisted of the following for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Interest income	$ 2,757	$ 835	$ 6,089	$ 1,915
Other income (loss), net	(158)	71	(167)	26
Total interest and other income, net	$ 2,599	$ 906	$ 5,922	$ 1,941

Note 5 – Inventories

Inventories consisted of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Raw materials (1)	$ 4,662	$ 4,464
Finished goods	2,932	2,877
Total inventories	$ 7,594	$ 7,341

(1) $1.7 million of raw materials are included within other non-current assets on the condensed consolidated balance sheets at December 31, 2023. These raw materials are not expected to be manufactured and sold within the next 12 months. Changes in non-current assets are reflected on the condensed consolidated statements of cash flows within the caption of other non-current assets.

Note 6 – Fair Value Measurements

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

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

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

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

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

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

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

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

No transfers between levels have occurred during the periods presented.

Assets measured at fair value on a recurring basis based on Level 1 and Level 2 fair value measurement criteria as of September 30, 2024 are as follows (in thousands):

		Fair Value Measurements Using	
	Balance as of September 30, 2024	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash equivalents			
Money market funds	$ 20,878	$ 20,878	$ —
Commercial paper	3,991	—	3,991
Total cash equivalents	24,869	20,878	3,991
Marketable securities			
U.S. government	75,732	75,732	—
Corporate bonds	15,596	—	15,596
Commercial paper	36,995	—	36,995
Certificates of deposit	978	—	978
Total marketable securities	129,301	75,732	53,569
Total assets at fair value	$ 154,170	$ 96,610	$ 57,560

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

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

The Company's investments in U.S. government bonds and money market funds are measured based on publicly available quoted market prices for identical securities as of September 30, 2024 and December 31, 2023. The Company's investments in corporate bonds, commercial paper and certificates of deposits are measured based on quotes from market makers for similar items in active markets.

Note 7 – Investments

The following table summarizes the Company's investments as of September 30, 2024 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Assets:				
Cash equivalents				
Money market funds	$ 20,878	$ —	$ —	$ 20,878
Commercial paper	3,991	—	—	3,991
Total cash equivalents	24,869	—	—	24,869
Marketable securities:				
U.S. government	75,608	125	(1)	75,732
Corporate bonds	15,539	59	(2)	15,596
Commercial paper	36,940	55	—	36,995
Certificates of deposit	978	—	—	978
Total marketable securities	129,065	239	(3)	129,301
Total assets at fair value	$ 153,934	$ 239	$ (3)	$ 154,170

The Company classifies its investments as available-for-sale, and they consist entirely of debt securities. As of September 30, 2024, the amortized cost of investments included an immaterial amount of accrued interest. As of September 30, 2024, marketable securities were in a net unrealized gain position. Unrealized gains and losses on available-for-sale debt securities are included as a component of comprehensive loss.

As of September 30, 2024, the aggregate fair value of investments held by the Company in an unrealized loss position was $4.6 million which consisted of 4 securities. The unrealized loss was primarily driven by minor fluctuations in the fair value of certain U.S. government and corporate bond positions. 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 September 30, 2024, the Company believes the cost basis for its marketable securities were recoverable in all material aspects and no allowance for credit losses were recognized in the period.

The Company's investments as of September 30, 2024 mature at various dates through August 2026. The fair values of investments by contractual maturity consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Maturities within one year	$ 149,528	$ 51,670
Maturities after one year through three years	4,642	4,502
Total investments	$ 154,170	$ 56,172

Note 8 – Property and Equipment

Property and equipment, consists of the following as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024	December 31, 2023
Laboratory equipment	$ 473	$ 464
Computer equipment and software	2,460	2,293
Furniture	612	612
Leasehold improvements	621	617
Manufacturing equipment	655	655
	4,821	4,641
Less: accumulated depreciation and amortization	(4,213)	(3,952)
Property and equipment, net	$ 608	$ 689

Depreciation and amortization expense was $0.1 million and $0.3 million for the three and nine months ended September 30, 2024 and $0.2 million and $0.6 million for the three and nine months ended September 30, 2023.

Note 9 – Prepaid Forward Obligation

In March 2021, the Company entered into a prepaid forward agreement with RTW. Under the terms of the RTW Transaction, the Company received $75.0 million ($72.4 million net of transaction costs) to support the launch of *Jelmyto* and the development of UGN-102. In return for the transferred funds, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of *Jelmyto* and, if approved, UGN-104, in an amount equal to: (i) 9.5% of annual net sales up to $200 million, (ii) 3.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 1.0% of annual net sales for annual net sales above $300 million. Pursuant to the agreement, the initial cash payment rate of 9.5% on *Jelmyto* aggregate worldwide annual net sales of up to $200 million was increased to 13.0% and remained at that rate during the nine months ended September 30, 2024 because certain revenue thresholds were not met. This rate may decrease in the future back to 9.5% if the Company subsequently meets certain *Jelmyto* aggregate worldwide annual net sales thresholds.

In addition, subject to FDA approval of UGN-102 and UGN-103, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of UGN-102 and UGN-103 in an amount equal to: (i) 2.5% of annual net sales up to $200 million, (ii) 1.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 0.5% of annual net sales for annual net sales above $300 million. If the Company does not receive FDA approval for UGN-102 by June 30, 2025, the future cash payments to RTW with respect to aggregate worldwide annual net sales of *Jelmyto* across all *Jelmyto* annual net sales tiers will increase by 1.5%.

In accordance with the prepaid forward agreement, the Company will be required to make payments of amounts owed to RTW each calendar quarter, through and until the quarter in which the aggregate cash payments received by RTW are equal to or greater than $300 million. As of September 30, 2024, the cumulative amounts paid and payable by the Company were $31.6 million. As security for the payment and fulfilment of these amounts throughout the arrangement, the Company has granted RTW a first priority security interest in *Jelmyto,* UGN-102, UGN-103 and UGN-104, including the regulatory approvals, intellectual property, material agreements, proceeds and accounts receivable related to these products.

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

The following table shows the activity with respect to the carrying value of the prepaid forward liability for the year ended December 31, 2023 and for the nine months ended September 30, 2024, in thousands:

Carrying value of prepaid forward obligation as of December 31, 2022	$ 98,923
Financing on prepaid forward obligation	21,552
Amounts paid and payable (1)	(10,753)
Carrying value of prepaid forward obligation as of December 31, 2023	109,722
Financing on prepaid forward obligation	17,348
Amounts paid and payable (1)	(8,544)
Carrying value of prepaid forward obligation as of September 30, 2024	$ 118,526

(1) $3.3 million and $3.0 million of the Amounts paid and payable are included as current portion of the prepaid forward obligation within other current liabilities on the condensed consolidated balance sheets as of September 30, 2024 and December 31, 2023, respectively.

Note 10 – Long-Term Debt

On March 7, 2022, the Company entered into a loan agreement with Pharmakon for a senior secured term loan of up to $100 million in two tranches. The first tranche of $75 million was funded in March 2022. The second tranche of $25 million was funded in December 2022.

On June 29, 2023, the loan agreement with Pharmakon was amended to replace the benchmark governing the interest rate with a rate based on the secured overnight financing rate ("SOFR") published by the Federal Reserve Bank of New York. Effective July 2023, the loan accrued interest using a benchmark rate of 3-month SOFR plus 8.25% plus an additional adjustment of 0.26161%.

On March 13, 2024, the Company entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million was funded in September 2024. The fourth tranche of $75.0 million will become available at the Company's option no later than August 29, 2025, subject to (i) receiving FDA approval of a new drug application ("NDA") for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables. Under the amended and restated loan agreement, all outstanding loans with Pharmakon accrue interest using a benchmark rate of 3-month SOFR plus 7.25% plus an additional adjustment of 0.26161%. All outstanding principal will be required to be repaid in four equal quarterly installments commencing in the second quarter of 2026, with a one-year extension possible upon FDA approval of an NDA for UGN-102 by June 30, 2025. All outstanding loans with Pharmakon can be prepaid in whole at the Company's discretion, at any time, subject to prepayment premiums and make-whole amounts. The Company is not required to maintain any financial covenants.

The Company incurred financing expenses of $4.2 million related to the first and second tranches funded in 2022, and $0.5 million related to the third tranche funded in 2024, which are recognized as a direct offset to the long-term debt on the Company's condensed consolidated balance sheets. These debt issuance costs are amortized over the term of the debt using the effective interest method, and are recorded in the 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:

Carrying value of Pharmakon loan as of December 31, 2022	$ 97,537
Interest expense	14,715
Amounts paid	(13,701)
Carrying value of Pharmakon loan as of December 31, 2023	98,551
Third tranche of Pharmakon loan	25,000
Capitalized costs and discounts	(512)
Interest expense	8,629
Amounts paid	(9,959)
Carrying value of Pharmakon loan as of September 30, 2024	$ 121,709

Note 11 – Leases

Operating Leases

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

- In April 2016, UPL signed an addendum to its November 2014 lease agreement for the Company's offices located in Israel, in order to increase the office space rented and to extend the rent period for an additional three years until August 2022. In July 2022, the Company signed a lease extension agreement for the Company's offices located in Israel, extending the term of the lease through September 2025. The Company's remaining contractual obligation under this lease is approximately $0.3 million as of September 30, 2024.

- In April 2018, UPI entered into a new lease agreement for an office in Los Angeles, California. The lease commencement date was July 10, 2018 and terminated in March 2024. The landlord provided a tenant allowance for leasehold improvements of $0.2 million that was accounted for as a lease incentive. In November 2019, UPI entered into a sublease for this office space, with a lease commencement date of January 1, 2020 which continued until the end of the lease term in March 2024. The subtenants exercised their early access clause and moved into the premises at the end of November 2019. The Company accounted for the sublease as an operating lease in accordance with ASC 842.

- In November 2019, UPI entered into a new lease agreement for an office in Princeton, New Jersey, which the Company now uses as its headquarters. The lease commencement date was November 29, 2019 with an original lease term of 38 months, expiring January 31, 2023. In June 2022, the Company signed a lease extension for the Princeton office, extending the term of the lease through January 31, 2026. The Company's remaining contractual obligation under this lease is approximately $0.8 million as of September 30, 2024.

In addition, the Company has other operating office equipment and vehicle leases. The Company's operating leases may require minimum rent payments, contingent rent payments adjusted periodically for inflation, or rent payments equal to the greater of a minimum rent or contingent rent. The Company's leases do not contain any residual value guarantees or material restrictive covenants. The Company's active leases expire at various dates from 2025 through 2026, with varying renewal and termination options.

The components of lease cost for the three and nine months ended September 30, 2024 and 2023 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating lease cost	$ 225	$ 225	$ 675	$ 710
Sublease income	—	(56)	(42)	(168)
Variable lease cost	14	13	57	51
	$ 239	$ 182	$ 690	$ 593

The amounts recognized as of September 30, 2024 and December 31, 2023 were as follows (in thousands):

	September 30, 2024	December 31, 2023
Right-of-use assets	$ 1,052	$ 1,671
Long-term lease liabilities	212	844
Other current liabilities	825	819

As of September 30, 2024, no impairment losses have been recognized.

Supplemental information related to leases for the nine months ended September 30, 2024 and 2023 is as follows (in thousands, except for lease terms and discount rate amounts):

	Nine Months Ended September 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 714	$ 878
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 122
Weighted-average remaining lease term of operating leases (in years)	1.26	2.11
Weighted-average discount rate of operating leases	10.26%	10.16%

As of September 30, 2024, maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
Remainder of 2024	$ 219
2025	820
2026	58
Total future minimum lease payments	1,097
Less: Interest	(60)
Present value of lease liabilities	$ 1,037

As of September 30, 2023, maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
Remainder of 2023	$ 291
2024	923
2025	813
2026	57
Total future minimum lease payments	2,084
Less: Interest	(200)
Present value of lease liabilities	$ 1,884

Note 12 – Revenue From Product Sales

Net product sales consist of the following for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Jelmyto	$ 25,204	$ 20,852	$ 65,833	$ 59,183

Net revenue recognized includes gross revenue and management's estimate of returns, consideration paid to the customer, chargebacks relating to differences between the wholesale acquisition cost and the contracted price offered to the end consumer, chargebacks relating to 340b drug pricing programs and other government sponsored programs, Medicaid drug rebate programs, the Company's copay assistance program, and Medicare refunds for discarded drug, which are estimated based on the Company's historical experience. Reserves related to items that are contractually able to be net settled are recognized as contra accounts receivable while other remaining reserves are recognized within other current liabilities on the condensed consolidated balance sheets. The following table shows the activity with respect to sales reserves for period ended of September 30, 2024 (in thousands):

	Reserves related to government sponsored programs	Medicare refunds for discarded drug reserve	Other reserves	Total accrued sales reserves
Balance as of December 31, 2023	$ 1,062	$ 3,451	$ 1,458	$ 5,971
Accruals	9,833	3,113	7,703	20,649
Utilizations	(10,206)	—	(7,219)	(17,425)
Balance as of September 30, 2024	$ 689	$ 6,564	$ 1,942	$ 9,195

Note 13 – License and Collaboration Agreements

Agenus Agreement

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

Note 14 – Shareholders' Equity

The Company had 100.0 million ordinary shares authorized for issuance as of September 30, 2024 and December 31, 2023. The Company had 42.2 million and 32.5 million ordinary shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively. Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors (the "Board"). Since the Company's inception, the Board has not declared any dividends.

ATM Sales Agreement

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

During the first quarter of 2024, the Company sold 3,400,468 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $56.1 million. The net proceeds to the Company after deducting sales commissions to TD Cowen were approximately $54.7 million. The remaining capacity under the ATM Sales Agreement was approximately $27.3 million as of September 30, 2024. The shares will be offered and sold pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC on November 15, 2022, which was declared effective on November 29, 2022.

Securities Purchase Agreement

On July 26, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain institutional and other accredited investors (the "Purchasers"), pursuant to which the Company agreed to sell and issue to the Purchasers 7,300,380 ordinary shares of the Company ("Shares") and 5,278,776 of pre-funded warrants to purchase ordinary shares of the Company at a purchase price of $9.54 per Share or $9.539 for each ordinary share underlying a pre-funded warrant, in a private placement transaction that closed on July 28, 2023 and August 9, 2023 (the "Private Placement") for aggregate gross proceeds of $120.0 million, before deducting fees to placement agents and financial advisors and before other expenses paid by the Company. Each pre-funded warrant has an exercise price of $0.001 per ordinary share, subject to customary adjustments, became exercisable upon original issuance and will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation. The aggregate fee paid by the Company to placement agents and financial advisors was $3.6 million, plus the reimbursement of certain expenses.

Resales of the Shares and the ordinary shares issuable upon exercise of the pre-funded warrants were registered pursuant to the Company's registration statement on Form S-3 (File No. 333-274423) filed with the SEC on September 8, 2023, which was declared effective

on September 15, 2023. On December 20, 2023, the Company issued 1,599,733 ordinary shares through a cashless conversion of 1,599,840 pre-funded warrants for the purchase of ordinary shares of the Company.

Monograph Capital Partners I, L.P. ("Monograph"), a life sciences venture firm that is affiliated with Fred Cohen, M.D., a director of the Company at the time, purchased 1,572,327 of the Shares in the Private Placement, for an aggregate purchase price of $15.0 million. Dr. Cohen is the Chair and Chief Investment Officer of Monograph.

Underwritten Public Offering

On June 17, 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with TD Securities (USA) LLC and Guggenheim Securities, LLC, as representatives of the several underwriters named therein (collectively, the "Underwriters"), relating to the issuance and sale in a public offering of 5,000,000 ordinary shares of the Company for $17.50 per share and pre-funded warrants to purchase 1,142,857 ordinary shares of the Company for $17.499 per pre-funded warrant. The offering closed on June 20, 2024. The gross proceeds to the Company from this closing of the offering were $107.5 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company of $7.3 million. Each pre-funded warrant has an exercise price of $0.001 per ordinary share, subject to customary adjustments, is exercisable at any time and will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation. In addition, the Underwriters were granted an option exercisable for 30 days, to purchase up to 921,428 additional shares at the public offering price, less the underwriting discounts and commissions. On July 18, 2024, the Company completed the closing of the sale of 921,428 additional shares in the offering following the exercise in full of the Underwriters' option to purchase additional shares, which resulted in additional gross proceeds to the Company of $16.1 million before deducting underwriting discounts and commissions and offering expenses paid by the Company of $1.0 million.

Note 15 – Share-Based Compensation

In October 2010, the Board approved a share option plan (the "2010 Plan") for grants to Company employees, consultants, directors, and other service providers. Subsequently, in March 2017, the Board adopted the 2017 Equity Incentive Plan (the "2017 Plan" and, together with the 2010 Plan, the "Plans"), which was approved by the shareholders in April 2017. The 2017 Plan provides for the grant of stock options, stock appreciation rights, restricted stock awards, RSU awards, performance share awards, performance cash awards, and other forms of share awards to the Company's employees, directors and consultants.

The grant of options to Israeli employees under the Plans is subject to the terms stipulated by Section 102 of the Israeli Income Tax Ordinance ("Section 102"). The option grants are subject to the track chosen by the Company, either the "regular income" track or the "capital gains" track, as set out in Section 102. The Company registered the Plans under the capital gains track, which offers more favorable tax rates to the employees. As a result, and pursuant to the terms of Section 102, the Company is not allowed to claim as an expense for tax purposes the amounts credited to the employees in respect of options granted to them under the Plans, including amounts recorded as salary benefits in the Company's accounts, with the exception of the work-income benefit component, if any, determined on grant date. For non-employees and for non-Israeli employees, the Plans is subject to Section 3(i) of the Israeli Income Tax Ordinance.

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

The Company's RSU and option grants provide for accelerated or continued vesting in certain circumstances as defined in the plans and related grant agreements, including a termination in connection with a change in control. RSUs generally vest in a 33% increment upon the first anniversary of grant, and in either equal quarterly or annual amounts for the two years following the one-year anniversary of the grant date. Options generally vest in a 33% increment upon the first anniversary of the grant date, and in either equal quarterly or annual amounts for the two years following the one-year anniversary of the grant date. The Company also grants PSUs to certain employees. The PSU's currently outstanding vest based on either the earlier of obtaining regulatory approval for the Company's lead product candidate UGN-102 or the occurrence of a change in control, or for certain other awards, the achievement of the first commercial sale of UGN-102 in the United States following UGN-102's receipt of regulatory approval. In June 2024, the Company amended certain RSU and PSU awards granted to the chief executive officer to defer vesting until the end of 2025. The Company accounted for the modification as a Type I probable-to-probable modification under ASC 718. As the modification did not result in any incremental fair value at the modification date, the Company continues to recognize the original grant-date fair value ratably over the original service period or expected performance period.

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

The maximum number of ordinary shares that was initially authorized for issuance under the 2017 Plan was 1,400,000. On January 1, 2018, the share reserve increased by 250,167 shares to 1,650,167 shares. On October 12, 2018, the Company increased the number of ordinary shares authorized for issuance under the 2017 Plan by 1,900,000 shares to 3,550,167 shares. On June 8, 2020, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 400,000 shares to a total share reserve of 3,950,167 shares. On June 7, 2021, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 400,000 shares to a total share reserve of 4,350,167 shares. On June 8, 2022, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 400,000 shares to a total share reserve of 4,750,167 shares. On September 7, 2023, the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 450,000 shares to a total share reserve of 5,200,167 shares. On August 6, 2024 the Company's shareholders approved an increase to the number of ordinary shares authorized for issuance under the 2017 Plan by 800,000 shares to a total of 6,000,167 shares.

In May 2019, the Company adopted the UroGen Pharma Ltd. 2019 Inducement Plan (the "Inducement Plan"). Under the Inducement Plan, the Company is authorized to issue up to 900,000 ordinary shares pursuant to inducement awards. The only persons eligible to receive grants under the Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1, including individuals who were not previously an employee or director of the Company or are following a bona fide period of non-employment, in each case as an inducement material to such individual's agreement to enter into employment with the Company. In December 2021, the Board approved an increase to the number of shares authorized for issuance under the Inducement Plan of 300,000 shares. In June 2024, the Board approved an increase to the number of shares authorized for issuance under the Inducement Plan of 600,000 shares to a total of 1,800,000 shares.

As of September 30, 2024, 3,961,302 ordinary shares are subject to outstanding awards under the Company's share-based compensation plans and 1,853,992 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expenses	$ 579	$ 415	$ 1,691	$ 1,436
Selling, general and administrative expenses	2,910	1,809	8,114	5,296
Total share-based compensation expense	$ 3,489	$ 2,224	$ 9,805	$ 6,732

The total unrecognized compensation cost of options and RSUs at September 30, 2024 is $15.1 million with a weighted average recognition period of 1.82 years.

Note 16 – Income Taxes

UroGen Pharma Ltd. is taxed under Israeli tax laws. As of September 30, 2024, 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 2023, 2022 and 2021, and for the nine months ended September 30, 2024. 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 $3.2 million as of September 30, 2024, 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 September 30, 2024, the Company's liability for uncertain tax positions includes $1.2 million of accrued interest and penalties.

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

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

Note 17 – Related Parties

There were no related party transactions for the nine months ended September 30, 2024. See Note 14 for discussion regarding an affiliated investor in the private placement transaction for the nine months ended September 30, 2023.

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 September 30, 2024 and December 31, 2023. The Company does not anticipate recognizing any significant losses relating to these arrangements.

The Company received from Teva Pharmaceuticals, Inc. ("Teva"), a Paragraph IV Certification Notice Letter dated February 20, 2024, providing notification that Teva submitted an abbreviated new drug application ("ANDA") to the FDA seeking approval to manufacture, use or sell a generic version of *Jelmyto*. In the Notice Letter, Teva alleges that two of the patents listed in the FDA Orange Book for *Jelmyto*, U.S. Patent Numbers 9,040,074 and 9,950,069, each of which expires in January 2031, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission. On April 2, 2024, the Company filed a lawsuit in the U.S. District Court for the District of Delaware against Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd., alleging infringement of U.S. Patent Numbers 9,040,074 and 9,950,069 and seeking a permanent injunction preventing U.S. market entry of Teva's generic product prior to the expiry of such patents. The Company stipulated to the dismissal of Teva Pharmaceutical Industries, Ltd. without prejudice and the action continues against the other two Teva entities. If the Company is unsuccessful in securing the requested court relief, *Jelmyto* may be subject to immediate competition from an FDA approved generic product after regulatory exclusivity for *Jelmyto* expires in April 2027.

Separation Agreement

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

Leases

See Note 11 for further discussion regarding lease commitments.

Note 19 – **Subsequent Events**

On October 7, 2024, the Company entered into a separation and consulting agreement with Don Kim, pursuant to which Mr. Kim resigned from his positions as the Company's Chief Financial Officer, principal financial officer and principal accounting officer, effective October 8, 2024. The arrangement includes cash severance and target annual bonus for calendar year 2024 of approximately $0.5 million, which will be recognized in the fourth quarter of 2024, as well as a post-separation consulting arrangement. Mr. Kim's outstanding share-based awards will remain eligible for continued vesting during the post-separation consulting period.

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, 2023 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, 2023 ("Annual Report"), which was filed with the SEC on March 14, 2024. 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, trends, seasonality, 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. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. 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 agents.

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

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

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

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

- increasing the exposure of active drugs in the bladder and upper urinary tract by significantly extending the dwell time of the active drug while conforming to the anatomy of the bladder and the upper urinary tract, which allows for enhanced drug tissue coverage. For example, the average dwell time of the standard aqueous mitomycin formulation, currently used as adjuvant treatment, in the upper urinary tract is approximately five minutes, compared to approximately six hours when mitomycin is formulated with *RTGel*;

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

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

These characteristics of *RTGel* enable sustained release of mitomycin in the urinary tract for 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 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 upper urinary tract tissue to mitomycin, thereby enabling the treatment of tumors by non-surgical means. New product exclusivity for *Jelmyto* expired on April 15, 2023, however, Orphan Drug exclusivity extends until April 15, 2027. Additionally, the main patents that protect *Jelmyto* in the United States are set to expire in January 2031. These patents are 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, which consists of the kidneys and ureters. 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 upper urinary tract system. Prior to *Jelmyto*, the standard of care included endoscopic resection(s) and radical nephroureterectomy, the latter involving 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 was based on results from our Phase 3 OLYMPUS trial showing *Jelmyto* achieved clinically significant disease eradication in adults with low-grade UTUC. Findings from the final study results include:

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

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

In 2024, we released data from a post-hoc analysis of the OLYMPUS trial assessing the long-term effects in treating low grade-UTUC with *Jelmyto*. Of the 71 patients who enrolled in OLYMPUS, 41 achieved a CR and their health outcomes were tracked for up to 12 months. Twenty of the patients remaining in CR enrolled in a 5-year rollover study. All 41 patients with an initial CR indicated a promising median DOR of 47.8 months, based on a median follow-up of 28.1 months. In the 5-year rollover trial, 75% (N=15) showed no disease recurrence at the time of the 4-year data cutoff, indicating potential for extended disease-free periods.

In June 2020, we initiated our commercial launch of *Jelmyto* in the United States. We have staffed, trained and prepared a customer-facing team that includes territory business managers with deep experience in both urology and oncology. These territory business manager positions are led by seven regional business director positions, who are in turn supported by seven regional operations manager positions. Each region is additionally supported by one to two clinical nurse educators to provide education and training around instillation, as well as a field reimbursement manager to help ensure access and reimbursement for appropriate patients and key account directors who engage with C-suite individuals to introduce a *Jelmyto* service line. In addition, our organization currently includes several medical science liaisons who appropriately engage with physicians interested in learning more about UroGen, *Jelmyto* and our technology, both in person and virtually. In total, our customer-facing team comprises approximately 90 colleagues.

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

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

In each of the first three fiscal years beginning after the initiation of our commercial launch of *Jelmyto* in June 2020, we experienced a moderate decline in revenue during the third quarter from the preceding quarter. We believe this result was primarily attributable to the nature of low-grade disease, which does not require immediate treatment and therefore we believe there could be an impact in the summer months.

However, we did not observe this trend in 2024 and therefore cannot say with confidence whether this seasonality trend will continue in future periods. Moreover, our future *Jelmyto* revenue will be impacted by various factors and we expect our *Jelmyto* revenue to fluctuate quarter-to-quarter for the foreseeable future.

UGN-102 (mitomycin) for intravesical solution

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

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

In October 2021, we reported final data from the Phase 2b OPTIMA II trial. The single-arm, open label trial completed enrollment of 63 patients at clinical sites across the United States and Israel in September 2019. Patients were treated with six weekly instillations of UGN-102 and underwent assessment of CR rate (the primary endpoint) four to six weeks following the last instillation; 65.1%, or 41 out of 63 patients, treated with UGN-102 achieved a CR three months after the start of therapy. In this subset of patients, 39 (95%), 30 (73%), and 25 (61%) remained disease-free at six, nine, and 12 months after treatment initiation, respectively. The probability of durable response nine months after CR (12 months after treatment initiation) was estimated to be 69.9% by Kaplan-Meier analysis. Median DOR was not reached. Thirteen patients had documented recurrences. Fifty-seven of 63 (90%) patients completed all six instillations of UGN-102 according to the study protocol. The most common adverse events, occurring in greater than 10% of participants, 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 were published online in The Journal of Urology in October 2021 and was included in the January 2022 print edition.

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

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

In February 2022, we announced the initiation of the Phase 3 ENVISION trial, targeting enrollment of 220 patients across 90 sites. In December 2022, we completed our target enrollment of the Phase 3 ENVISION trial. As a result of the FDA's acceptance of a single arm approach, we stopped enrollment of the Phase 3 ATLAS trial without knowledge of the data. However, at the time enrollment was stopped, patients who had signed an informed consent were able to complete screening, and if eligible were randomized into the trial. ATLAS continued until the last ongoing patient completed the month 15 visit. On July 27, 2023, we announced topline data from our Phase 3 trials, ATLAS and ENVISION. In the ATLAS trial, UGN-102 with or without TURBT met its primary endpoint of disease-free survival, reducing risk of recurrence, progression, or death by 55% compared to TURBT alone. Results of the ATLAS trial also showed a 64.8% CR rate at three months for patients who only received UGN-102, compared to a 63.6% CR rate at three months for patients who only received a TURBT. The ENVISION trial met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.6% rate of CR at three-months following the initial instillation. In both trials, the safety profile of UGN-102 was acceptable, and comparable to that observed in previous clinical trials of UGN-102.

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

In October 2023 we announced our agreement with the FDA on plans for submission of an NDA for UGN-102 (mitomycin) for intravesical solution. The FDA indicated that the current clinical development plan for UGN-102, which includes evaluation of duration of response 12 months after 3-month CR from the pivotal ENVISION trial, will support submission of an NDA for the treatment of low-grade intermediate risk NMIBC. The FDA indicated that it may seek the advice of the Oncologic Drugs Advisory Committee as part of the NDA review process. The FDA also agreed that the UGN-102 NDA can utilize a rolling review, allowing for early submission of the Chemistry, Manufacturing and Controls ("CMC") sections of the NDA, which we submitted in January 2024.

On June 13, 2024, we announced positive secondary endpoint DOR data from the Phase 3 ENVISION trial investigating UGN-102 for intravesical solution in patients with low-grade intermediate risk NMIBC. In the ENVISION trial, the 12-month DOR data by Kaplan-Meier estimate for patients who achieved a CR at three months after the first instillation of UGN-102 was 82.3% (95% CI, 75.9%, 87.1%). The ENVISION trial met its primary endpoint with patients having a 79.6% (73.9%, 84.5%) CR rate at three months after the first instillation of UGN-102. Among the patients in the ENVISION trial who achieved a CR at three months, 76.4% (69.8%, 82.3%) maintained a CR at 12 months. Among all 240 patients enrolled in the ENVISION trial, 60.8% (54.3%, 67.0%) were in CR at 12 months. In the ENVISION trial, DOR Kaplan-Meier estimates at 15 (n=43) and 18 (n=9) months were both 80.9% (95% CI, 73.9%, 86.2%). The ENVISION trial demonstrated a

similar safety profile to that observed in the OPTIMA II and ATLAS trials, with treatment-emergent adverse events typically mild-to-moderate in severity.

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

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

In January 2024 we entered into a licensing and supply agreement with medac Gesellschaft für klinische Spezialpräparate m.b.H. (“medac”) to develop UGN-103 and UGN-104 which are intended to be a next-generation formulation of UGN-102 and *Jelmyto*, respectively, that combine medac’s proprietary 80 mg mitomycin formulation with our *RTGel* technology, which we believe will provide advantages related to production, cost, supply and product convenience. In April 2024, we announced that the FDA accepted our Investigational New Drug Application ("IND") for UGN-103 and we initiated our Phase 3 UTOPIA trial, a single-arm, multicenter study that will evaluate the efficacy and safety of UGN-103 in low-grade intermediate risk NMIBC. We plan to enroll 87 patients in the UTOPIA trial, with patients receiving 75 mg of UGN-103 via intravesical instillation once a week for six weeks. Efficacy will be assessed by the complete response rate at the three-month visit. Patients who have a complete response at the three-month visit, defined as having no detectable disease in the bladder, will enter the follow-up period of the study. Patients will remain on study until disease recurrence, disease progression, death, or the last patient completes 12 months of follow-up (i.e., 15 months after the first instillation), whichever occurs first. In October 2024, we announced the first patient dosed in the UTOPIA trial. An NDA submission is projected for the first half of 2026, followed by a standard review period and potential approval and, if approved, the commercial launch in the first half of 2027. We also plan to initiate a Phase 3 trial of UGN-104 in low-grade UTUC in early 2025.

UGN-301 (zalifrelimab) intravesical solution

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

High-grade NMIBC is a highly aggressive form of bladder cancer. TURBT followed by adjuvant intravesical immunotherapy with 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.

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

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

Research and Development and License Agreements

Agenus Agreement

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

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.

Components of Operating Results

Revenue

During the three and nine months ended September 30, 2024, we recognized $25.2 million and $65.8 million of revenue, respectively, from sales of our product, *Jelmyto*.

Cost of Revenue

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

Research and Development Expenses

Research and development expenses, net consists primarily of:

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

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

	Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**
Personnel, facility and equipment, and other overhead costs	$ 12,320	$ 12,178
Clinical and other development costs	29,930	22,134
Total	$ 42,251	$ 34,312

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

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

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

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

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

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

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

Other than *Jelmyto*, which was approved by the FDA in April 2020, we have not received approval of any of our product candidates. UGN-102, UGN-103, UGN-104 and UGN-301 are still in clinical development. As such, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements.

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

Selling and Marketing Expenses

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

General and Administrative Expenses

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

Financing on Prepaid Forward Obligation

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

Interest and Other Income, Net

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

Income Taxes

We have yet to generate taxable income in Israel. We have historically incurred operating losses resulting in carry forward tax losses totaling approximately $452.0 million as of December 31, 2023. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. We have provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses. Income tax expense also consists of our estimate of uncertain tax positions, and related interest and penalties. See Note 16 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report 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 U.S. generally accepted accounting principles ("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 September 30, 2024 and 2023

The following table sets forth our results of operations for the three months ended September 30, 2024 and 2023.

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Revenue	$ 25,204	$ 20,852	$ 4,352
Cost of revenue	2,453	2,367	86
Gross profit	22,751	18,485	4,266
Operating expenses:			
Research and development	11,355	10,230	1,125
Selling and marketing	17,780	12,597	5,183
General and administrative	11,161	9,158	2,003
Total operating expenses	40,296	31,985	8,311
Operating loss	(17,545)	(13,500)	(4,045)
Financing on prepaid forward obligation	(5,915)	(5,479)	(436)
Interest expense on long-term debt	(2,721)	(3,815)	1,094
Interest and other income, net	2,599	906	1,693
Loss before income taxes	(23,582)	(21,888)	(1,694)
Income tax expense	(91)	9	(100)
Net loss	$ (23,673)	$ (21,879)	$ (1,794)

Revenue

Revenue was $25.2 million and $20.9 million for the three months ended September 30, 2024 and 2023, respectively. The increase in revenue of $4.3 million primarily reflects the increased volume of sales of *Jelmyto,* including CREATES Act sales of $2.6 million in the third quarter of 2024, compared to $1.1 million of CREATES Act sales in the third quarter of 2023. The increase in volume of sales of *Jelmyto* was partially offset by higher revenue reserves primarily driven by estimated Medicare refunds for discarded drugs.

Cost of Revenue

Cost of revenue was $2.5 million and $2.4 million for the three months ended September 30, 2024 and 2023, respectively. The increase of $0.1 million is primarily attributable to the increased volume of sales of *Jelmyto,* partially offset by certain nonrecurring payments made in connection with our supply arrangement in the prior year.

Research and Development Expenses

Research and development expenses were $11.4 million and $10.2 million for the three months ended September 30, 2024 and 2023, respectively. The increase of $1.2 million is primarily attributable to higher costs related to the initiation of the Phase 3 UTOPIA trial for UGN-103, partially offset by lower UGN-102 clinical trial costs and costs related to the research into ingredient scale-up and production efficiency for *Jelmyto*.

Selling and Marketing Expenses

Selling and marketing expenses were $17.8 million and $12.6 million for the three months ended September 30, 2024 and 2023, respectively. The increase in selling and marketing expenses of $5.2 million is primarily attributable to UGN-102 brand marketing costs as well as an increase in overall commercial operation costs related to the planned expansion of the sales force and incentive compensation, meetings, conferences, and trainings.

General and Administrative Expenses

General and administrative expenses were $11.2 million and $9.2 million for the three months ended September 30, 2024 and 2023, respectively. The increase in general and administrative expenses of $2.0 million is primarily attributable to higher compensation expenses, expenses related pre-commercialization readiness support related to UGN-102, general third-party advisory services, and ongoing managed services.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation was $5.9 million and $5.5 million for the three months ended September 30, 2024 and 2023, respectively. The measurement of financing on prepaid forward obligation is an accounting estimate under the "imputed interest method" of accounting (see Note 3 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report) which is affected by estimated future payments to RTW Investments (“RTW"), which are based on a percentage of revenues. The increase in financing on prepaid forward obligation of $0.4 million was driven primarily by changes in underlying assumptions for remeasuring the effective rate.

Interest Expense on Long-term Debt

Interest expense was $2.7 million and $3.8 million for the three months ended September 30, 2024 and 2023, respectively. The decrease of $1.1 million was primarily attributable to the decrease in the margin interest rate and the related impact to amortization of the discount on the Pharmakon loan as a result of the amended and restated loan agreement in March 2024.

Interest and Other Income, Net

Interest and other income, net was $2.6 million and $0.9 million for the three months ended September 30, 2024 and 2023, respectively. The increase of $1.7 million in interest and other income, net was primarily due to higher cash and investment balances.

Comparison of the nine months ended September 30, 2024 and 2023

The following table sets forth our results of operations for the nine months ended September 30, 2024 and 2023.

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Revenue	$ 65,833	$ 59,183	$ 6,650
Cost of revenue	6,410	7,075	(665)
Gross profit	59,423	52,108	7,315
Operating expenses:			
Research and development	42,251	34,312	7,939
Selling and marketing	53,751	40,670	13,081
General and administrative	32,545	28,053	4,492
Total operating expenses	128,547	103,035	25,512
Operating loss	(69,124)	(50,927)	(18,197)
Financing on prepaid forward obligation	(17,348)	(16,047)	(1,301)
Interest expense on long-term debt	(8,629)	(11,129)	2,500
Interest and other income, net	5,922	1,941	3,981
Loss before income taxes	(89,179)	(76,162)	(13,017)
Income tax expense	(183)	(66)	(117)
Net loss	$ (89,362)	$ (76,228)	$ (13,134)

Revenue

Revenue was $65.8 million and $59.2 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in revenue of $6.6 million primarily reflects the increased volume of sales of *Jelmyto,* including CREATES Act sales of $2.8 million for the nine months ended September 30, 2024, compared to $2.0 million of CREATES Act sales in same period in 2023.

Cost of Revenue

Cost of revenue was $6.4 million and $7.1 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of $0.7 million is primarily attributable to certain nonrecurring payments made in connection with our supply arrangement in the prior year, lower shipping and warehousing costs, and a decrease in the *Jelmyto* unit cost.

Research and Development Expenses

Research and development expenses were $42.3 million and $34.3 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of $8.0 million is primarily attributable to higher manufacturing costs, which are recognized as research and development expense prior to our product candidates receiving FDA approval, and regulatory related expense in connection with UGN-102 as well as research and development expenses, in connection with the Phase 3 UTOPIA trial for UGN-103, partially offset by lower UGN-102 clinical trial costs and costs related to the research into ingredient scale-up and production efficiency for *Jelmyto*.

Selling and Marketing Expenses

Selling and marketing expenses were $53.8 million and $40.7 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in selling and marketing expenses of $13.1 million is primarily attributable to UGN-102 brand marketing costs as well as an increase in overall commercial operation costs including compensation, advisory, meetings, conferences, trainings and software costs.

General and Administrative Expenses

General and administrative expenses were $32.5 million and $28.1 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in general and administrative expenses of $4.4 million is primarily attributable to higher compensation expenses, communication expenses related to UGN-102, third-party advisory services, and ongoing managed services.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation was $17.3 million and $16.0 million for the nine months ended September 30, 2024 and 2023, respectively. The measurement of financing on prepaid forward obligation is an accounting estimate under the "imputed interest method" of accounting (see Note 3 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report) which is affected by estimated future payments to RTW, which are based on a percentage of revenues. The increase in financing on prepaid forward obligation of $1.3 million was driven primarily by changes in underlying assumptions for remeasuring the effective rate.

Interest Expense on Long-term Debt

Interest expense was $8.6 million and $11.1 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of $2.5 million was primarily attributed to the decrease in the margin interest rate and the related impact to amortization of the discount on the Pharmakon loan as a result of the amended and restated loan agreement in March 2024.

Interest and Other Income, Net

Interest and other income, net was $5.9 million and $1.9 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of $4.0 million in interest and other income, net was primarily due to higher cash and investment balances.

Liquidity and Capital Resources

As of September 30, 2024, we had $254.2 million in cash and cash equivalents and marketable securities. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation, and is held primarily in U.S. dollars.

Through September 30, 2024, we funded our operations primarily through public equity offerings, private placements of equity securities and our funding arrangements with RTW and Pharmakon.

ATM Sales Agreement

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

In the first quarter of 2024, we sold 3,400,468 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $56.1 million. The net proceeds to us after deducting sales commissions to TD Cowen were approximately $54.7 million. We did not sell any ordinary shares under the ATM Sales Agreement in the three months ended September 30, 2024. The remaining capacity under the ATM Sales Agreement was approximately $27.3 million as of September 30, 2024. The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 filed with the SEC on November 15, 2022, which was declared effective on November 29, 2022.

Prepaid Forward Agreement

In March 2021, we entered into a prepaid forward agreement with RTW, pursuant to which RTW agreed to provide us with an upfront cash payment of $75.0 million to support the launch of *Jelmyto* and the development of UGN-102, and we agreed to provide RTW with tiered future payments based on global annual net product sales of *Jelmyto* and, subject to FDA approval, UGN-102, UGN-103 and UGN-104. In May 2021, following the receipt of necessary regulatory approvals, we received the $75.0 million prepaid forward payment ($72.4 million net of transaction costs) from RTW.

Pharmakon Loan Agreement

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

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million was funded in September 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables.

Securities Purchase Agreement

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

Underwritten Public Offering

On June 17, 2024, we entered into the Underwriting Agreement with the Underwriters, relating to the issuance and sale in a public offering of 5,000,000 ordinary shares of the Company for $17.50 per share and pre-funded warrants to purchase 1,142,857 ordinary shares of the Company for $17.499 per pre-funded warrant. The offering closed on June 20, 2024. The gross proceeds from this closing of the offering were $107.5 million, before deducting underwriting discounts and commissions and estimated offering expenses of $7.3 million. Each pre-funded warrant has an exercise price of $0.001 per ordinary share, subject to customary adjustments, is exercisable at any time and will not expire until exercised in full. The pre-funded warrants may not be exercised if the aggregate number of ordinary shares beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation. In addition, the Underwriters were granted an option exercisable for 30 days, to purchase up to 921,428 additional shares at the public offering price, less the underwriting discounts and commissions. On July 18, 2024, we completed the closing of the sale of 921,428 additional shares in the offering following the exercise in full of the Underwriters' option to purchase additional shares, which resulted in additional gross proceeds of $16.1 million before deducting underwriting discounts and commissions and offering expenses of $1.0 million.

We have incurred losses since our inception and negative cash flows from our operations, and as of September 30, 2024 we had an accumulated deficit of $768.7 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 routinely evaluate our liquidity needs, including assessment of our current financial condition, sources of liquidity including current cash and cash equivalents and marketable securities and management's cash flow projections. Our ability to continue as a going concern is expected to be impacted by our ability to raise additional capital to fund our operations, produce cash inflows from *Jelmyto* product sales and advance UGN-102 through regulatory approval. Based on our cash, cash equivalents and marketable securities as of September 30, 2024, together with management's cash flow projections, we believe we have sufficient cash and cash equivalents to fund our operations beyond one year from the issuance of our condensed consolidated financial statements appearing elsewhere in this Quarterly Report. We may need to raise additional capital in the future. There can be no assurances that we will be able to secure such additional financing on terms that are satisfactory to us, in an amount sufficient to meet our needs, or at all. In the event we are not successful in obtaining sufficient funding, this could force us to delay, limit, or reduce our product development, commercialization efforts or other operations.

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

Funding and Material Cash Requirements

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

- the progress, timing and completion of clinical trials for UGN-102, UGN-301, UGN-103 and UGN-104;
- nonclinical studies and clinical trials for any of our other product candidates;
- the costs related to obtaining regulatory approval UGN-102, UGN-301, UGN-103, UGN-104 and any of our other product candidates, and any delays we may encounter as a result of regulatory requirements or adverse clinical trial results with respect to any of these product candidates;
- selling, marketing and patent-related activities undertaken in connection with the commercialization of *Jelmyto* and 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, UGN-103, UGN-104, *RTGel* reverse thermal hydrogel technology and any other product candidates; and
- the repayment of outstanding debt.

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

We may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants that further limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, the terms of the Forward Contract with RTW and the loan agreement with Pharmakon 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 July 2022, we signed a lease extension agreement extending the term of the lease through September 2025.

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

The total obligation for future minimum lease payments under our operating leases is $1.1 million as of September 30, 2024. See Note 11 to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report for further information.

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

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million was funded in September 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables.

All outstanding loans with Pharmakon accrue interest using a benchmark rate of 3-month SOFR plus 7.25% plus an additional adjustment of 0.26161%. All outstanding principal will be required to be repaid in four equal quarterly installments commencing in the second quarter of 2026, with a one-year extension possible upon FDA approval of an NDA for UGN-102 by June 30, 2025. All outstanding loans with Pharmakon can be prepaid in whole at our discretion, at any time, subject to prepayment premiums and make-whole amounts.

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

On June 26, 2024, we entered into a separation agreement with Jeff Bova, our former Chief Commercial Officer, which sets forth the terms of Mr. Bova's termination of employment, effective as of September 30, 2024. The arrangement includes cash severance, a pro rata portion of the target annual bonus for calendar year 2024, and partial acceleration of share-based compensation. We recognized $1.1 million during the nine months ended September 30, 2024 in relation to this arrangement. On October 7, 2024, we entered into a separation and consulting agreement with Don Kim, pursuant to which Mr. Kim resigned from his positions as our Chief Financial Officer, principal financial officer and principal accounting officer, effective October 8, 2024. The arrangement includes cash severance and target annual bonus for calendar year 2024 of approximately $0.5 million, which will be recognized in the fourth quarter of 2024, as well as a post-separation consulting arrangement. Mr. Kim's outstanding share-based awards will remain eligible for continued vesting during the post-separation consulting period.

Cash Flows

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

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (83,147)	$ (63,380)
Investing activities	(81,234)	10,391
Financing activities	194,548	116,891
Net change in cash and cash equivalents	$ 30,167	$ 63,902

Operating Activities

Net cash used in operating activities was $83.1 million during the nine months ended September 30, 2024, compared to $63.4 million during the nine months ended September 30, 2023. The $19.7 million increase was attributable primarily to higher net loss driven by increased operating expenses such as regulatory and brand marketing costs related to UGN-102, as well as timing of certain accruals.

Investing Activities

Net cash used in investing activities was $81.2 million during the nine months ended September 30, 2024, compared to net cash provided by investing activities of $10.4 million during the nine months ended September 30, 2023. The net change of $91.6 million is attributable primarily to additional investment in marketable securities in 2024 as compared to 2023.

Financing Activities

Net cash provided by financing activities was $194.5 million during the nine months ended September 30, 2024, compared to $116.9 million during the nine months ended September 30, 2023. The increase of $77.6 million is attributable primarily to proceeds from the issuance of ordinary shares under the ATM Sales Agreement, the underwritten public offering and the issuance of debt related to the third tranche of the Pharmakon loan.

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, cash equivalents and marketable securities. As of September 30, 2024, we had $254.2 million in cash and cash equivalents and marketable securities. We invest our cash primarily in money market accounts and marketable securities such as debt instruments of the U.S. government-sponsored agencies and the U.S. Treasury, and commercial paper. 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 September 30, 2024, this change would not have had a material effect on the fair value of our cash, 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 nine months ended September 30, 2024 or 2023.

Foreign Currency Exchange Risk

The U.S. dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in the New Israeli Shekel ("NIS"). As a result, we are exposed to the risk that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation, if any, of the NIS against the dollar. For example, the dollar appreciated against the NIS during 2023 by a total of 2.4%. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future. If a 10% change in NIS-to-Dollar exchange rates were to have occurred during the nine months ended September 30, 2024, 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 September 30, 2024. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

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 September 30, 2024, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II—Other Information

Item 1. Legal Proceedings.

On April 2, 2024, UroGen Pharma Ltd. filed a lawsuit in the U.S. District Court for the District of Delaware against Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd., alleging infringement of U.S. Patent Numbers 9,040,074 and 9,950,069 and seeking a permanent injunction preventing market entry of a generic product from Teva prior to the expiry of such patents. The Company stipulated to the dismissal of Teva Pharmaceutical Industries, Ltd. without prejudice and the action continues against the other two Teva entities. Both patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for *Jelmyto*. The lawsuit follows an Abbreviated New Drug Application filed by Teva Pharmaceuticals, Inc., which seeks authorization from the FDA to manufacture, use or sell a generic version of mitomycin for pyelocalyceal solution, 40 mg/vial in the United States before the expiry of the two patents referenced above.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Other than as set forth above, we are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Risk Factor Summary

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

- We may require additional financing to fund our operations and achieve our goals, and a failure to obtain this capital when needed and on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.
- We are highly dependent on the successful commercialization of our only approved product, *Jelmyto*.
- We have limited experience as an organization in marketing and distributing products and are therefore subject to certain risks in relation to the commercialization of *Jelmyto* and any of our product candidates that receive regulatory approval.
- The market opportunities for *Jelmyto* and our product candidates may be smaller than we anticipate or limited to those patients who are ineligible for established therapies or for whom prior therapies have failed and may be small.
- *Jelmyto* and any of our product candidates that receive regulatory approval may fail to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success.
- *Jelmyto* and our product candidates, if approved, will face significant competition with competing technologies and our failure to compete effectively may prevent us from achieving significant market penetration.
- In addition to *Jelmyto*, we are dependent on the success of our lead product candidate, UGN-102, and our other product candidates, including obtaining regulatory approval to market our product candidates in the United States.
- The data from our pivotal Phase 3 ENVISION trial and supporting ATLAS and OPTIMA II trials may be insufficient to support regulatory approval of UGN-102.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.

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

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

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

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

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

- Our indebtedness resulting from our loan agreement with Pharmakon could adversely affect our financial condition or restrict our future operations.

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

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

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

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

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

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

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

Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report, before deciding whether to purchase, hold or sell our ordinary shares. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time. When evaluating our business, you should consider all of the factors described as well as the other information in our Annual Report and this Quarterly Report, including our financial statements and the related notes, "Management's Discussion and Analysis of Financial Condition and Results of Operation" and Item 1A, "Risk Factors." We have marked with an asterisk (*) those risk factors that did not appear as risk factors in, or contain changes to the similarly titled risk factors included in, Item 1A of our Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our ordinary shares would likely decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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

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

We are a biotechnology company with a limited operating history upon which you can evaluate our business and prospects. We are not profitable and have incurred net losses in each period since we commenced operations in 2004, including net losses of $102.2 million for the year ended December 31, 2023 and a net loss of $23.7 million for the quarter ended September 30, 2024. As of September 30, 2024 we had an accumulated deficit of $768.7 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*.

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

We are not profitable and have had negative cash flow from operations since our inception. Since our inception, almost all our resources have been dedicated to the nonclinical and clinical development of our first commercial product, *Jelmyto*, and our lead product candidate UGN-102. As of September 30, 2024, we had cash and cash equivalents and marketable securities of $254.2 million. To fund our operations and develop our product candidates and commercialize *Jelmyto*, we have relied primarily on equity and debt financings and, following the launch of *Jelmyto* in June 2020, revenue generated from sales of *Jelmyto*.

In December 2019, we entered into the ATM Sales Agreement with TD Cowen pursuant to which we may from time to time offer and sell our ordinary shares having an aggregate offering price of up to $100.0 million. As of September 30, 2024, $27.3 million remain available for sale under the ATM Sales Agreement.

In March 2021, we announced the RTW Transaction with 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.

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

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million was funded in September 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables.

We may require additional capital to complete clinical trials, obtain regulatory approval for and commercialize our product candidates, and otherwise fund our operations. Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity financings, convertible debt or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. We may also require additional capital to pursue nonclinical and clinical activities, and pursue regulatory approval for, and to commercialize, our pipeline product candidates.

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

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

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

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

Our indebtedness resulting from our loan agreement with Pharmakon could adversely affect our financial condition or restrict our future operations.*

In March 2022, we entered into a loan agreement with Pharmakon pursuant to which the Lenders funded the Initial Term Loans to the Borrower in an aggregate principal amount of $100.0 million in two tranches. In March of 2024, we amended and restated the loan agreement, pursuant to which the Lenders agreed to make additional term loans to the Borrower in an aggregate principal amount of up to $100.0 million to be funded in two tranches. The third tranche of $25.0 million was funded in September 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (ii) the satisfaction of customary bring down conditions and deliverables. There is no assurance that the additional term loans will become available.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Business and Strategy

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

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

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

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

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

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

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

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

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

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

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

Our sales force has only promoted *Jelmyto* since its launch in June 2020. In addition, *Jelmyto* is the first drug approved by the FDA for the treatment of low-grade UTUC. As a result, we are and will continue to be required to expend significant time and resources to train our sales force to be credible, persuasive, and compliant with applicable laws in marketing *Jelmyto* for the treatment of low-grade UTUC to physicians and nurses. In addition, we must train our sales force to ensure that a consistent and appropriate message about *Jelmyto* is being delivered to our customers. We generally manage and deploy our sales force by geographic coverage across the United States. Lack of coverage due to turnover of personnel, and/or inability to identify and integrate additional personnel would have a negative impact on our ability to engage with physicians and other stakeholders. If we are unable to effectively train, deploy and retain our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate customers about the benefits and risks of *Jelmyto,* any future product candidates, and their proper administration, our efforts to successfully commercialize *Jelmyto* and any future product candidates could be put in jeopardy, which would negatively impact our ability to generate product revenues.

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

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

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

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

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

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

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

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

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

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

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

We are aware of several pharmaceutical companies that are developing drugs in the general fields of urology and uro-oncology, such as AADi, LLC, Biocancell Ltd., Bristol Myers Squibb, CG Oncology Inc., enGene Holdings, Ferring Pharmaceuticals, FKD Therapies Oy, GSK, ImmunityBio, Janssen, Merck Sharp & Dohme Corp, Pfizer, Prokarium, Protara Therapeutics, Roche, Samyang Biopharma, Steba Biotech Ltd., SURGE Therapeutics, Viralytics Limited and Vyriad. We are aware that Ferring Pharmaceuticals is marketing Adstiladrin, approved by the FDA for the treatment of high-risk BCG-unresponsive NMIBC, and that in 2024 the FDA approved ImmunityBio's product ANKTIVA for the treatment of BCG-unresponsive NMIBC with CIS, with or without papillary tumors. We are also aware there are companies among this list conducting clinical trials in various phases in the same indications in which we are developing products. In addition, we received from Teva a Paragraph IV Certification Notice Letter in February 2024, providing notification that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of *Jelmyto*. In the Notice Letter, Teva alleges that two of the patents listed in the FDA Orange Book for *Jelmyto*, U.S. Patent Numbers 9,040,074 and 9,950,069, each of which expires in January 2031, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission. See Part II, Item 1. "Legal Proceedings" for additional discussion. If we are unable to maintain patent protection for *Jelmyto, Jelmyto* may be subject to immediate competition from FDA approved generic entrants after orphan drug exclusivity for *Jelmyto* expires in April 2027.

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

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

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

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

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

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

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

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

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

While the FDA accepted our NDA for UGN-102 in October 2024, there is no guarantee that the FDA will eventually approve UGN-102 for the indication and patient population that we request or approve the labeling that we believe is necessary or desirable for the successful commercialization of UGN-102, as the FDA has the authority to refuse to approve NDAs for a variety of reasons. Additionally, the FDA or other comparable foreign regulatory authorities may also require a panel of experts, referred to as an advisory committee, to deliberate on the adequacy of the safety and efficacy data to support approval of UGN-102. We currently anticipate that the FDA will require an advisory committee for UGN-102. The opinion of the advisory committee, although not binding, may have a significant impact on our ability to obtain approval for UGN-102 based on the completed clinical trials, as the FDA or comparable foreign regulatory authorities often adheres to the advisory committee's recommendations. However, even if the advisory committee provides a positive recommendation, there is no guarantee that the FDA will follow the advisory committee's recommendations and there are numerous examples of the FDA departing from the recommendations of its advisory committee. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

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

- the FDA's acceptance of our parameters for regulatory approval relating to UGN-102 and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways, and proposed labeling and packaging;
- our ability to successfully complete the FDA requirements related to CMC, for UGN-102 and our other product candidates, and if completed, their sufficiency to support an NDA;
- the FDA's timely acceptance of our INDs, for our product candidates and our inability to commence clinical trials in the United States without such IND acceptances;
- the FDA's acceptance of the design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from nonclinical studies or clinical trials;
- the FDA's acceptance of the population studied in our clinical trials being sufficiently large, broad and representative to assess efficacy and safety in the patient population for which we seek approval;
- our ability to successfully complete the clinical trials of our product candidates, including timely patient enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of the product candidates undergoing such clinical trials;
- our ability to demonstrate meaningful clinical or other benefits which outweigh any safety or other perceived risks, through the completion of our clinical trials for our product candidates;
- the FDA's decision to schedule an advisory committee meeting, and to conduct such meeting, in a timely manner to evaluate and make a recommendation regarding our NDA for UGN-102;
- if an advisory committee meeting is scheduled, the outcome of remains uncertain and it is possible that the advisory committee will have an adverse or split recommendation with respect to our applications to market UGN-102 and our other product candidates in the United States;
- if applicable, even if FDA's advisory committee recommends approval of our applications to market UGN-102 and our other product candidates in the United States, without limiting the approved labeling, specifications, distribution or use of the products, or imposing other restrictions, the FDA is not bound by the advisory committee's recommendation and there are a number of instances where the FDA has voted against the recommendations of advisory committees;
- the FDA's determination of safety and efficacy of our product candidates;
- the FDA's determination that the Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") regulatory pathway ("505(b)(2)") is available for our product candidates;
- the prevalence and severity of adverse events associated with our product candidates, including UGN-102, as there are no drugs and related drug administration procedures approved for the primary treatment of low-grade NMIBC, that are based on *RTGel* technology;
- the timely and satisfactory performance by third-party contractors of their obligations in relation to our clinical trials;
- our success in educating physicians and patients about the benefits, risks, administration and use of our product candidates, if approved, particularly in light of the fact that there are no drugs that have been approved by the FDA for the primary treatment of low-grade NMIBC, and only a limited number of drugs have been approved by the FDA as adjuvant treatment for high-grade NMIBC;

- the availability, perceived advantages, relative cost, safety and efficacy of alternative and competing treatments for the indications addressed by our product candidates;
- the effectiveness of our marketing, sales and distribution strategy, and operations, as well as that of any current and future licensees;
- the FDA's acceptance of the quality of our drug substance or drug product, formulation, labeling, packaging, or the specifications of our product candidates is sufficient for approval;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP;

- the FDA's acceptance of the manufacturing processes or facilities of third-party manufacturers with which we contract;
- our ability to secure supplies for our product candidates to support clinical trials and commercial use;
- our ability to manufacture or secure active ingredient, *RTGel* hydrogel, and finished product from third-party suppliers for product candidates, including UGN-102, UGN-103, UGN-104, UGN-201 and UGN-301, if approved;
- our ability to obtain, maintain, protect and enforce our intellectual property rights with respect to our product candidates;
- the extent to which the costs of our products, once approved, are covered and reimbursed by third-party payors, including the availability of a physician reimbursement code for our treatments, and patients' willingness to pay for our products; and
- our ability to properly train physicians or nurses for the skillful preparation and administration of any of our product candidates that receive approval, including UGN-102, and our ability to develop a broad experiential knowledge base of aggregated clinician feedback from which we can refine appropriate procedures for product administration, without which there could be a risk of adverse events.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These risks and uncertainties impact all our nonclinical programs that we pursue. If we are unsuccessful in advancing our nonclinical product candidates into clinical trials in a timely fashion, our business may be harmed. Even if we are successful in advancing our nonclinical product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this Quarterly 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 CROs and clinical trial sites, and have such CROs and sites effect the proper and timely conduct of our clinical trials;
- obtain and maintain institutional review board ("IRB") approval at each clinical trial site;
- identify, recruit, enroll and retain suitable patients to participate in a trial;
- have a sufficient number of patients enrolled, complete a trial or return for post-treatment follow-up;
- ensure clinical investigators and clinical trial sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- manufacture sufficient quantities at the required quality of product candidate for use in clinical trials; or
- raise sufficient capital to fund a trial.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of September 30, 2024, we had 217 employees, of whom 40 are based in Israel and 177 are based in the United States. We will need to continue to expand our development, quality, managerial, operational, finance, marketing, sales and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

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

As we continue to grow as an organization, including by expanding our development efforts and building out and developing our commercial capabilities to support our commercialization of *Jelmyto* and pre-commercialization efforts for UGN-102, we will evaluate, and may implement, changes to our organization that may be appropriate in order to properly manage and direct our growth and transformation into a commercial-stage company. Due to our limited financial resources and our limited experience in managing a larger company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion or other significant changes to our organization could delay the execution of our development, commercialization and strategic objectives or disrupt our operations; and if we are not successful in commercializing our approved product or any of our product candidates that may receive regulatory approval, either on our own or through collaborations with one or more third parties, our revenues will suffer, and we would incur significant additional losses.

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

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

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

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

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

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

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

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

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

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

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, attacks enhanced or facilitated by AI, and other similar threats. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

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

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

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

such identified vulnerabilities. Therefore, such vulnerabilities could be exploited and result in a security incident, which may not be detected until after the incident has occurred.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Sensitive Information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business. Additionally, our Sensitive Information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

We seek patent protection for our product candidates, and we hold a broad collection of intellectual property comprised of issued patents, in-licensed patents, pending patent applications, trade secrets and trademarks covering our proprietary *RTGel* technology, the pharmaceutical compositions, methods of use and manufacturing aspects of our product candidates. In the United States, we currently own, co-own or exclusively license 25 patents that are directed to protect our approved product, *Jelmyto* and our lead product candidate, UGN-102, as well as UGN-103 and UGN-104, a proprietary *RTGel* technology, local compositions comprising different active ingredients, inter alia compositions comprising a Botulinum Toxin, UGN-201, the use of UGN-201 and UGN-301, and our future product candidates that are under company research. These IP rights relate to certain aspects of cancer treatment. These issued patents are set to expire between 2024 and 2037. In total, our IP portfolio includes 43 granted patents worldwide, and more than 45 pending patent applications filed in the U.S., Europe, Israel, Japan, Canada, China and Australia that are directed to cover various methods, systems and compositions for treating cancer locally, by intravesical means, utilize various active ingredients and the combinations thereof. These patent applications, if issued, are set to expire between 2031 and 2043.

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

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

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

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

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

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

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

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

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

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

The strength of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to 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. 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. We received a Paragraph IV Certification Notice Letter from Teva in February 2024, providing notification that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of *Jelmyto*. In the Notice Letter, Teva alleges that two of the patents listed in the FDA Orange Book for *Jelmyto*, U.S. Patent Numbers 9,040,074 and 9,950,069, each of which expires in January 2031, are invalid, unenforceable, or will not be infringed by Teva's manufacture, use, or sale of the generic product described in its ANDA submission. See Part II, Item 1. "Legal Proceedings" for additional discussion. If we are unable to maintain patent protection for *Jelmyto*, *Jelmyto* will be subject to immediate competition from generic entrants after regulatory exclusivity expires in April 2027. Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

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

Our trade secrets may not have sufficient intellectual property protection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Drug manufacturers may develop, seek approval for, and launch generic versions of our products. For example, we received a Paragraph IV Certification Notice Letter from Teva in February 2024, providing notification to us that Teva has submitted an ANDA to the FDA seeking approval to manufacture, use, or sell a generic version of *Jelmyto*. See Part II, Item 1. “Legal Proceedings” for additional discussion.

If we do not file a patent infringement lawsuit against a generic manufacturer within 45 days of receiving notice of its Paragraph IV certification, the ANDA applicant may not be subject to a 30-month stay. If we file an infringement action against a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors’ patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

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

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

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

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

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

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

Additionally, there have been several recent U.S. presidential executive orders, Congressional inquiries and proposed and enacted legislation at the federal and state levels designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, for example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, on November 15, 2021, President Biden signed into law the Infrastructure Investment and Jobs Act. Beginning on January 1, 2023, manufacturers will be required to pay quarterly refunds to CMS for discarded amounts of certain single-dose container and single-use package drugs payable under part B of the Medicare program. Refunds will generally be based on the discarded volume above 10% of the total allowed amount. However, in unique circumstances, CMS will increase the applicable threshold to 35%. At this time, CMS has determined that *Jelmyto* fits within this unique circumstance classification. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS will select up to fifteen additional drugs covered under Part D for price negotiation in 2025. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of Our Ordinary Shares

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

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

- the success of our ongoing 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, including factors unrelated to our operating performance.

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

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

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

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

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

In order to raise additional capital, we may in the future offer additional ordinary shares or other securities convertible into or exchangeable for our ordinary shares at prices that we determine from time to time, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. We may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. On December 20, 2019, we entered into the ATM Sales Agreement pursuant to which we may from time to time offer and sell our ordinary shares, having an aggregate offering price of up to $100.0 million, to or through TD Cowen, acting as sales agent or principal, in any manner deemed to be an "at-the market offering". As of September 30, 2024, $27.3 million remain available for sale under the ATM Sales Agreement. The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 filed with the SEC on November 15, 2022, which was declared effective on November 29, 2022.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Operations in Israel

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

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

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

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

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

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

Further, our operations could be disrupted by the obligations of our employees to perform military service. As of September 30, 2024, we had 40 employees based in Israel. Of these employees, some may be military reservists, and may be called upon to perform military reserve duty of up to 36 days per year (and in some cases more) until they reach the age of 40 (and in some cases, up to the age of 45 or older). Since October 7, 2023, the Israeli Defense Force has called up more than 350,000 of its reserve forces to serve. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows.

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

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

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

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

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

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

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

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

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

Risks Related to Our Management and Employees

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

Our success depends upon the continued service and performance of our executive officers who are essential to our growth and development. The loss of one or more of our executive officers could delay or prevent the continued successful implementation of our growth strategy, could affect our ability to manage our company effectively and to carry out our business plan, or could otherwise be detrimental to us. As of September 30, 2024, we had 217 employees. Therefore, knowledge of our product candidates and clinical trials is concentrated among a small number of individuals. Members of our executive team as well as key clinical, scientific, technical and commercial personnel may resign at any time and there can be no assurance that we will be able to continue to retain such personnel. If we cannot recruit suitable replacements in a timely manner, our business will be adversely impacted.

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

General Risk Factors

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

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

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

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

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

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

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

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

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

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

Other international and geo-political events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. In October 2023, Hamas initiated an attack against Israel, provoking a state of war and the risk of a larger conflict. While we cannot predict the broader consequences, these conflicts and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

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

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning environmental, social and corporate governance matters. We may be, or be perceived to be, not acting responsibly in connection with these matters, which could negatively impact us. For instance, the SEC recently finalized rules designed to enhance and standardize climate-related disclosures. These climate disclosure rules have been challenged in court and the SEC has issued an order staying their implementation pending the outcome of judicial review. These new climate-related disclosures, if required, may significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to impact our reputation negatively and/or that harm our share price.

Item 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† **	Pre-Paid Forward Contract by and among the Registrant and RTW Investments ICAV for and on behalf of RTW Fund 2, dated as of March 18, 2021, as amended April 30, 2021 and August 14, 2024.
10.2	Separation Agreement between the Company and Don Kim, dated October 7, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38079), filed with the SEC on October 9, 2024).
10.3	Employment Agreement between the Company and Chris Degnan, dated October 7, 2024 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on form 10-Q (File No. 001-38079), filed with the SEC on October 9, 2024).
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

† Certain information in this exhibit has been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is the type of information that the registrant treats as private or confidential.

** Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

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.

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.

November 6, 2024

By: /s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer
(Principal Executive Officer)

November 6, 2024

By: /s/ Chris Degnan
Chris Degnan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT UROGEN PHARMA LTD. TREATS AS PRIVATE OR CONFIDENTIAL

PRE-PAID FORWARD CONTRACT

BY AND BETWEEN

UROGEN PHARMA LTD.

AND

RTW INVESTMENTS ICAV FOR RTW FUND 2

DATED AS OF MARCH 18, 2021

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Index of Exhibits, Schedules and Annexes

PRE-PAID FORWARD CONTRACT

This PRE-PAID FORWARD CONTRACT, dated as of March 18, 2021 (this "Agreement"), is made and entered into by and between RTW Investments ICAV, an Irish Collective Asset-management Vehicle registered in Ireland as an umbrella fund with segregated liability between sub-funds (the "Payer"), for and on behalf of its sub-fund, RTW Fund 2, and UroGen Pharma Ltd., an Israel corporation with company registration number 513537621 (the "Company").

W I T N E S S E T H:

WHEREAS, the Company is in the business of, among other things, developing and commercializing the Products (as defined below); and

WHEREAS, the Company and the Payer desire to enter into a pre-paid forward contract providing for the Company's grant to the Payer of the right to receive cash payments as a participation in future revenues of the Company through the Revenue Participation Right (as defined below) in exchange for payment of the Pre-Paid Forward Price (as defined below), and the Company desires to grant the Revenue Participation Right to the Payer in exchange for the Payer's payment of the Pre-Paid Forward Price, in each case on the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the representations, warranties, covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Payer hereby agree as follows:

ARTICLE 1
DEFINITIONS

Section 1.1 Definitions. The following terms, as used herein, shall have the following meanings:

"Acceptable Intercreditor Agreement" means (a) a first-lien/second lien intercreditor agreement between the Payer and Senior Debt Provider providing [***] [***] and (b) any other intercreditor agreement between Payer and a Senior Debt Provider in form and substance reasonably satisfactory to Payer, such Senior Debt Provider and the Company. As used in this definition of "Acceptable Intercreditor Agreement," "Payer Disposition Proceeds Amount" means, with respect to any disposition, sale or other transfer of Product Collateral, the lesser of (x) [***] of the proceeds from such disposition (or sale or transfer, as applicable), after payment of all fees, costs and expenses (including attorneys' fees and costs) in connection with such disposition and any other costs or expenses incurred in connection with the enforcement of any right or remedy thereunder and (y) the Remaining Obligations. For the avoidance of doubt, for purposes of any waterfall referenced above, the Payer Disposition Proceeds Amount shall have the same priority of payment as any principal and interest obligations due to the Senior Debt Provider and shall not be subordinated in right of payment to such obligations.

"Affiliate" means, with respect to any particular Person, any other Person directly or indirectly controlling, controlled by or under common control with such particular Person. For purposes of the foregoing sentence, the term "control" means direct or indirect ownership of (x) fifty percent (50%) or more, including ownership by trusts with substantially the same beneficial interests, of the voting and equity rights of such Person, firm, trust, corporation, partnership or other entity or combination thereof, or (y) the power to direct the management of such Person, firm, trust, corporation, partnership or other entity or combination thereof, by contract or otherwise.

"Agreement" is defined in the preamble.

"Bankruptcy Court" is defined in Exhibit B hereto.

"Bankruptcy Laws" means, collectively, bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance, fraudulent transfer or other similar laws or regulations affecting the enforcement of creditors' rights generally, including any proceedings under the Israeli Insolvency Law.

"Board" means the board of directors of the Company.

"Business Day" means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in New York are permitted or required by applicable law or regulation to remain closed.

"Capital Lease" means, as applied to any Person, any lease of any property by that Person as lessee which, in accordance with GAAP, is required to be accounted for as a capital lease on the balance sheet of that Person; provided that, for the avoidance of doubt, any lease that was (or would have been) accounted for by such Person as an operating lease prior to the issuance of the Accounting Standards Update No. 2016-02 by the Financial Accounting Standards Board and any similar lease entered into thereafter by such Person shall be accounted for as an operating lease and not as a Capital Lease.

"Clinical Trial" means a clinical trial intended to support the Marketing Approval or Commercialization of a Product.

"Clinical Updates" means [***].

"Closing" means the closing of the grant of the Revenue Participation Right hereunder.

"Closing Date" means the date on which the Closing occurs pursuant to Section 3.1.

"CMC" means chemistry, manufacturing and controls with respect to a Product.

"Combination Product" means:

(a) a single pharmaceutical formulation (whether co-formulated or administered together via the same administration route) containing as its active ingredients both a Product and one or more other therapeutically or prophylactically active pharmaceutical or biologic ingredients (each an "Other Component"), or

(b) a combination therapy comprised of a Product and one or more Other Component(s), whether priced and sold in a single package containing such multiple products, packaged separately but sold together for a single price, or sold under separate price points but labeled for use together,

in each case, including all dosage forms, formulations, presentations, and package configurations. Drug delivery vehicles, adjuvants and excipients will not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant or excipient is recognized by the FDA as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7). All references to Products in this Agreement shall be deemed to include Combination Products.

"Commercial Updates" means [***].

"Commercialization" means any and all activities directed to the distribution, marketing, detailing, promotion, selling and securing of reimbursement of a Product (including the using, importing, selling and offering for sale of such Product), and shall include post-Marketing Approval studies to the extent required by a Regulatory Authority, post-launch marketing, promoting, detailing, distributing, selling such Product, importing, exporting or transporting such Product for sale, and regulatory compliance with respect to the foregoing. When used as a verb, "Commercialize" shall mean to engage in Commercialization. Except with respect to post-Marketing Approval studies required by a Regulatory Authority, Commercialization shall not include any activities directed to the research or development (including pre-clinical and clinical development) or manufacture of a Product.

"Commercialization License" means any Out-License, or any other agreement between the Company or any of its Affiliates and any Third Party, pursuant to which rights are granted to a Third Party (other than any Distributor) to market, detail, promote, sell or secure reimbursement of any Product, whether through a license, sublicense, covenant not to sue, or similar arrangement under any Intellectual Property Right or the transfer, assignment or other conveyance of ownership rights in or to any Intellectual Property Right.

"Commercially Reasonable Efforts" means the level of efforts and resources (measured as of the time that such efforts and resources are required to be used under this Agreement) that are commonly used by a commercial-stage public biotechnology company of similar size and resources to Company (provided that such size and resources shall not decrease below the size and resources of the Company as of the Closing Date), to develop, manufacture or commercialize, as the case may be, a comparable product for a comparable clinical indication (with respect to market size and commercial opportunity) at a similar stage in its development or product life and of a similar market and potential to the Product, but without regard to the Company's financial obligations under this Agreement.

"Company" is defined in the preamble. References to the Company herein shall be deemed to include any assignee of the Company pursuant to Section 10.4.

"Company Certificate" is defined in Section 5.1(g).

"Company Indemnified Parties" is defined in Section 7.1(b).

"Confidential Information" is defined in Section 8.1.

"Consensus Value of Net Sales" is defined in Exhibit B hereto.

"Covered Jurisdiction" means [***].

"Disclosing Party" is defined in Section 8.1.

"Disclosure Schedule" means the Disclosure Schedule, dated as of the date hereof, delivered to the Payer by the Company concurrently with the execution of this Agreement.

"Distributor" means a Third Party that (a) (i) purchases or has the option to purchase any Product in finished form from or at the direction of the Company or any of its Affiliates, (ii) has the right, option or obligation to distribute, market and sell such Product (with or without packaging rights) in one or more regions, and (iii) does not otherwise make any royalty, milestone, profit share or other similar payment to the Company or its Affiliate based on such Third Party's sale of the Product or (b) (i) does not take title to such Product, (ii) does not invoice sales of such Product to Third Party customers and (iii) is responsible only for inventory management and distribution with respect to such Product on behalf of the Company or its Affiliate. The term "packaging rights" in this definition will mean the right for the Distributor to package or have packaged Product supplied in unpackaged bulk form into individual ready-for-sale packs.

"EMA" means the European Medicines Agency, or any successor agency thereto.

"ERISA" means the Employee Retirement Income Security Act of 1974.

"Escrow Account" means that certain bank account established pursuant to the Escrow Agreement and controlled by the Escrow Agent.

"Escrow Agent" means an escrow agent to be mutually agreed upon by the Company and the Payer.

"European Countries" means, collectively, each member within the European Union, each member of the European Economic Area (to the extent such member is not a member of the European Union), Switzerland and the United Kingdom

"Excluded Collateral" means, each of (i) any "intent to use" trademark applications for which a statement of use has not been filed (but only until such statement is filed), (ii) equipment, (iii) cash, cash equivalents, investment property and securities and bank accounts (except, in each case with respect to identifiable proceeds from the disposition of the Product Collateral in connection with any enforcement of the security interests granted pursuant to the Security Documents (which, for the avoidance of doubt, shall not include proceeds of inventory sold in the ordinary course of business or payments under any Permitted License)), and (iv) any permit, license or agreement entered into by the Company (A) to the extent that any such permit, license or agreement or any law applicable thereto prohibits the creation of a Lien thereon, but only to the extent, and for as long as, such prohibition is not terminated or rendered unenforceable or otherwise deemed ineffective by the Uniform Commercial Code or any other applicable law or (B) to the extent that the creation of a Lien in favor of the Payer would result in a breach or termination pursuant to the terms of or a default under any such permit, license or

agreement (other than to the extent that any such term would be rendered ineffective pursuant to the Sections 9-406, 9-407, 9-408 or 9-409 of the Uniform Commercial Code or any other applicable law (including the Bankruptcy Code) or principles of equity).

"Excluded Out-License" means any Out-License other than any Commercialization License.

"Existing Patent Rights" is defined in Section 4.1(k)(i).

"FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act.

"FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.

"GAAP" means generally accepted accounting principles in the United States in effect from time to time.

"Governmental Entity" means any: (a) nation, principality, republic, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or other entity and any court, arbitrator or other tribunal); (d) multi-national organization or body; or (e) individual, body or other entity exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

"Gross Sales" is defined in the definition of "Net Sales".

"Improvements" means any improvement, invention or discovery relating to a Product (other than with respect to a new composition of matter), including the formulation, or the method of manufacture of a Product.

"IIA" is defined in Section 4.1(k)(ix).

"In-License" means any license, settlement agreement or other agreement or arrangement between the Company or any of its Affiliates and any Third Party pursuant to which the Company or any of its Affiliates obtains a license or a covenant not to sue or similar grant of rights to any Patents or other intellectual property rights of such Third Party that is necessary for the research, development, manufacture, use or Commercialization of a Product.

"Indebtedness" of any Person means any indebtedness for borrowed money, any obligation evidenced by a note, bond, debenture or similar instrument, or any guarantee of any of the foregoing.

"Indemnified Party" is defined in Section 7.2.

"Indemnifying Party" is defined in Section 7.2.

"Insolvency Event" means in relation to each of the Company or its Affiliates: (a) any voluntary or involuntary filing for it of a petition under any Bankruptcy Laws; (b) it institutes or has instituted against it a proceeding seeking the grant of an initiation of proceedings order ("tsav le-ptichat halichim") pursuant to the Israeli Insolvency Law, a judgment of insolvency or bankruptcy or any other relief under any Bankruptcy Laws or rehabilitation proceedings as defined under the Israeli Insolvency Law or other Bankruptcy Laws, or a petition is presented for its winding-up or liquidation by it or any other person; (c) it has a resolution passed for its winding-up, dissolution, rehabilitation, official management or liquidation; (d) it seeks or becomes subject to the appointment of a liquidator, administrator, provisional liquidator, conservator, receiver, administrative receiver, compulsory manager, special manager, trustee, supervisor custodian or other similar official for it or relating to all or substantially all its assets (whether temporary or permanent); (e) (i) it is dissolved; (ii) it is or becomes unable or admits inability to pay its debts as they fall due or it obligations (including future and contingent obligations) exceed the value of its assets; (iii) it is otherwise deemed insolvent under any applicable Bankruptcy Law; (iv) it has a secured party take possession of all or substantially all its assets or has a distress, execution, attachment, sequestration or other legal process levied, enforced or sued on or against all or substantially all its assets and such party maintains possession, or any such process is not dismissed, discharged, stayed or restrained, in each case within 10 days thereafter; or (v) it makes a general assignment, arrangement or composition with or for the benefit of its creditors; (f) a moratorium or stay of proceedings ("ikuv halichim") is declared in respect of any of its Indebtedness or a petition is presented whether by the Company (including by virtue of section 319c of the Israeli Insolvency Law) or any other person, for such moratorium or stay of proceedings; (g) a notification is made to any of its creditors of the commencement of protected negotiations ("masa u-matan mugan") pursuant to the Israeli Insolvency Law; (h) any other corporate action or legal proceedings in relation to the events specified in the foregoing clauses (a) to (g) (inclusive); or (i) it causes or is subject to any event with respect to it which, under the applicable laws of any jurisdiction, has an analogous effect to any of the events specified in the foregoing clauses (a) to (h) (inclusive).

"Intellectual Property Product Rights" means any and all of the following as they exist throughout the world at any time: (a) the Intellectual Property Rights; (b) rights in registered and unregistered trademarks, service marks, trade names, trade dress, logos, packaging design, slogans and Internet domain names, and registrations and applications for registration of any of the foregoing, in each case, with respect to any Product that are owned or in-licensed by Company or any of its Affiliates; and (c) any and all other intellectual property rights and/or proprietary rights, whether or not patentable, specifically relating to any of the foregoing, as necessary for the development, manufacture or Commercialization of a Product that are owned or in-licensed by Company or any of its Affiliates.

"Intellectual Property Rights" means any and all of the following as they exist throughout the world at any time: (a) the Patent Rights and (b) the Know-How Rights.

"Intellectual Property Updates" means [***].

"Israeli Companies Law" means the Israeli Companies Law, 1999, as amended from time to time and any regulations promulgated thereunder.

"Israeli Insolvency Law" means the Israeli Insolvency and Rehabilitation Law, 2018 as amended from time to time and any regulations promulgated thereunder;

"Israeli Security Agreement" means the security agreement to be governed by Israeli law and granted by the Company in favor of the Payer pursuant to which the Company grants the Payer a first ranking fixed charge over the Product Collateral and Payer Priority Collateral and a floating charge over the inventory and all future Product Collateral.

"Jelmyto" means (a) the pharmaceutical product known as JELMYTO® (mitomycin) (and foreign-named equivalents) for pyelocalyceal solution, (b) 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 (c) any pharmaceutical product that contains any of the foregoing, in each case of (a)–(c), in any dosage form, dosing regimen, strength, or route of administration.

"Jelmyto Launch Sales Threshold" means the threshold amount for each corresponding Jelmyto Launch Year as set forth in the chart below:

Jelmyto Launch Year	**Jelmyto Launch Sales Threshold (Annual Jelmyto Net Sales)**
A. [***]	$[***]
B. [***]	$[***]
C. [***]	$[***]

"Jelmyto Launch Year" is defined in the definition of "[***]".

"Jelmyto Net Sales" means the Net Sales of Jelmyto.

"Jelmyto Net Sales Revenue Rate" means the applicable percentage based on the portion of the corresponding level of annual Jelmyto Net Sales in a calendar year as set forth in the chart below; provided, however, that in the event that the Company does not receive Marketing Approval from the FDA on or before [***] for UGN-102 to treat low-grade intermediate risk non-muscle invasive bladder cancer, the Jelmyto Net Sales Revenue Rate will increase by 1.5% (applicable to all tiers) on worldwide annual Jelmyto Net Sales from and after [***] (the "UGN-102 Delay Payment"), which for clarity will be in addition to any rate increase pursuant to the definition of "[***]" below:

Payment Tiers based on Annual Jelmyto Net Sales	**Jelmyto Net Sales Revenue Rate Applicable to Each Net Sales Tier**
A. Annual Jelmyto Net Sales of up to $200,000,000	Jelmyto Tier 1 Rate
B. Annual Jelmyto Net Sales exceeding $200,000,000 and less than or equal to $300,000,000	3.0%
C. Annual Jelmyto Net Sales in excess of $300,000,000	1.0%

"Jelmyto Revenue Payments" means, for each calendar quarter, an amount payable to the Payer equal to the amount of Jelmyto Net Sales during such calendar quarter multiplied by the Jelmyto Net Sales Revenue Rate. For clarity, the Jelmyto Net Sales Revenue Rate used to calculate the Jelmyto Revenue Payments for a given date in a calendar quarter (a) will be based on the worldwide aggregate annual Jelmyto Net Sales billed or invoiced for the calendar year through and including such date, and (b) may be different for different periods during such calendar quarter depending on the specific date the worldwide aggregate Jelmyto Net Sales crosses over to the next payment tier. By way of example, if worldwide aggregate Jelmyto Net Sales invoiced as of (i) April 12 for the calendar year equal $185,000,000, (ii) April 13 for the calendar year equal $210,000,000, and (c) June 30 for the calendar year equal $295,000,000, then the Jelmyto Net Sales Revenue Rate for such [calendar quarter] shall be equal to the Jelmyto Tier 1 Rate with respect to Jelmyto Net Sales through and including April 12, and 3.0% with respect to Jelmyto Net Sales from April 13 through and including June 30, in each case subject to further adjustment by the UGN-102 Delay Payment.

"Jelmyto Tier 1 Rate" means 9.5% (subject to potential upward adjustment based on any UGN-102 Delay Payments as set forth in the definition of Jelmyto Net Sales Revenue Rate); provided, however, that if in any of [***] [***], [***] or [***] (each, a "Jelmyto Launch Year") worldwide annual Jelmyto Net Sales are below the applicable Jelmyto Launch Sales Threshold, then the Jelmyto Tier 1 Rate will increase by 3.5% starting the following [***]. For clarity, the aggregate maximum increase pursuant to the foregoing is 3.5%, regardless of the number of years the worldwide annual Jelmyto Net Sales are below the applicable Jelmyto Launch Sales Threshold. If annual Jelmyto Net Sales subsequently exceed the applicable Jelmyto Launch Sales Threshold in the following [***], then the Jelmyto Tier 1 Rate will decrease by 3.5% (which decrease would take effect with respect to the calendar year following the Jelmyto Launch Year in which the Jelmyto Launch Sales Threshold is achieved). If, at the end of [***], the Jelmyto Tier 1 Rate has been increased by 3.5% for the [***] calendar year because the annual Jelmyto Net Sales in [***] have not exceeded the Jelmyto Launch Sales Threshold applicable to [***], then the Jelmyto Tier 1 Rate will remain increased by 3.5%; provided, however, that if worldwide annual Jelmyto Net Sales exceeds $[***] in any of the [***] through [***] calendar years, then the Jelmyto Tier 1 Rate will decrease by 3.5% (which decrease would take effect with respect to the [***] following the [***] in which such $[***] threshold is first achieved) and remain at such rate thereafter.

"Judgment" means any judgment, order, writ, injunction, citation, award or decree of any nature.

"Know-How" means any and all proprietary or confidential information, know-how and trade secrets, including processes, formulae, models and techniques (but excluding rights in research in progress, algorithms, data, databases, data collections, chemical and biological materials and the results of experimentation and testing).

"Know-How Rights" means any and all Know-How owned or in-licensed by the Company or any of its Affiliates or under which the Company or any of its Affiliates is or may become empowered to grant licenses necessary for the development, manufacture, or Commercialization of a Product.

"Knowledge of the Company" means the actual knowledge of the individuals listed on Schedule 1.1 of the Disclosure Schedule, after reasonable due inquiry.

"Licensee" means, with respect to any Product, a Third Party to whom the Company or any Affiliate of the Company has granted a Commercialization License. For clarity, a Distributor shall not be deemed to be a "Licensee."

"Lien" means any mortgage, lien, pledge, participation interest, charge, adverse claim, security interest, encumbrance or restriction of any kind, including any restriction on use, transfer or exercise of any other attribute of ownership of any kind; provided that, for the avoidance of doubt, Permitted Licenses shall not be deemed to be a "Lien".

"Loss" means any and all Judgments, damages, losses, claims, costs, liabilities and expenses, including reasonable and documented fees and out-of-pocket expenses of counsel.

"Loss of Market Exclusivity" shall mean, on a Product-by-Product and country-by-country basis, the later to occur of: (a) the expiration of the last-to-expire Valid Claim of a Patent Right covering such Product in such country; and (b) the expiry of all Regulatory Exclusivity Periods for such Product in such country.

"Marketing Approval" means, an NDA approved by the FDA, a Marketing Authorization Application approved by the EMA under the centralized European procedure, or any corresponding non-U.S. or non-EMA application, registration or certification, necessary or reasonably useful to market a Product approved by the corresponding Regulatory Authority, including pricing and reimbursement approvals where required. For clarity, notwithstanding the foregoing, solely with respect to Section 6.2, "Marketing Approval" shall not include pricing and reimbursement approvals.

"Material Adverse Effect" means (a) an adverse effect in any material respect on the timing, duration or amount of the Revenue Payments, (b) a material adverse effect on (i) a Product, (ii) any of the Intellectual Property Rights, including the Company's rights in or to any Intellectual Property Rights, (iii) any Marketing Approval of a Product or the timing thereof, (iv) the legality, validity or enforceability of any provision of this Agreement or any other Transaction Document, (v) the ability of the Company to perform any of its obligations under this Agreement or any other Transaction Document, (vi) the rights or remedies of the Payer under this Agreement or any other Transaction Document, or (vii) the business of the Company or its Affiliates or (c) an adverse effect in any material respect on the Revenue Participation Rights, the Product Collateral, or the Security Documents.

"Minimum Return Date" means [***].

"NDA" means a New Drug Application submitted to the FDA in the United States in accordance with the FD&C Act with respect to a pharmaceutical product or any analogous application or submission with any Regulatory Authority outside of the United States.

"Net Sales" means, with respect to a Product, the gross amount invoiced, billed or otherwise recorded for sales of such Product anywhere in the world by or on behalf of the Company, its Affiliates, or any Licensee of the Company or any of the Company's Affiliates (each of the foregoing Persons, for purposes of this definition, shall be considered a "Related Party") to a Third Party in an arms-length transaction ("Gross Sales") less the following amounts, to the extent actually incurred or accrued, and not reimbursed by such Third Party, provided, that any given amount may be taken as a permitted deduction only once:

(a) reasonable and customary rebates, chargebacks, quantity, trade and similar discounts, credits and allowances and other price reductions reasonably granted, allowed, incurred or paid in so far as they are applied to sales of a Product;

(b) discounts (including cash, quantity, trade, governmental, and similar discounts), coupons, retroactive price reductions, charge back payments and rebates granted to managed care organizations or to federal, state and local governments, or to their agencies (including payments made under the new "Medicare Part D Coverage Gap Discount Program" and the "Annual Fee for Branded Pharmaceutical Manufacturers" specific to the Product), in each case, as applied to sales of the Product and actually given to customers;

(c) reasonable and customary credits, adjustments, and allowances, including those granted on account of price adjustments, billing errors, and damage, Product otherwise not in saleable condition, and rejection, return or recall of a Product;

(d) reasonable and customary freight and insurance costs incurred with respect to the shipment of a Product to customers, in each case if charged separately and invoiced to the customer;

(e) customs duties, surcharges and other similar governmental charges incurred in connection with the exportation or importation of a Product to the extent included in the gross amount invoiced;

(f) sales, use, value-added, excise, turnover, inventory and other similar Taxes (excluding income Taxes), and that portion of annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and any other fee imposed by any equivalent applicable law, in each of the foregoing cases, that Company allocates to sales of a Product in accordance with Company's standard policies and procedures consistently applied across its products, as adjusted for offsets, rebates and refunds, imposed in connection with the sales of the Product to any Third Party, to the extent such Taxes are not paid by the Third Party;

(g) actual copayment waiver amounts uncollected or uncollectible debt amounts with respect to sales of a Product, provided that if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid;

(h) reasonable, customary and documented out of pocket amounts directly relating to co-pay programs, bridging programs or other similar patient assistance programs which may be implemented from time to time by the Company; and

(i) other similar or customary deductions taken in the ordinary course of business as permitted in calculating net sales or net revenue (as applicable).

Each of the amounts set forth shall be determined consistent with a Related Party's customary practices and in accordance with GAAP or International Financial Reporting Standards.

For clarity, "Net Sales" will not include (i) sales or dispositions for charitable, promotional, pre-clinical, clinical, regulatory, compassionate use, named patient use or indigent or other similar programs, reasonable quantities of Products used as samples, and Products used in the development of Products, (ii) sales or dispositions between any of the Related Parties (unless a Related Party is the final end-user of such Product), but will include subsequent sales or dispositions of Products to a non-Related Party, or (iii) any amounts or other consideration received by a Related Party from a Licensee, Distributor, or a non-Related Party in consideration of the grant of a (sub)license or co-promotion or distribution right to such non-Related Party, including any upfront or milestone payments (whether or not such milestones are based on net sales of a Product).

With respect to sales of a Product invoiced in U.S. dollars, Net Sales shall be determined in U.S. dollars. With respect to sales of a Product invoiced in a currency other than U.S. dollars, Net Sales shall be determined by converting the currencies at which the sales are made into U.S. dollars, at rates of exchange determined in a manner consistent with the Company's or a Licensee's, as applicable, method for calculating rates of exchange in the preparation of the Company's or such Licensee's annual financial statements in accordance with GAAP or International Financial Reporting Standards.

Net Sales for any Combination Product shall be calculated on a country-by-country basis by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where "A" is the weighted average invoice price of the Product contained in such Combination Product when sold separately in such country during the applicable accounting period in which the sales of the Combination Product were made, and "B" is the combined weighted average invoice prices of all of the Other Components contained in such Combination Product sold separately in such country during such same accounting period. If a Product contained in such Combination Product is not sold separately in finished form in such country, the Company and the Payer shall determine Net Sales for such Product by mutual agreement based on the relative contribution of such Product and each such other active ingredient in such Combination Product in accordance with the above formula, and shall take into account in good faith any applicable allocations and calculations that may have been made for the same period in other countries.

Notwithstanding the foregoing, in the event that the Related Party is any party other than Company or its Affiliates, then Net Sales (including Combination Product allocations in connection with such Net Sales) will be calculated based on the corresponding definition of net sales in the applicable Permitted License permitting such sales, provided that such definition is commercially reasonable.

"Non-Exclusive Patent Rights" means any Patent Rights non-exclusively in-licensed or otherwise held on a non-exclusive basis by Company or any of its Affiliates pursuant to rights granted by customers, suppliers, or service providers in the ordinary course of business.

"Order" means any order, judgment, injunction, award, decree, ruling, stipulation, determination, or writ of any Governmental Entity.

"Other Component" is defined in the definition of "Combination Products".

"Out-License" means each license or other agreement between the Company or any of its Affiliates and any Third Party pursuant to which the Company or any of its Affiliates (a) grants a license or sublicense of any Intellectual Property Right, or (b) transfers, assigns or otherwise conveys or grants any access or rights in or to any Intellectual Property Right.

"Patent Rights" means (a) those Patents listed in Schedule 4.1(k)(i)(A); (b) any continuation, continuation-in-part, division, provisional or any substitute applications of the foregoing; (c) any patent issued with respect to any of the foregoing; (d) any certificate, reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any of the foregoing or other governmental actions which extend any of the subject matter of any of the foregoing; (e) any substitution patent, confirmation patent or registration patent or patent of addition based on any of the foregoing; (f) foreign counterparts of any of the foregoing; and (g) existing or future Patents covering any Improvements.

"Patents" means any and all patents and patent applications existing as of the date of this Agreement and all patent applications filed hereafter, including any continuation, continuation-in-part, division, provisional or any substitute applications, any patent issued with respect to any of the foregoing patent applications, any certificate, reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent or other governmental actions which extend any of the subject matter of a patent, and any substitution patent, confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

"Payer" is defined in the preamble.

"Payer Indemnified Parties" is defined in Section 7.1(a).

"Payer Priority Collateral" means, the Revenue Participation Right and the Revenue Payments, and any proceeds thereof. For the further avoidance of doubt, the Payer Priority Collateral is part of the Product Collateral.

"Payment Obligations" means the Remaining Obligations plus expenses, default interest, penalties, and enforcement costs.

"Permitted License" is defined in Section 6.7(a).

"Permitted Liens" means the following:

(a) Liens for Taxes, assessments or governmental charges or levies not yet due or which are being contested in good faith and by appropriate proceedings diligently conducted, if adequate reserves with respect thereto are maintained on the books of the applicable Person in accordance with GAAP or International Financial Reporting Standards;

(b) statutory Liens of landlords and Liens of carriers, warehousemen, mechanics, materialmen and suppliers and other Liens imposed by law or pursuant to customary reservations or retentions of title arising in the ordinary course of business, provided, that, such Liens secure only amounts not yet due and payable or, if due and payable, are unfiled and no other action has been taken to enforce the same or are being contested in good faith by appropriate proceedings for which adequate reserves determined in accordance with GAAP or International Financial Reporting Standards have been established;

(c) Liens on property existing at the time of acquisition of such property provided that such liens were in existence prior to such acquisition and not incurred in contemplation thereof;

(d) Permitted Licenses, including any interest or title of a licensee under a Permitted License;

(e) Any interest of a licensor or sublicensor under any In-License entered into by Company;

(f) pledges or deposits in the ordinary course of business in connection with workers' compensation, unemployment insurance and other social security legislation, other than any Lien imposed by ERISA;

(g) deposits to secure the performance of bids, trade contracts and leases (other than Indebtedness), statutory obligations, surety and appeal bonds, indemnity and performance bonds and other obligations of a like nature incurred in the ordinary course of business;

(h) easements, rights-of-way, restrictions and other similar encumbrances affecting real property which, in the aggregate, are not substantial in amount, and which do not materially interfere with the ordinary conduct of the business of the applicable Person;

(i) leases or subleases granted to others in the ordinary course of business and as permitted under this Agreement, and not interfering in any material respect with the Revenue Participation Right, the Product Rights, the Product Collateral, or the Security Documents;

(j) any interest of title of a lessor under, and Liens arising from UCC financing statements (or equivalent filings, registrations or agreements in foreign jurisdictions) relating to, leases permitted by this Agreement;

(k) normal and customary Liens and rights of setoff upon deposits of cash and securities in favor of banks or other depository institutions;

(l) normal and customary Liens on cash and cash equivalents incurred to secure treasury, depository, overdraft, cash pooling, netting, credit card processing services, foreign exchange swap obligations, electronic funds transfer (including automated clearing house funds transfers), and other cash management arrangements;

(m) Liens on specific items of inventory or other goods (and the proceeds thereof) of the Company securing such Person's obligations in respect of bankers' acceptances issued or created for the account of such Person to facilitate the purchase, shipment or storage of such inventory or other goods;

(n) Liens arising out of conditional sale, title retention, consignment or similar arrangements for the sale of goods entered into in the ordinary course of business;

(o) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of customs duties in connection with the importation of goods in the ordinary course of business;

(p) Liens in the nature of right of setoff in favor of counterparties to contractual agreements with the Company in the ordinary course of business; and

(q) Liens securing Permitted Secured Debt.

"Permitted Secured Debt" means: (a) obligations under Capital Leases and purchase money financings, (b) Indebtedness related to insurance premium financing arrangements, (c) reimbursement obligations in respect of letters of credit and banker's acceptances (other than letters of credit securing Indebtedness for borrowed money or obligations in respect of any royalty or revenue interest sale or financing) and (d) other Indebtedness, in each case of (a), (b), (c) and (d) to the extent the Permitted Secured Debt is secured by Lien(s) on any of the Product Collateral and subject to an Acceptable Intercreditor Agreement executed and delivered by the Payer, the Company, and the applicable Senior Debt Provider.

"Person" means any individual, firm, corporation, company, partnership, limited liability company, trust, joint venture, association, estate, trust, Governmental Entity or other entity, enterprise, association or organization.

"Pre-Paid Forward Price" is defined in Section 2.2.

"Prime Rate" means the prime rate published by The Wall Street Journal, from time to time, as the prime rate.

"Product" and "Products" means, individually and collectively, Jelmyto and UGN-102.

"Product Collateral" means the Company's rights, title and interests in (a) the Products (including all inventory of the Products), (b) the Product Rights owned, licensed or otherwise held by the Company, (c) Payer Priority Collateral and (d) any proceeds in addition to those described in clause (c) from either (a) or (b) above, including all accounts receivable and general intangibles resulting from the sale, license or other disposition of Products by the Company or its Licensees. Notwithstanding the foregoing, "Product Collateral" shall not include any Excluded Collateral.

"Product Rights" means any and all of the following, as they exist throughout the world: (a) Intellectual Property Product Rights, (b) regulatory filings, submissions and approvals, including Marketing Approvals, with or from any Regulatory Authorities with respect to any of the Products, (c) In-Licenses, (d) Commercialization Licenses, and (e) agreements necessary for, or otherwise material to, the development, manufacture, use, marketing, promotion, sale or distribution of any of the Products.

"Quarterly Deadline" is defined in Section 6.1(a).

"Receiving Party" is defined in Section 8.1.

"Regulatory Authority" means any national or supranational governmental authority, including the FDA, the EMA or such equivalent regulatory authority, or any successor agency thereto, that has responsibility in granting a Marketing Approval.

"Regulatory Exclusivity Period" shall mean, with respect to each Product in any country, any period of data, market or other regulatory exclusivity (other than Patent exclusivity) granted or afforded by law or by a Regulatory Authority in such country that confers exclusive marketing rights with respect to such Product in such country or prevents another party from using or otherwise relying on any data supporting the Marketing Approval for such Product.

"Regulatory Updates" means [***].

"Related Party" is defined in the definition of "Net Sales".

"Remaining Obligations" means the lesser of (x) the Revenue Payment Cap less Revenue Payments actually received by the Payer at such time and (y) the [***] to be payable through [***] (without regard to any bankruptcy or insolvency of the Company, any of its Affiliates or any Third Party) (which shall be determined in accordance with Exhibit B).

"Report" is defined in Section 6.1.

"Representative" means, with respect to any Person, (a) any direct or indirect member or partner of such Person and (b) any manager, director, trustee, officer, employee, agent, advisor or other representative (including attorneys, accountants, consultants, contractors, actual and potential lenders, investors, co-investors and assignees, bankers and financial advisers) of such Person.

"Revenue Participation Right" means the right to receive the Revenue Payments on account of Net Sales of Products on or after the Effective Date and prior to the Revenue Payment Termination Date.

"Revenue Payment Cap" means if the aggregate payments of the Revenue Payments received by the Payer are equal to or greater than $300,000,000.

"Revenue Payments" means the Jelmyto Revenue Payments and UGN-102 Revenue Payments.

"Revenue Payment Termination Date" means the date at the end of the calendar quarter in which aggregate payments of the Revenue Payments actually received by the Payer equal the Revenue Payment Cap.

"RTGel" means the Company's proprietary hydrogel polymer reverse-thermal composition known as "RTGel™".

"RTGel Improvement" means any improvement, invention or discovery relating to (a) the composition or formulation of RTGel or (b) the method of manufacturing or administration of RTGel, including in each cases of (a) and (b), as such improvement, invention, or discovery relates to RTGel by itself or in combination with one or more additional therapeutically or prophylactically active pharmaceutical or biologic ingredients other than any [***].

"Safety Notices" means any recalls, field notifications, market withdrawals, warnings, "dear doctor" letters, investigator notices, safety alerts or other notices of action issued or instigated by the Company, any of its Affiliates or any Regulatory Authority relating to an alleged lack of safety or regulatory compliance of any Product.

"Securities Act" means the Securities Act of 1933, as amended.

"Security Documents" means the U.S. Security Documents and the Israeli Security Agreement.

"Senior Debt Provider" means, collectively, the lenders or providers (or its or their agents or representatives, as applicable) of Indebtedness secured by Lien(s) on any of the Product Collateral that enter into an Acceptable Intercreditor Agreement executed and delivered by the Payer, the Company, and the applicable Senior Debt Provider.

"Solvent" means it is able (and has not admitted its inability) to pay its debts as they fall due, its obligations (including known future and contingent obligations) do not exceed the value of its assets or it is otherwise not deemed insolvent under applicable law (including under the Israeli Insolvency Law).

"Subsidiary" means any and all corporations, partnerships, limited liability companies, joint ventures, associations and other entities controlled (by contract or otherwise) by the Company directly or indirectly through one or more intermediaries. For purposes hereof, the Company shall be deemed to control a partnership, limited liability company, association or other business entity if the Company, directly or indirectly through one or more intermediaries, shall be allocated a majority of partnership, limited liability company, association or other business entity gains or losses or shall be or control the managing director or general partner of such partnership, limited liability company, association or other business entity.

"Tax" or "Taxes" means any income, gross receipts, license, payroll, employment, excise, severance, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, abandoned property, value added, alternative or add-on minimum, estimated or other tax of any kind whatsoever, including any interest, penalty or addition thereto, whether disputed or not.

"Territory" means all countries of the world.

"Third Party" means any Person that is not the Company or the Company's Affiliates.

"Transaction Documents" means this Agreement, the Security Documents, any closing certificate, and any other documents or agreements to be delivered pursuant to this Agreement and the Security Documents.

"Transaction Expenses" means the aggregate amount of any and all documented fees and expenses reasonably incurred by or on behalf of, or paid or to be paid directly by, the Payer in connection with the diligence of the transactions contemplated hereby or thereby, and the negotiation, preparation or execution of the Transaction Documents and any ancillary documents, the filing, registration and perfection of the Transaction Documents, or the performance or consummation of the transactions contemplated hereby or thereby [***].

"UCC" means the Uniform Commercial Code as in effect from time to time in the State of New York; provided, that, if, with respect to any financing statement or by reason of any provisions of applicable law, the perfection or the effect of perfection or non-perfection of the security interest or any portion thereof granted pursuant to Section 2.1(b) is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than the State of New York, then "UCC" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of this Agreement and any financing statement relating to such perfection or effect of perfection or non-perfection.

"UGN-102" means (a) the pharmaceutical product known as UGN-102 (mitomycin) for intravesical solution, (b) 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 (c) any pharmaceutical product that contains any of the foregoing, in each case of (a)–(c), in any dosage form, dosing regimen, strength, or route of administration.

"UGN-102 Delay Payment" is defined in the definition of "Jelmyto Net Sales Revenue Rate".

"UGN-102 Net Sales" means Net Sales of UGN-102.

"UGN-102 Net Sales Revenue Rate" means the applicable percentage based on the portion of the corresponding level of worldwide annual UGN-102 Net Sales in a calendar year as set forth in the chart below:

Payment Tiers based on Annual UGN-102 Net Sales	**UGN-102 Net Sales Revenue Rate Applicable to Each Net Sales Tier**
A. Annual UGN-102 Net Sales of up to $200,000,000	2.5%
B. Annual UGN-102 Net Sales exceeding $200,000,000 and less than or equal to $300,000,000	1.0%
C. Annual UGN-102 Net Sales in excess of $300,000,000	0.5%

"UGN-102 Revenue Payments" means, for each calendar quarter, an amount payable to the Payer equal to the amount of worldwide aggregate annual UGN-102 Net Sales during such calendar quarter multiplied by the UGN-102 Net Sales Revenue Rate. For clarity, the UGN-102 Net Sales Revenue Rate used to calculate the UGN-102 Revenue Payments for a given date in a calendar quarter (a) will be based on the worldwide aggregate annual UGN-102 Net Sales billed or invoiced for the calendar year through and including such date, and (b) may be different for different periods during such calendar quarter depending on the specific date the worldwide aggregate UGN-102 Net Sales crosses over to the next payment tier. By way of example, if worldwide aggregate UGN-102 Net Sales invoiced as of (i) April 12 for the calendar year equal $185,000,000, (ii) April 13 for the calendar year equal $210,000,000, and (c) June 30 for the calendar year equal $295,000,000, then the UGN-102 Net Sales Revenue Rate for such calendar quarter shall be equal to 2.5% with respect to UGN-102 Net Sales through and including April 12, and 1.0% with respect to UGN-102 Net Sales from April 13 through and including June 30.

"U.S. Security Documents" means the security agreements to be governed by U.S. law and granted by the Company in favor of the Payer pursuant to which the Company grants the Payer a security interest over the Product Collateral and the Patent Rights.

"Valid Claim" shall mean: (a) any claim of an issued and unexpired Patent included within the Patent Rights, that shall not have been withdrawn, lapsed, abandoned, revoked, canceled or disclaimed, or held invalid or unenforceable by a court, Governmental Entity, national or regional patent office or other appropriate body that has competent jurisdiction in a decision being final and unappealable or unappealed within the time allowed for appeal; and (b) a claim of a pending Patent application included within the Patent Rights that is filed and being prosecuted in good faith and that has not been finally abandoned or finally rejected and which has been pending for no more than seven years from the date of filing of the earliest Patent application to which such pending Patent application claims priority.

"Withholding Action" is defined in Section 6.16(b).

Section 1.2 Certain Interpretations. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

(a) "either" and "or" are disjunctive but not necessarily exclusive and "include," "includes" and "including" are not limiting and shall be deemed to be followed by the words "without limitation";

(b) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if";

(c) "hereof," "hereto," "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement;

(d) references to a Person are also to its permitted successors and assigns;

(e) definitions are applicable to the singular as well as the plural forms of such terms;

(f) references to an "Article", "Section" or "Exhibit" refer to an Article or Section of, or an Exhibit to, this Agreement, and references to a "Schedule" refer to the corresponding part of the Disclosure Schedule;

(g) references to "$" or otherwise to dollar amounts refer to the lawful currency of the United States; and

(h) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement.

ARTICLE 2
GRANT OF THE REVENUE PARTICIPATION RIGHT

Section 2.1 Grant.

(a) At the Closing and upon the terms and subject to the conditions of this Agreement, the Company shall grant to the Payer, and the Payer shall receive and accept from the Company, the Revenue Participation Right, free and clear of all Liens, except for any Liens in favor of, or granted by or otherwise applicable to, the Payer and Liens for Taxes, assessments or governmental charges or levies not yet due. Immediately upon the grant to the Payer by the Company of the Revenue Participation Right pursuant to this Section 2.1, all of the Company's right, title and interest in and to the Revenue Participation Right shall terminate, and all such right, title and interest shall vest in the Payer.

(b) As security for the payment and fulfilment of the Payment Obligations, until the Minimum Return Date, (i) the Company does hereby grant to the Payer a first priority security interest in and to all right, title and interest in, to and under the Product Collateral, and (ii) the Company does hereby grant to the Payer a security interest in and to all right, title and interest in, to and under the Revenue Participation Right and the Revenue Payments, in each case, pursuant to the terms of the Security Documents. The Company hereby authorizes the Payer, from and after the Closing, to file financing statements (and continuation statements with respect to such financing statements when applicable) naming the Company as the debtor and the Payer as the secured party, and in such manner and such jurisdictions as are necessary or appropriate to perfect the Security Documents (including, without limitation, in Israel and the United States), including updating such financing statements when and if there are any new Intellectual Property Product Rights; provided that, notwithstanding the foregoing, the Security Documents (and the collateral thereunder) shall not include, and shall not extend to any Excluded Collateral.

(c) Upon the receipt of Marketing Approval in any Covered Jurisdiction outside of Israel and the United States, and until the Minimum Return Date, the Company shall take such actions as reasonably requested by the Payer (including the filing of any financing statements, and any continuation statements with respect to such financing statements when applicable) to grant and perfect the security interest granted hereby and by the Security Documents with respect to any Patent Rights and Marketing Approvals constituting Product Collateral and any other material Product Collateral located in such jurisdiction (to the extent reasonably practicable).

Section 2.2 Pre-Paid Forward Price. At the Closing and upon the terms and subject to the conditions of this Agreement, the price to be paid as consideration to the Company for the grant of the Revenue Participation Right to the Payer is Seventy-Five Million Dollars ($75,000,000) in cash (the "Pre-Paid Forward Price").

Section 2.3 No Assumed Obligations, Etc. Notwithstanding any provision in this Agreement to the contrary, the Payer is only agreeing, on the terms and conditions set forth in this Agreement, to receive and accept the Revenue Participation Right and is not assuming any liability or obligation of the Company of whatever nature, whether presently in existence or arising or asserted hereafter.

ARTICLE 3
CLOSING

Section 3.1 Closing. The Closing shall take place remotely via the exchange of documents and signatures on the date that is two Business Days after the satisfaction or waiver of the conditions set forth in ARTICLE 5 (other than those conditions that by their nature are to be satisfied at the Closing), or as otherwise mutually agreed by the Payer and the Company.

Section 3.2 Payment of Pre-Paid Forward Price. The Escrow Agent shall be instructed to automatically release the payment of the Pre-Paid Forward Price to the Company at the Closing by electronic funds transfer or wire transfer of immediately available funds to one or more accounts specified by the Company pursuant to Section 6.15.

ARTICLE 4
REPRESENTATIONS AND WARRANTIES

Section 4.1 Company's Representations and Warranties. Except as set forth on the Disclosure Schedules attached hereto, the Company hereby represents and warrants to the Payer that as of the date hereof and as of the Closing Date:

(a) Existence; Good Standing. The Company is a corporation duly incorporated, validly existing and in good standing under the laws of Israel. The Company is duly licensed or qualified to do business and is in corporate good standing in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned, leased or operated by it makes such licensing or qualification necessary, except where the failure to be so licensed or qualified and in corporate good standing has not and would not reasonably be expected to have, either individually or in the aggregate, a Material Adverse Effect. The Company is not a "company in violation" ("hevrah meferah") as defined in Section 362A of the Israeli Companies Law and it has not received notice that it is expected to be registered as such.

(b) Authorization. The Company has all requisite corporate power and authority to execute, deliver and perform its obligations under the Transaction Documents. The execution, delivery and performance of the Transaction Documents, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary corporate action on the part of the Company.

(c) Enforceability. The Transaction Documents have been duly executed and delivered by an authorized officer of the Company and constitute the valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) No Conflicts. The execution, delivery and performance by the Company of the Transaction Documents and the consummation of the transactions contemplated hereby and thereby do not and will not (i) contravene or conflict with the Articles of Association of the Company, (ii) contravene or conflict with or constitute a material default under any law binding upon or applicable to the Company or the Revenue Participation Right or (iii) contravene or conflict with or constitute a material default under any material agreement or Judgment binding upon or applicable to the Company or the Revenue Participation Right.

(e) Consents. Except for the consents that have been obtained on or prior to the Closing, the UCC financing statements contemplated by Section 2.1(b), or any filings required by the federal securities laws or stock exchange rules, or any filings and registrations of the Security Documents at the Israeli Registrar of Companies and to the extent applicable, at the Israeli Patent Office, no consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by the Company in connection with (i) the execution and delivery by the Company of the Transaction Documents, (ii) the performance by the Company of its obligations under the Transaction Documents or (iii) the consummation by the Company of any of the transactions contemplated by the Transaction Documents.

(f) No Litigation. Neither the Company nor any of its Subsidiaries is a party to, and has not received any written notice of, any action, suit, investigation or proceeding pending before any Governmental Entity and, to the Knowledge of the Company, no such action, suit, investigation or proceeding has been threatened against the Company, that, individually or in the aggregate, has had or would, if determined adversely, reasonably be expected to have a Material Adverse Effect.

(g) Compliance.

(i) All applications, submissions, information and data related to a Product submitted or utilized as the basis for any request to any Regulatory Authority by or on behalf of the Company were true and correct in all material respects as of the date of such submission or request, and, to the Knowledge of the Company any material updates, changes, corrections or modification to such applications, submissions, information or data required under applicable laws or regulations have been submitted to the necessary Regulatory Authorities.

(ii) Neither the Company nor any of its Subsidiaries has committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA or EMA to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", or similar policies, set forth in any applicable laws or regulations.

(iii) The Company has provided to the Payer prior to the date hereof in a data room available to the Payer true and correct copies or summaries of all material written communications sent or received by the Company and any of its Affiliates to or from any Regulatory Authorities that relate to each Product since [***].

(iv) None of the Company, any of its Subsidiaries and, to the Knowledge of the Company, any Third Party manufacturer of any Product, has received from the FDA a "Warning Letter", Form FDA-483, "Untitled Letter," or similar material written correspondence or notice alleging violations of applicable laws and regulations enforced by the FDA, or any comparable material written correspondence from any other Regulatory Authority with regard to either Product or the manufacture, processing, packaging or holding thereof, the subject of which communication is unresolved and if determined adversely to the Company or such Subsidiary would, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(v) Since [***], (A) there have been no Safety Notices, (B) to the Knowledge of the Company, there are no unresolved material product complaints with respect to any Product, which would result in a Material Adverse Effect, and (C) to the Knowledge of the Company, there are no facts currently in existence that would, individually or in the aggregate, reasonably be expected to result in (1) a material Safety Notice with respect to any Product, or (2) a material change in the labeling of any Product. Since [***], neither the Company nor any of its Subsidiaries has experienced any significant failures in the manufacturing of any Product for clinical use or commercial sale that, individually or in the aggregate, have had or would reasonably be expected to result in, if such failure occurred again, a Material Adverse Effect.

(h) Licenses.

(i) In-Licenses. There are no In-Licenses.

(ii) Out-Licenses. There are no Out-Licenses other than Excluded Out-Licenses.

(i) No Liens; Title to Revenue Participation Right. Neither the Product Collateral nor any of the property or assets, in each case, that specifically relate to the Products, including Intellectual Property Rights, of the Company or any of its Subsidiaries is subject to any Lien, except for any Permitted Lien or any non-exclusive license or rights to use granted to customers, suppliers, manufacturers or service providers in the ordinary course of business.

(j) Manufacturing; Supply. All Products have, since [***], been manufactured, transported, stored and handled in all material respects in accordance with applicable law and with good manufacturing practices. Since [***], neither the Company nor any Affiliate of the Company has experienced any significant failures in the manufacturing or supply of any Product that, individually or in the aggregate, have had or would reasonably be expected to result in, if such failure occurred again, a Material Adverse Effect. The Company has on hand or has made adequate provisions to secure sufficient clinical quantities of Products to complete all clinical trials and all activities required for Marketing Approvals, in each case, that are ongoing or planned as of the date hereof. The Company has on hand or has made adequate provisions to secure sufficient quantities of Jelmyto to support the commercial launch of Jelmyto in the Territory.

(k) Intellectual Property.

(i) Schedule 4.1(k)(i)(A) of the Disclosure Schedule lists all of the currently existing Patents included within the Patent Rights (other than the Non-Exclusive Patent Rights) (the "Existing Patent Rights"). Except as set forth on Schedule 4.1(k)(i)(A) of the Disclosure Schedule, the Company is the sole and exclusive registered owner of all of the Existing Patent Rights. Schedule 4.1(k)(i)(A) of the Disclosure Schedule specifies as to each listed patent or patent application the jurisdictions by or in which each such patent has issued as a patent or such patent application has been filed, including the respective patent or application numbers. The Existing Patent Rights comprise all the Patent Rights (other than the Non-Exclusive Patent Rights) that are owned or in-licensed by the Company or any of its Affiliates or under which the Company or any of its Affiliates is or may become empowered to grant licenses that are necessary for, or used in, the development, manufacture, use, marketing, promotion, sale or distribution of a Product as of the date hereof and the Closing Date.

(ii) Neither Company nor any of its Subsidiaries is a party to any pending and, to the Knowledge of the Company, there is no threatened, litigation, interference, reexamination, opposition or like procedure involving any of the Existing Patent Rights.

(iii) All of the issued patents within the Existing Patent Rights are (A) to the Knowledge of the Company, valid and enforceable, and (B) in full force and effect. None of the issued patents within the Existing Patent Rights have lapsed, expired or otherwise terminated. Neither Company nor any of its Subsidiaries has received any written notice relating to the lapse, expiration or other termination of any of the issued patents within the Existing Patent Rights, and neither Company nor its Subsidiaries has received any written legal opinion that alleges that, an issued patent within any of the Existing Patent Rights is invalid or unenforceable.

(iv) Neither Company nor any of its Subsidiaries has received any written notice that there is any, and, to the Knowledge of the Company, there is no, Person who is or claims to be an inventor under any of the Existing Patent Rights who is not a named inventor thereof.

(v) Neither the Company not its Affiliates has received any written notice of any claim by any Person challenging the inventorship or ownership of, the rights of the Company in and to, or the patentability, validity or enforceability of, any of the Existing Patent Rights, or asserting that the development, manufacture, importation, sale, offer for sale or use of the Product infringes, misappropriates or otherwise violates or will infringe, misappropriate or otherwise violate such Person's Patents or other intellectual property rights.

(vi) To the Knowledge of the Company, the discovery, development manufacture, importation, sale, offer for sale or use of each Product, in each case in the form such Product exists as of the date hereof and as such activity is currently contemplated by the Company, has not and will not, infringe, misappropriate or otherwise violate any Patents or other intellectual property rights owned by any Third Party.

(vii) To the Knowledge of the Company, no Person has infringed, misappropriated or otherwise violated, or is infringing, misappropriating or otherwise violating, any of the Intellectual Property Rights.

(viii) The Company has paid all maintenance fees, annuities and like payments required as of the date hereof with respect to each of the Existing Patent Rights.

(ix) The Company does not have any obligations to the Innovation Authority in Israel ("IIA") (including any payments or royalties) nor has it applied for any grant from the IIA which has not been repaid in full or terminated, other than the commitment to continue to employ at least 75% of its research and development jobs in Israel (at the time of the settlement between the Company and the IIA regarding unwinding the Company's obligations to the IIA regarding grants that were loaned by the IIA to the Company between January 2004 and September 2016) for a period of at least [***], until [***], which such commitment the Company is in full compliance with. There are no restrictions on transferring or pledging the Product Collateral and the Payer Priority Collateral or manufacturing the Products outside of the State of Israel, nor is any approval required from the IIA for the transactions contemplated by this Agreement and the other Transaction Documents (including the grant of the Security Documents).

(l) Indebtedness. The Company does not have any outstanding Indebtedness in excess of $[***] in the aggregate principal amount.

(m) Solvency. No Insolvency Event has occurred in respect of the Company. The Company has no plan or intention of, and the Company has not received any notice that any other Person has any plan or intention of, filing, making, or obtaining any petition, notice, Order, or resolution as specified in the definition of Insolvency Event or of seeking the appointment of a receiver, trustee, custodian, or similar fiduciary as specified in clause (e) of the definition of Insolvency Event. The Company is Solvent and has sufficient assets and capital to carry on its business as currently conducted and to perform its obligations hereunder.

(n) Security. At the Closing, and upon filing, registration and perfection of the Security Documents within the time periods required by applicable law, the Payer will have a valid first priority security interest in and to all right, title and interest in, to and under the Product Collateral.

(o) Lien Related Representation and Warranties. The Company's exact legal name is, and for the immediately preceding five years has been, "UroGen Pharma Ltd." The Company is, and for the prior five years has been, incorporated in Israel.

(p) Brokers' Fees. Except for Cowen and Company, there is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of the Company who might be entitled to any fee or commission in connection with the transactions contemplated by the Transaction Documents.

Section 4.2 Payer's Representations and Warranties. The Payer hereby represents and warrants to the Company that as of the date hereof and as of the Closing Date:

(a) Existence; Good Standing. The Payer is an Irish Collective Asset-management Vehicle registered in Ireland as an umbrella fund with segregated liability between sub-funds, for and on behalf of its sub-fund, RTW Fund 2.

(b) Authorization. The Payer has the requisite trust right, power and authority to execute, deliver and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated hereby, have been duly authorized by all necessary action on the part of the Payer.

(c) Enforceability. This Agreement has been duly executed and delivered by an authorized person of the owner trustee of the Payer and constitutes the valid and binding obligation of the Payer, enforceable against the Payer in accordance with its terms, except as may be limited by applicable Bankruptcy Laws or by general principles of equity (whether considered in a proceeding in equity or at law).

(d) No Conflicts. The execution, delivery and performance by the Payer of this Agreement do not and will not (i) contravene or conflict with the organizational documents of the Payer, (ii) contravene or conflict with or constitute a default under any material provision of any law binding upon or applicable to the Payer or (iii) contravene or conflict with or constitute a default under any material contract or other material agreement or Judgment binding upon or applicable to the Payer.

(e) Consents. Except for any filings required by the federal securities laws or stock exchange rules, no consent, approval, license, order, authorization, registration, declaration or filing with or of any Governmental Entity or other Person is required to be done or obtained by the Payer in connection with (i) the execution and delivery by the Payer of this Agreement, (ii) the performance by the Payer of its obligations under this Agreement or (iii) the consummation by the Payer of any of the transactions contemplated by this Agreement.

(f) No Litigation. There is no action, suit, investigation or proceeding pending or, to the knowledge of the Payer, threatened before any Governmental Entity to which the Payer is a party that would, if determined adversely, reasonably be expected to prevent or materially and adversely affect the ability of the Payer to perform its obligations under this Agreement.

(g) Financing. The Payer has sufficient cash to pay the Pre-Paid Forward Price at the Closing. The Payer acknowledges that its obligations under this Agreement are not contingent on obtaining financing.

(h) Brokers' Fees. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of the Payer who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

(i) Tax Residency. The Payer is a resident of Ireland for Irish tax purposes and, as of the date hereof and as a matter of Irish law, is treated as eligible to claim the benefit of the double tax treaty concluded (a) between Ireland and the State of Israel and (b) between Ireland and the United States.

Section 4.3 No Implied Representations and Warranties. The Payer acknowledges and agrees that, other than the express representations and warranties of the Company specifically contained in ARTICLE 4 and the other Transaction Documents, (a) there are no representations or warranties of the Company either expressed or implied with respect to the Patent Rights or Revenue Payment and that the Payer does not rely on, and shall have no remedies in respect of, any representation or warranty not specifically set forth in ARTICLE 4 and the other Transaction Documents, and all other representations and warranties are hereby expressly disclaimed, and (b) nothing contained herein guarantees that sales of the Products or the aggregate Revenue Payments due to the Payer will achieve any specific amounts (it being understood and agreed that nothing in this Section 4.3 shall limit in any way the Company's obligations under ARTICLE 8). Notwithstanding the foregoing, claims for fraud, gross negligence, or willful misconduct shall not be waived or limited in any way by this Section 4.3. Except for the Revenue Participation Right, the Security Documents and the Payer's rights under Section 6.5(d), the Payer further acknowledges and agrees that no licenses or assignments under any assets (including the Patent Rights or any other intellectual property) of the Company and its Affiliates are granted pursuant to this Agreement, including by implication, estoppel, exhaustion or otherwise.

ARTICLE 5
CONDITIONS TO CLOSING

Section 5.1 Conditions to the Payer's Obligations. The obligations of the Payer to consummate the transactions contemplated hereunder on the Closing Date are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) The Company shall have performed and complied in all material respects with all agreements, covenants, obligations and conditions required to be performed and complied with by it under this Agreement at or prior to the Closing Date, and the Payer shall have received a certificate executed by a duly authorized officer of the Company on the Closing Date certifying on behalf of the Company to the effect of the foregoing.

(b) The representations and warranties of the Company contained in Section 4.1 shall have been true and correct in all material respects as of the date hereof and shall be true and correct in all material respects as of the Closing Date as though made at and as of the date hereof and as of the Closing Date, respectively, except to the extent any such representation or warranty expressly speaks as of a particular date, in which case it shall be true and correct in all material respects as of such date; provided that, to the extent that any such representation or warranty is qualified by the term "material" or "Material Adverse Effect," such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Closing Date or such other date, as applicable. The Payer shall have received a certificate executed by an authorized officer of the Company on the Closing Date certifying on behalf of the Company to the effect of the foregoing.

(c) No event or events shall have occurred, or be reasonably likely to occur, that, individually or in the aggregate, have had or would reasonably be expected to result in (or, with the giving of notice, the passage of time or otherwise, would result in) a Material Adverse Effect. The Payer shall have received a certificate executed by a duly authorized officer of the Company on the Closing Date certifying on behalf of the Company to the effect of the foregoing.

(d) There shall not have been issued and be in effect any Judgment of any Governmental Entity enjoining, preventing or restricting the consummation of the transactions contemplated by this Agreement.

(e) There shall not have been instituted or be pending any action or proceeding by any Governmental Entity or any other Person (i) challenging or seeking to make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the consummation of the transactions contemplated hereby, (ii) seeking to obtain material damages in connection with the transactions contemplated hereby or (iii) seeking to restrain or prohibit the Payer's receipt and acceptance of the Revenue Participation Right.

(f) The Company shall have delivered to the Payer the legal opinions of Cooley LLP and Hamburger Evron & Co., each as counsel to the Company, in substantially the forms attached hereto as Exhibit A.

(g) The Payer shall have received a certificate of an officer of the Company, dated the Closing Date, certifying as to (i) the incumbency of each officer of the Company executing this Agreement and (ii) the attached thereto copies of (A) the Company's Articles of Association, and (B) resolutions adopted by the Company's Board authorizing the execution and delivery by the Company of this Agreement and the consummation by the Company of the transactions contemplated hereby (the "Company Certificate").

(h) The Company shall have confirmed it has scheduled delivery to Payer of a CD or USB containing copies of all documents uploaded to the Datasite data room related to the transactions contemplated by this Agreement, as of the date hereof, maintained by the Company and made available to the Payer, including all documents referred to in Section 4.1(g)(iii) and Section 4.1(h)(ii).

(i) The Company shall have executed and delivered the Security Documents in form and substance reasonably acceptable to the Payer, and all deliverables required in connection with the Security Documents and their registration or perfection, including: (i) an original notice of charge (Form 10) with respect to each of the Security Documents, as required for the registration of each of the Security Documents at the Israeli Registrar of Companies and (ii) a power of attorney duly completed and signed by an authorized representative(s) of the Company in favor of the Payer's Israeli legal counsel, with respect to the registration of the Liens over the Israeli Patents at the Israeli Patent Office.

(j) The Security Documents, including any deliverables required, shall have been filed at all applicable registries (including the Israeli Registrar of Companies and in respect of any Israeli Patents, at the Israeli Patent Office) in each applicable jurisdiction and the actual completed registration of such Security Documents at such registries shall have been obtained.

Section 5.2 Conditions to the Company's Obligations. The obligations of the Company to consummate the transactions contemplated hereunder on the Closing Date are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) The Payer shall have performed and complied in all material respects with all agreements, covenants, obligations and conditions required to be performed and complied with by it under this Agreement at or prior to the Closing Date, and the Company shall have received a certificate executed by a duly authorized representative of the Payer on the Closing Date certifying on behalf of the Payer to the effect of the foregoing.

(b) The representations and warranties of the Payer contained in Section 4.2 shall have been true and correct in all material respects as of the date hereof and shall be true and correct in all material respects as of the Closing Date as though made at and as of the date hereof and Closing Date, respectively, except to the extent any such representation or warranty expressly speaks as of a particular date, in which case it shall be true and correct in all material respects as of such date; provided, that to the extent that any such representation or warranty is qualified by the term "material," or "Material Adverse Effect" such representation or warranty (as so written, including the term "material" or "Material Adverse Effect") shall have been true and correct in all respects as of the date hereof and shall be true and correct in all respects as of the Closing Date or such other date, as applicable. The Company shall have received a certificate executed by a duly authorized officer of the Payer on the Closing Date certifying on behalf of the Payer to the effect of the foregoing.

(c) There shall not have been issued and be in effect any Judgment of any Governmental Entity enjoining, preventing or restricting the consummation of the transactions contemplated by this Agreement.

(d) There shall not have been instituted or be pending any action or proceeding by any Governmental Entity or any other Person (i) challenging or seeking to make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the consummation of the transactions contemplated hereby, (ii) seeking to obtain material damages in connection with the transactions contemplated hereby or (iii) seeking to restrain or prohibit the Payer's receipt and acceptance of the Revenue Participation Right.

(e) The Payer shall have delivered to the Company standard existence and authority opinions in respect of the Payer, enforceability opinions on this Agreement, and an opinion that this Agreement does not conflict with the organizational documents of the Payer or applicable law, each such opinion in a form previously agreed upon by the Company and the Payer.

(f) The Company shall have received a certificate of an authorized person of the owner trustee of the Payer, dated the Closing Date, certifying as to the incumbency of the officers executing this Agreement on behalf of the Payer.

(g) The Payer shall have executed and delivered the Security Documents in form and substance reasonably acceptable to the Payer, and all deliverables required thereunder.

(h) The Payer shall complete, sign and deliver a United States Internal Revenue Service Form W-8BEN-E certifying that it is exempt from U.S. federal withholding Tax under a United States income Tax treaty with respect to each of "royalties," "interest" and "other income" and shall, to the extent permitted under applicable law, update such form upon the expiration, obsolescence or other invalidity of such form.

(i) The Payer shall complete, sign and deliver, to the extent applicable, an official tax residency certificate for the purpose of applying benefits under the double tax treaty between the state of Israel and Ireland, issued by the Irish revenue commissioners and shall, to the extent permitted under applicable law, update such form upon the expiration, obsolescence or other invalidity of such forms.

ARTICLE 6
COVENANTS

Section 6.1 Reporting. From and after the date hereof and until the Revenue Payment Termination Date, the Company shall provide the Payer:

(a) concurrently with, and in any case no later than the [***] after, the earlier of the following dates (the "Quarterly Deadline"): (i) the filing of the Quarterly Report on Form 10-Q or Annual Report on Form 10-K, as applicable, for the immediately preceding quarter and (ii) the applicable due date for such reports (but in no event later than [***] following the end of the first three fiscal quarters and [***] following the end of the fourth fiscal quarter), a reasonably detailed quarterly report setting forth, with respect to such same period, (A) the [***], (B) the [***], (C) the [***], and (D) the [***] (collectively the "Reports"); provided that for any such updates made by a Licensee or other Third Party for which the Company receives such update fewer than [***] prior to the Quarterly Deadline, such update will be included in the following calendar quarter's Reports;

(b) the Company shall include in each Report any (i) material [***] updates and (ii) reasonable details as to the achievement of any [***] set forth in each Commercialization License; and

(c) the Company shall also provide the Payer with such additional information regarding the updates included in each Report as the Payer may reasonably request from time to time. The Company shall meet [***] (or as otherwise requested by the Payer) with the Payer to review such Reports and any other material updates. The Company shall prepare and maintain and shall cause its Affiliates and use commercially reasonable efforts to cause Licensees to prepare and maintain reasonably complete and accurate records of the information to be disclosed in each Report. All Reports, and the Confidential Information contained therein, shall be the Confidential Information of Company and subject to the obligations of confidentiality set forth in ARTICLE 8.

Section 6.2 Revenue Payments; Revenue Participation and Revenue Payment Details.

(a) From and after the Closing Date and until the Revenue Payment Termination Date, the Company shall pay to the Payer, without any setoff or offset (subject, in each case, to Section 6.16), the Revenue Payment for each calendar quarter on the [***], provided that for any Net Sales made by a Licensee for which payment is received by the Company fewer than [***] prior to the [***], such payment to the Payer will be paid with the following calendar quarter's Revenue Payment. The Revenue Payment payable for the calendar quarter during which the Closing occurs shall be prorated from the Effective Date through the end of such calendar quarter. A late fee of [***]% over the Prime Rate (calculated on a per annum basis) will accrue on all unpaid amounts with respect to any Revenue Payment from the date such obligation was due. The imposition and payment of a late fee shall not constitute a waiver of the Payer's rights with respect to such payment default.

(b) From and after the Closing Date and until the Revenue Payment Termination Date, the Company shall deliver to Payer a report for each [***] concurrently with, and in any case no later than the [***] after, the [***], in a form to be mutually agreed to by the parties, setting forth in reasonable detail with respect to each Product, (i) Gross Sales and Net Sales for the applicable [***] and [***], on a country-by-country basis (including a reasonably detailed break-down of all permitted deductions from Gross Sales used to determine Net Sales and any proceeds treated as Net Sales pursuant to Section 6.5(d)), and (ii) (A) the calculation of the Revenue Payment payable to the Payer for the applicable [***], identifying, on a country-by-country basis, the number of units of each Product sold by the Company, its Affiliates and each Licensee and (B) foreign currency exchange rates used (which shall be rates of exchange determined in a manner consistent with the Company's method for calculating rates of exchange in the preparation of the Company's annual financial statements in accordance with GAAP); provided that, for any reports received by the Company with respect to Net Sales by Licensees fewer than [***] prior to the [***], the Company shall deliver to the Payer the relevant information from such reports in the following [***]'s report.

(c) Any payments required to be made by either party under this Agreement shall be made in United States Dollars via electronic funds transfer or wire transfer of immediately available funds to such bank account as the other party shall designate in writing prior to the date of such payment.

Section 6.3 Disclosures. Except for a press release and the Company's Current Report on Form 8-K describing the material terms of this Agreement and the transactions contemplated by this Agreement, in each case previously approved in form and substance by the Company and the Payer, or any other public announcement using substantially the same disclosure as such press release or Form 8-K, neither the Payer nor the Company shall, and each party hereto shall cause its respective Representatives, Affiliates and Affiliates' Representatives not to, issue a press release or other public announcement or otherwise make any public disclosure with respect to this Agreement or the subject matter hereof without the prior written consent of the other party hereto (which consent shall not be unreasonably withheld or delayed), except as may be required by applicable law, regulation or stock exchange rule (in which case the party hereto required to make the press release or other public announcement or disclosure shall allow the other party hereto reasonable time to comment on, and, if applicable, reasonably direct the disclosing party to seek confidential treatment in respect of portions of, such press release or other public announcement or disclosure in advance of such issuance); provided that (a) no review or consent shall be required with respect to disclosures by either party hereto otherwise previously approved pursuant to this Section 6.3 and (b) notwithstanding anything herein to the contrary, each party hereto may, without the review or consent of the other party hereto, disclose (and nothing herein shall be construed to restrict either party hereto from disclosing) the Pre-Paid Forward Price and the amount and nature of the Revenue Participation Right (and related accounting disclosures of the transactions contemplated hereby) in such party's periodic reports and financial statements.

Section 6.4 Inspections and Audits of the Company. Following the Closing and until [***] after the Revenue Payment Termination Date, upon at least [***] written notice and during normal business hours, no more frequently than [***] per [***], the Payer may cause an inspection and/or audit by an independent public accounting firm reasonably acceptable to the Company to be made of the Company's books of account for the [***] prior to the audit for the purpose of determining the correctness of Revenue Payments made under this Agreement. Upon the Payer's reasonable request, no more frequently than [***] per [***] while any Commercialization License remains in effect, the Company shall use Commercially Reasonable Efforts to exercise any rights it may have under any Commercialization License relating to a Product to cause an inspection and/or audit by an independent public accounting firm to be made of the books of account of any counterparty thereto for the purpose of determining the correctness of Revenue Payments made under this Agreement. All of the out-of-pocket expenses of any inspection or audit requested by the Payer hereunder (including the fees and expenses of such independent public accounting firm designated for such purpose) shall be borne solely by the Payer, unless the independent public accounting firm determines that Revenue Payments previously paid during the period of the audit were underpaid by an amount greater than [***]% of the Revenue Payments actually paid during such period, in which case such expenses shall be borne by the Company. Any such accounting firm shall not disclose the confidential information of the Company or any such Licensee relating to a Product to the Payer, except to the extent such disclosure is necessary to determine the correctness of Revenue Payments or otherwise would be included in a Report. All information obtained by the Payer as a result of any such inspection or audit shall be Confidential Information subject to ARTICLE 8. If any audit discloses any underpayments by the Company to the Payer, then such underpayment, shall be paid by the Company to the Payer within [***] of it being so disclosed. If any audit discloses any overpayments by the Company to the Payer, then the Company shall have the right to credit the amount of the overpayment against each subsequent quarterly Revenue Payment due to the Payer until the overpayment has been fully applied. If the overpayment is not fully applied prior to the final quarterly Revenue Payment due hereunder, the Payer shall promptly refund an amount equal to any such remaining overpayment.

Section 6.5 Intellectual Property Matters. During the term of the Revenue Participation Right:

(a) The Company shall provide to the Payer a copy of any written notice received by the Company from a Third Party alleging or claiming that the making, having made, using, importing, offering for sale or selling of a Product infringes or misappropriates any Patents or other intellectual property rights of such Third Party, together with copies of material correspondence sent or received by the Company related thereto, as soon as practicable and in any event not more than [***] following such delivery or receipt.

(b) The Company shall promptly inform the Payer of any infringement by a Third Party of any Patent Right of which any of the individuals named in the definition of "Knowledge of the Company" (or the successors of such Person at the Company) becomes aware. Without limiting the foregoing, the Company shall provide to the Payer a copy of any written notice of any suspected infringement of any Patent Rights delivered or received by the Company, as well as copies of material correspondence related thereto, as soon as practicable and in any event not more than [***] following such delivery or receipt. The Company shall use Commercially Reasonable Efforts to diligently enforce and defend the Patent Rights (other than Patent Rights non-exclusively in-licensed or otherwise held on a non-exclusive basis by Company or any of its Affiliates), including Commercially Reasonable Efforts to bring any legal action for infringement or defend any counterclaim of invalidity or unenforceability or action of a Third Party for declaratory judgment of non-infringement or non-interference.

(c) From and after the date hereof and until the Revenue Payment Termination Date, within [***] of initiating, or permitting a Licensee to initiate, an enforcement action regarding any suspected infringement by a Third Party of any Patent Right or defending any counterclaim of invalidity or unenforceability or action of a Third Party for declaratory judgment of non-infringement or non-interference, the Company shall provide the Payer with written notice of such action.

(d) If the Company recovers monetary damages from a Third Party in an action brought for such Third Party's infringement of any Patent Rights relating to a Product, where such damages, whether in the form of judgment or settlement, are awarded for such infringement of such Patent Rights, (i) such recovery will be allocated first to the reimbursement of any expenses incurred by the Company (or any party to an In-License or Permitted License of such Patent Rights entitled to such reimbursement under any such In-License or Permitted License) in bringing such action (including all reasonable attorney's fees), (ii) any remaining amounts will be reduced, if applicable, to comply with allocation of recovered damages with licensors of such Patent Rights required under any In-Licenses or Permitted License of such Patent Rights under any such In-License or Permitted License, if any, and

(iii) any residual amount of such damages after application of (i) and (ii) will be treated as Net Sales with respect to the applicable Product for purposes of the Transaction Documents.

Section 6.6 In-Licenses. During the term of the Revenue Participation Right:

(a) The Company shall promptly (and in any event within [***]) provide the Payer with (i) executed copies of any In-License entered into by the Company or its Affiliates after the date hereof, and (ii) executed copies of each amendment, supplement, modification or written waiver of any provision of any In-License.

(b) The Company shall use Commercially Reasonable Efforts to comply in all material respects with its obligations under any In-Licenses it enters into and shall not take any action or forego any action that would reasonably be expected to result in a material breach thereof. Promptly, and in any event within [***], after receipt of any (written or oral) notice from a counterparty to any In-License or its Affiliates of an alleged material breach under any In-License, the Company shall provide the Payer a copy thereof (or if restricted by applicable confidentiality obligations under such In-License, notice thereof and a summary of such material breach). The Company shall use its Commercially Reasonable Efforts to cure any material breaches by it under any In-License and shall give written notice to the Payer upon curing any such breach. The Company shall provide the Payer with written notice following becoming aware of a counterparty's material breach of its obligations under any In-License. The Company shall not terminate any In-License without providing the Payer prior written notice. Promptly, and in any event within [***] following the Company's notice to a counterparty to any In-License of an alleged breach by such counterparty under any such In-License, the Company shall provide the Payer a copy thereof.

Section 6.7 Out-Licenses. During the term of the Revenue Participation Right:

(a) Subject to compliance with this Section 6.7, the Company, or any of its Affiliates, may enter into a new Out-License with a Third Party (each such Out-License that complies with this Section 6.7, a "Permitted License"), provided, that any such Out-License that is a Commercialization License and grants, transfers or otherwise conveys rights to Commercialize a Product within [***] shall be subject to Payer's prior written consent (not to be unreasonably, withheld, conditioned, or delayed), unless the Licensee is [***] of at least (i) $[***] or (ii) $[***] with at least $[***] in [***] in the [***] prior to enter into such new Commercialization License.

(b) The Company shall promptly (and in any event within [***]) provide the Payer with (i) executed copies of each Commercialization License, and (ii) executed copies of each amendment, supplement, modification or written waiver of any material provision of any Commercialization License.

(c) The Company shall include in all Commercialization Licenses provisions permitting the Company to audit such Licensee and shall use commercially reasonable efforts to include terms and conditions consistent in all material respects with the Payer's rights to audit the Company set forth in Section 6.4.

(d) The Company shall provide the Payer prompt (and in any event within [***]) written notice of a Licensee's material breach of its obligations under any Commercialization License of which any of the individuals named in the definition of "Knowledge of the Company" (or the successors of such Person at the Company) becomes aware.

(e) The Company shall provide the Payer with written notice promptly (and in any event within [***]) following the termination of any Commercialization License.

(f) The Payer acknowledges and agrees that in the event that Company enters into (or plans to enter into) any Permitted License, the Payer shall, at the reasonable request of the Company, enter into non-disturbance and similar agreements in a form reasonably acceptable to the Payer in connection with such Permitted License to the extent reasonably requested by the counter-party to such (or prospective counter-party) thereto.

Section 6.8 Negative Pledge and Intercreditor Agreement. At any time prior to the Minimum Return Date, the Company shall not, without the prior written consent of the Payer, create, incur, assume or suffer to exist any Lien upon or with respect to the Product Collateral, except for Permitted Liens. For the avoidance of doubt, nothing herein shall restrict the Company from incurring unsecured Indebtedness or Indebtedness secured by assets that are not Product Collateral or Revenue Participation Rights.

Section 6.9 Insolvency Event. Upon an Insolvency Event, the Company agrees that the amounts comprising the Payment Obligations shall automatically and immediately accelerate and become immediately due and payable, in each case, without any action or notice by any party or Person and the Payer may take such other steps as it sees fit including enforcing the Liens pursuant to the Security Documents subject to any applicable Acceptable Intercreditor Agreement entered into prior to such date. The parties hereto acknowledge and agree that (a) this Agreement is a non-executory contract, (b) the Payer will have fully and completely performed all of its obligations and duties due hereunder as of the Closing, including having paid in cash the entire Pre-Paid Forward Price, which is adequate and proper consideration for the Remaining Obligations outstanding to the Payer under this Agreement, (c) the Company's Remaining Obligations to the Payer are fully-earned, irrevocable and unconditional, including in an Insolvency Event, (d) in light of the impracticality and difficulty of ascertaining actual damages, the Remaining Obligations are intended to be a reasonable calculation of the actual damages that would be suffered by the Payer as a result of any such Insolvency Event and are not intended to act as a penalty, (e) the process by which the Remaining Obligations are to be determined shall not be considered an action that may be blocked by the automatic stay or any other provision of Bankruptcy Law in an Insolvency Event but rather a fair and rational approach for establishing the value of such amount and (f) it would be inequitable and unjust for all parties hereto and all other interested parties or Persons for any bankruptcy court, other court, Governmental Entity or other Person to not honor or carry out the process for establishing the Remaining Obligations as set forth in this Agreement.

Section 6.10 Use of Proceeds; Diligence.

(a) All amounts paid by the Payer to the Company under this Agreement will be solely used by the Company to [***], [***], and [***].

(b) The Company shall use Commercially Reasonable Efforts to (i) complete clinical development, (ii) prepare, execute, deliver and file any and all agreements, documents or instruments that are necessary or desirable to secure and maintain all Marketing Approval required to Commercialize the Products in the Territory, (iii) not withdraw or abandon, or fail to take any action necessary to prevent the withdrawal or abandonment of, any such Marketing Approvals, and (iv) Commercialize (either directly or through Licensees) the Products in the Territory.

(c) On a country-by-country and Product-by-Product basis, if a Loss of Market Exclusivity has occurred in such country for such Product, the Company's obligations under Section 6.10(b) shall no longer apply in such country for such Product.

Section 6.11 IIA. The Company agrees (a) to not apply for or take further grants or funding from the IIA, and (b) to comply with its current obligations to the IIA regarding the commitment to continue to employ at least 75% of its research and development jobs in Israel for a period of at least [***], until [***].

Section 6.12 Efforts to Consummate Transactions. Subject to the terms and conditions of this Agreement, each of the Company and the Payer will use its commercially reasonable efforts prior to the Closing to take, or cause to be taken, all actions and to do, or cause to be done, all things reasonably necessary under applicable law to consummate the transactions contemplated by the Transaction Documents. Each of the Payer and the Company agrees to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by the Transaction Documents.

Section 6.13 Further Assurances. After the Closing, the Company and the Payer agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary in order to give effect to the transactions contemplated by the Transaction Documents. During the term of the Revenue Participation Right, the Company shall not, and shall cause its Affiliates not to, develop, commercialize or Out-License any pharmaceutical product (that is not a Product) incorporating (a) [***] or (b) [***], in each case of (a) or (b) without the prior written consent of the Payer.

Section 6.14 Product Collateral. To the extent additional Product Collateral is created, obtained or acquired by the Company, the Company shall promptly take all such steps to ensure that such additional Product Collateral are subject to the Liens conferred by the Security Documents including by way of entering into any amendments or supplements to the Security Documents or any additional Security Documents to the satisfaction of the Payer and promptly making all such necessary filings and registrations as are required including at the Israeli Registrar of Companies and if in respect of Israeli Patents, with the Israeli Patent Office within the required timeframe and in each case to the satisfaction of the Payer. For the avoidance of doubt, the Company shall not be required to take any action to grant or perfect the security interests granted hereby and the Security Documents in any jurisdiction outside of the Covered Jurisdictions.

Section 6.15 Escrow. As promptly as practicable after the date hereof the Company and the Payer shall enter into a mutually acceptable Escrow Agreement, at the sole cost of the Company, and the Payer will deposit the Pre-Paid Forward Price into the Escrow Account. If the satisfaction or waiver of all conditions set forth in ARTICLE 5 occurs, such that the Closing would occur upon release of the Pre-Paid Forward Price, then the parties shall provide joint written instructions to the Escrow Agent directing the Escrow Agent to promptly release the Pre-Paid Forward Price to the Company. If this Agreement is terminated prior to the Closing Date pursuant to ARTICLE 9, then the Payer shall provide written instructions to the Escrow Agent directing the Escrow Agent to promptly return the Pre-Paid Forward Price to the Payer.

Section 6.16 Certain Tax Matters.

(a) If there is an inquiry by any Governmental Entity of the Payer or the Company related to the treatment of the transactions contemplated by this Agreement, the parties hereto shall cooperate with each other in responding to such inquiry in a reasonable manner.

(b) The parties acknowledge and agree that, as of the date hereof, all payments by the Company to the Payer and by the Payer to the Company shall be made without deduction or withholding for any Taxes. If any change in applicable law requires the deduction or withholding of any Tax from any payment by the Company, then the Company shall be entitled to withhold and deduct (or cause to be withheld and deducted) from any amount payable under this Agreement to the Payer any Tax that it is required to withhold and deduct under applicable law. The Company shall timely pay the full amount deducted or withheld to the relevant governmental authority in accordance with applicable law. For the avoidance of doubt and notwithstanding anything to the contrary in this Agreement, any amount payable by the Company to the Payer shall be increased as necessary so that after deduction or withholding of any Tax has been made (including such deductions and withholdings applicable to additional sums payable under this Paragraph) (whether as a result of a change in applicable law or otherwise), the Payer receives an amount equal to the sum it would have received had no such deduction or withholding been made; provided, however, that if as a result of a Withholding Action by the Payer (including any assignee or successor), the amount of any tax withheld or deducted exceeds the amount of such withholding or deduction that would have been required in the absence of such Withholding Action, the Company shall be required to pay an additional amount only to the extent that the Company would be required to pay any additional amount to the Payer pursuant to this Section 6.16(b) if the Payer had not committed such Withholding Action (except to the extent such excess additional amounts results from a change in applicable law that occurs after the date of such Withholding Action). For purposes of this Section 6.16(b), "Withholding Action" means (i) a permitted assignment of this Agreement (in whole or in part) by the Payer to an Affiliate or a Third Party resident in a different jurisdiction; (ii) a redomiciliation of such party, an assignee or a successor to a jurisdiction other than Ireland or Israel; and (iii) any action taken after the date of this Agreement by the Payer (other than at the request of the Company and other than actions required by applicable law) that causes the representation in Section 4.2(i) to be inaccurate (disregarding for this purpose the reference to "as of the date hereof").

(c) The parties hereto shall use commercially reasonable efforts to give or cause to be given to the other party hereto such assistance and such information concerning the reasons for withholding or deduction (including, in reasonable detail, the method of calculation for the deduction or withholding thereof) as may be reasonably necessary to claim exemption therefrom, or credit therefor, or relief (whether at source or by reclaim) therefrom, and, in each case, shall furnish the other party with proper evidence of the taxes withheld and deducted and remitted to the relevant taxing authority.

ARTICLE 7
INDEMNIFICATION

Section 7.1 General Indemnity. From and after the Closing:

(a) the Company hereby agrees to indemnify, defend and hold harmless the Payer and its Affiliates and its and their directors, managers, trustees, officers, agents and employees (the "Payer Indemnified Parties") from, against and in respect of all Losses suffered or incurred by the Payer Indemnified Parties to the extent arising out of or resulting from (i) any breach of any of the representations or warranties of the Company in the Transaction Documents, and (ii) any breach of any of the covenants or agreements of the Company in the Transaction Documents; and

(b) the Payer hereby agrees to indemnify, defend and hold harmless the Company and its Affiliates and its and their directors, officers, agents and employees (the "Company Indemnified Parties") from, against and in respect of all Losses suffered or incurred by the Company Indemnified Parties to the extent arising out of or resulting from (i) any breach of any of the representations or warranties of the Payer in the Transaction Documents, and (ii) any breach of any of the covenants or agreements of the Payer in the Transaction Documents.

Section 7.2 Notice of Claims. If either a Payer Indemnified Party, on the one hand, or a Company Indemnified Party, on the other hand (such Payer Indemnified Party on the one hand and such Company Indemnified Party on the other hand being hereinafter referred to as an "Indemnified Party"), has suffered or incurred any Losses for which indemnification may be sought under this ARTICLE 7, the Indemnified Party shall so notify the other party from whom indemnification is sought under this ARTICLE 7 (the "Indemnifying Party") promptly in writing describing such Loss, the amount or estimated amount thereof, if known or reasonably capable of estimation, and the method of computation of such Loss, all with reasonable particularity and containing a reference to the provisions of this Agreement in respect of which such Loss shall have occurred. If any claim, action, suit or proceeding is asserted or instituted by or against a Third Party with respect to which an Indemnified Party intends to claim any Loss under this ARTICLE 7, such Indemnified Party shall promptly notify the Indemnifying Party of such claim, action, suit or proceeding and tender to the Indemnifying Party the defense of such claim, action, suit or proceeding. A failure by an Indemnified Party to give notice and to tender the defense of such claim, action, suit or proceeding in a timely manner pursuant to this Section 7.2 shall not limit the obligation of the Indemnifying Party under this ARTICLE 7, except to the extent such Indemnifying Party is actually prejudiced thereby.

Section 7.3 Limitations on Liability. Except for claims arising from a breach of confidentiality obligations under ARTICLE 8 or in cases of fraud, gross negligence, or willful misconduct, no party hereto shall be liable for any lost profits or revenue, lost opportunity, consequential, punitive, special or incidental damages under this ARTICLE 7 (and no claim for indemnification hereunder shall be asserted) as a result of any breach or violation of any covenant or agreement of such party (including under this ARTICLE 7) in or pursuant to this Agreement. In connection with the foregoing, the parties hereto acknowledge and agree that (i) the Payer's damages, if any, for any such action or claim will typically include Losses for Revenue Payments that the Payer was entitled to receive but did not receive timely or at all due to such indemnifiable event and (ii) the Payer shall be entitled to make claims for all such missing or delayed Revenue Payments as Losses hereunder, and such missing or Revenue Payments shall not be deemed consequential, punitive, special, indirect or incidental damages.

Section 7.4 Exclusive Remedy. Except as set forth in Section 6.9, Section 10.11, and Exhibit B, and except for any event of default or the enforcement of any remedies under the Security Documents, from and after Closing, the rights of the parties hereto pursuant to (and subject to the conditions of) this ARTICLE 7 shall be the sole and exclusive remedy of the parties hereto and their respective Affiliates with respect to any Losses (whether based in contract, tort or otherwise) resulting from or relating to any breach of the representations and warranties made under this Agreement or any certificate, document or instrument delivered hereunder, and each party hereto hereby waives, to the fullest extent permitted under applicable law, and agrees not to assert after Closing, any other claim or action in respect of any such breach. Notwithstanding the foregoing, claims for fraud, gross negligence, or willful misconduct shall not be waived or limited in any way by this ARTICLE 7.

Section 7.5 Tax Treatment of Indemnification Payments. For all purposes hereunder, any indemnification payments made pursuant to this ARTICLE 7 will be treated as an adjustment to the Pre-Paid Forward Price for tax purposes to the fullest extent permitted by applicable law.

ARTICLE 8
CONFIDENTIALITY

Section 8.1 Confidentiality. Except as provided in this ARTICLE 8, Section 10.4 or otherwise agreed in writing by the parties, the parties hereto agree that, during the term of this Agreement and for [***] thereafter, each party (the "Receiving Party") shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any information furnished to it by or on behalf of the other party (the "Disclosing Party") pursuant to this Agreement (such information, "Confidential Information" of the Disclosing Party), except for that portion of such information that:

(a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement or any other agreement;

(d) is independently developed by the Receiving Party or any of its Affiliates, as evidenced by written records, without the use of or reference of the Confidential Information; or

(e) is subsequently disclosed to the Receiving Party on a non-confidential basis by a Third Party without obligations of confidentiality with respect thereto.

Section 8.2 Authorized Disclosure.

(a) Either party may disclose Confidential Information to the extent such disclosure is reasonably necessary in the following situations:

(i) prosecuting or defending litigation;

(ii) complying with applicable laws and regulations, including regulations promulgated by securities exchanges;

(iii) complying with a valid order of a court of competent jurisdiction or other Governmental Entity;

(iv) for regulatory, Tax or customs purposes;

(v) for audit purposes, provided that each recipient of Confidential Information must be bound by customary and reasonable obligations of confidentiality and non-use prior to any such disclosure;

(vi) disclosure to its Affiliates and Representatives on a need-to-know basis, provided that each such recipient of Confidential Information must be bound by contractual or professional obligations of confidentiality and non-use at least as stringent as those imposed upon the parties hereunder prior to any such disclosure;

(vii) upon the prior written consent of the Disclosing Party;

(viii) disclosure to its potential investors, and other sources of funding, including debt financing, or potential partners, collaborators or acquirers, and their respective accountants, financial advisors and other professional representatives, provided, that such disclosure shall be made only to the extent customarily required to consummate such investment, financing transaction partnership, collaboration or acquisition and that each recipient of Confidential Information must be bound by customary obligations of confidentiality and non-use prior to any such disclosure;

(ix) as is necessary in connection with a permitted assignment pursuant to Section 10.4.

(b) Notwithstanding the foregoing, in the event the Receiving Party is required to make a disclosure of the Disclosing Party's Confidential Information pursuant to Section 8.2(a)(i), (ii), (iii) or (iv), it will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure and use reasonable efforts to secure confidential treatment of such information. In any event, the Payer shall not file any patent application based upon or using the Confidential Information of Company provided hereunder.

(c) Notwithstanding anything set forth in this Agreement, materials and documentation relating to the Company's Intellectual Property Rights may be only disclosed to or accessed by the Payer and its attorneys and auditors, without further disclosure to any other Representative of the Payer.

ARTICLE 9
TERMINATION

Section 9.1 Mutual Termination. This Agreement may be terminated by mutual written agreement of the Payer and the Company.

Section 9.2 Automatic Termination. Unless earlier terminated as provided in Section 9.1, this Agreement shall continue in full force and effect until: (a) if the Closing has not occurred, [***] after the date hereof, or (b) following the Closing, [***] after the Revenue Payment Termination Date, at which point this Agreement shall automatically terminate, except with respect to any rights that shall have accrued prior to such termination.

Section 9.3 Survival. Notwithstanding anything to the contrary in this ARTICLE 9, the following provisions shall survive termination of this Agreement: Section 6.3 (Disclosures), Section 6.4 (Inspections and Audits of the Company) (for the time period stated therein) ARTICLE 7 (Indemnification), ARTICLE 8 (Confidentiality) (for the time period stated therein), this Section 9.3 (Survival) and ARTICLE 10 (Miscellaneous). Termination of the Agreement shall not relieve any party of liability in respect of breaches under this Agreement by any party on or prior to termination.

ARTICLE 10
MISCELLANEOUS

Section 10.1 Headings. The table of contents and the descriptive headings of the several Articles and Sections of this Agreement and the Exhibits and Schedules are for convenience only, do not constitute a part of this Agreement and shall not control or affect, in any way, the meaning or interpretation of this Agreement.

Section 10.2 Notices. All notices and other communications under this Agreement shall be in writing and shall be by email with PDF attachment, facsimile, courier service or personal delivery to the following addresses, or to such other addresses as shall be designated from time to time by a party hereto in accordance with this Section 10.2:

If to the Company, to it at:

UroGen Pharma Ltd.
400 Alexander Park Drive
Princeton, NJ 08540

Attn: [***]
Email: [***]

with a copy to:

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

If to the Payer, to it at:

RTW Investments, LP
40 10th Avenue, Floor 7
New York, NY 10014
Attn: [***] and Bradley Sitko
Email: [***] bs@rtwfunds.com and [***]

with a copy to:

Gibson, Dunn & Crutcher LLP
555 Mission Street
San Francisco, CA 94105
Attention: Ryan Murr & Todd Trattner
E-mail: rmurr@gibsondunn.com; ttrattner@gibsondunn.com

All notices and communications under this Agreement shall be deemed to have been duly given (i) when delivered by hand, if personally delivered, (ii) when sent, if sent by facsimile, with an acknowledgement of sending being produced by the sending facsimile machine, (iii) when sent, if by email with PDF attachment, with an acknowledgement of receipt being produced by the recipient's email account, or (iv) one Business Day following sending within the United States by overnight delivery via commercial one-day overnight courier service.

Section 10.3 Expenses. The Company shall promptly reimburse the Payer for all Transaction Expenses. Except as otherwise provided herein, all fees, costs and expenses (including any legal, accounting and banking fees) incurred in connection with the preparation, negotiation, execution and delivery of this Agreement and to consummate the transactions contemplated hereby shall be paid by the party hereto incurring such fees, costs and expenses; provided however that the Company shall reimburse the Payer for all costs related to perfection and enforcement of the Transaction Documents.

Section 10.4 Assignment. The Company may not assign in whole or in part this Agreement, any of its rights or obligations hereunder, or any Product Rights, without the Payer's prior written consent, except to a Third Party in connection with the sale or transfer of all or substantially all of the Company's business or assets related to a Product, whether by merger, sale of assets, reorganization, or other conveyance of title and only if upon closing any such transaction, the Company causes such Affiliate or Third Party, as applicable, (a) to deliver a writing to the Payer in which it assumes all of the obligations of the Company to the Payer under this Agreement and other Transaction Documents, (b) such Affiliate or Third Party shall be deemed an assignee of Company under this Agreement, and (c) concurrent with such assignment, the effectiveness of which shall be conditional upon, to deliver to the Payer of the same or equivalent Liens on the Product Collateral under the Security Documents and perfect and register such Liens at all applicable registries in all applicable jurisdictions to the Payer's satisfaction; provided that (i) such assignment does not result in any adverse Tax consequences to the Payer as determined at the time of such assignment and (ii) for the avoidance of doubt, nothing in this Section 10.4 shall restrict the Company from incurring any Permitted Liens, entering into any Permitted License, from transferring the Marketing Approvals for any jurisdiction to any subsidiary or a Licensee (or an affiliate of a Licensee) in connection with a Permitted License, or incurring any Indebtedness. Following the Closing, the Payer may assign this Agreement in whole or in part to any Person, provided that such assignment (i) does not result in any adverse Tax consequences to the Company and (ii) is not made to a pharmaceutical company developing or Commercializing therapies for the treatment of urologic diseases, in each case as determined at the time of such assignment. This Agreement shall be binding upon, inure to the benefit of and be enforceable by, the parties hereto and their respective permitted successors and assigns. Any purported assignment of this Agreement in violation of this Section 10.4 shall be null and void.

Section 10.5 Amendment and Waiver.

(a) This Agreement may be amended, modified or supplemented only in a writing signed by each of the parties hereto. Any provision of this Agreement may be waived only in a writing signed by the party hereto granting such waiver.

(b) No failure or delay on the part of any party hereto in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other or further exercise thereof or the exercise of any other right, power or remedy. No course of dealing between the parties hereto shall be effective to amend, modify, supplement or waive any provision of this Agreement.

Section 10.6 Entire Agreement. This Agreement, the Exhibits annexed hereto and the Disclosure Schedule constitute the entire understanding between the parties hereto with respect to the subject matter hereof and supersede all other understandings and negotiations with respect thereto. As of the date hereof, the Confidentiality Agreement between the Payer and the Company, dated as of [***] is hereby terminated without further force and effect, superseded by ARTICLE 8 of this Agreement and all obligations between the parties relating to confidentiality shall be governed by ARTICLE 8 of this Agreement.

Section 10.7 No Third-Party Beneficiaries. This Agreement is for the sole benefit of the Company and the Payer and their permitted successors and assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the parties hereto and such

successors and assigns, any legal or equitable rights hereunder, except that the Indemnified Parties shall be third-party beneficiaries of the benefits provided for in Section 7.1.

Section 10.8 Governing Law. This Agreement shall be exclusively governed by, and construed in accordance with, the laws of the State of New York without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction.

Section 10.9 Jurisdiction; Venue.

(a) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY SUBMITS, FOR ITSELF AND ITS RESPECTIVE PROPERTY AND ASSETS, TO THE EXCLUSIVE JURISDICTION OF ANY NEW YORK STATE COURT OR FEDERAL COURT OF THE UNITED STATES OF AMERICA SITTING IN NEW YORK COUNTY, NEW YORK, AND ANY APPELLATE COURT THEREOF, IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT (INCLUDING IN RELATION TO ITS VALIDITY, ENFORCEMENT AND TERMINATION), OR FOR RECOGNITION OR ENFORCEMENT OF ANY JUDGMENT IN RESPECT THEREOF, AND THE PAYER AND THE COMPANY HEREBY IRREVOCABLY AND UNCONDITIONALLY AGREE THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN ANY SUCH NEW YORK STATE COURT OR, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, IN SUCH FEDERAL COURT. THE PAYER AND THE COMPANY HEREBY AGREE THAT A FINAL JUDGMENT IN ANY SUCH ACTION OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY APPLICABLE LAW. EACH OF THE PAYER AND THE COMPANY HEREBY SUBMITS TO THE EXCLUSIVE PERSONAL JURISDICTION AND VENUE OF SUCH NEW YORK STATE AND FEDERAL COURTS. THE PAYER AND THE COMPANY AGREE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THAT PROCESS MAY BE SERVED ON THE PAYER OR THE COMPANY IN THE SAME MANNER THAT NOTICES MAY BE GIVEN PURSUANT TO SECTION 10.2 HEREOF.

(b) EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE FULLEST EXTENT IT MAY LEGALLY AND EFFECTIVELY DO SO, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT IN ANY NEW YORK STATE OR FEDERAL COURT. EACH OF THE PAYER AND THE COMPANY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT.

(c) EACH PARTY HEREBY JOINTLY AND SEVERALLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY OTHER DOCUMENT DELIVERED HEREUNDER OR IN CONNECTION HEREWITH, OR ANY TRANSACTION ARISING FROM OR CONNECTED TO ANY OF THE FOREGOING. EACH OF THE PARTIES REPRESENTS THAT THIS WAIVER IS KNOWINGLY, WILLINGLY, AND VOLUNTARILY GIVEN.

(d) NOTHING IN THIS AGREEMENT SHALL AFFECT ANY RIGHT OF THE PAYER TO BRING ANY ACTION, LITIGATION OR PROCEEDING (INCLUDING ENFORCEMENT OF ANY LIEN) RELATED TO THE ISRAELI SECURITY AGREEMENT IN THE COURTS SPECIFIED IN THE ISRAELI SECURITY AGREEMENT.

Section 10.10 Severability. If any term or provision of this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any situation in any jurisdiction, then, to the extent that the economic and legal substance of the transactions contemplated hereby is not affected in a manner that is materially adverse to either party hereto, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect and the enforceability and validity of the offending term or provision shall not be affected in any other situation or jurisdiction.

Section 10.11 Specific Performance. Each of the parties acknowledges and agrees that the other party would be damaged irreparably in the event any of the provisions of this Agreement are not performed in accordance with their specific terms or otherwise are breached or violated. Accordingly, each of the parties agrees that, without posting bond or other undertaking, the other party will be entitled to seek an injunction or injunctions to prevent breaches or violations of the provisions of this Agreement and to seek to enforce specifically this Agreement and the terms and provisions hereof in any action, suit or other proceeding instituted in any court of the United States or any state thereof having jurisdiction over the parties and the matter in addition to any other remedy to which it may be entitled, at law or in equity. Each of the parties further agrees that, in the event of any action for specific performance in respect of such breach of violation, it will not assert the defense that a remedy at law would be adequate.

Section 10.12 Counterparts. This Agreement may be executed in any number of counterparts and by the parties hereto 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. Copies of executed counterparts transmitted by telecopy, facsimile or other similar means of electronic transmission, including "PDF," shall be considered original executed counterparts, provided receipt of such counterparts is confirmed.

Section 10.13 Relationship of the Parties. The relationship between the Payer and the Company is solely that of recipient and grantor, and neither the Payer nor the Company has any fiduciary or other special relationship with the other party or any of its Affiliates. This Agreement is not a partnership, investment or similar agreement, and nothing contained herein shall be deemed to constitute the Payer and the Company as a partnership, an association, a joint venture or any other kind of entity or legal form for any purposes, including any Tax purposes, or to constitute the Payer as an investor in the Company. The Payer and the Company agree that they shall not take any inconsistent position with respect to such treatment in a filing with any Governmental Entity.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

COMPANY
UroGen Pharma Ltd.

By: /s/ Molly Henderson
Name: Molly Henderson
Title: Chief Financial Officer

PAYER
RTW Investments ICAV for and on behalf of RTW Fund 2

By: /s/ Dermot Hanley
Name: Dermot Hanley
Title: Chairman

Exhibit A
Form of Company Opinions

Exhibit B
Valuation Procedures

[***]

AMENDMENT NO. 1 TO
PRE-PAID FORWARD CONTRACT

This Amendment No. 1 to Pre-Paid Forward Contract ("Amendment"), dated April 30, 2021 (the "Amendment Date"), is between RTW Investments ICAV, an Irish Collective Asset-management Vehicle registered in Ireland as an umbrella fund with segregated liability between sub-funds (the "Payer"), for and on behalf of its sub-fund, RTW Fund 2, and UroGen Pharma Ltd., an Israel corporation with company registration number 513537621 (the "Company"), and amends that certain Pre-Paid Forward Contract, dated as of March 18, 2021 (the "Agreement"), by and between the Payer and the Company.

WHEREAS, the parties mutually wish to amend the Agreement to, among other things, extend the automatic termination date; and

WHEREAS, Section 10.5 of the Agreement provides that the Agreement may be amended by a writing signed by each of the parties to the Agreement.

NOW THEREFORE, in consideration of the covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Payer hereby agree as follows:

1. Defined Terms. Capitalized terms that are used in this Amendment have the meaning set forth in the Agreement, unless otherwise defined in this Amendment.

2. Amendment. Effective as of the Amendment Date, Section 9.2 of the Agreement is amended to read in its entirety as follows:

> Automatic Termination. Unless earlier terminated as provided in Section 9.1, this Agreement shall continue in full force and effect until: (a) if the Closing has not occurred, [***] after the date hereof, or (b) following the Closing, [***] after the Revenue Payment Termination Date, at which point this Agreement shall automatically terminate, except with respect to any rights that shall have accrued prior to such termination.

3. Entire Agreement. The provisions of this Amendment supersede all provisions of the Agreement that are inconsistent with the provisions of this Amendment. The Agreement, as modified by this Amendment, remains in full force and effect and, with the Exhibits annexed thereto and the Disclosure Schedule constitute the entire understanding between the parties hereto with respect to the subject matter hereof and thereof and supersede all other understandings and negotiations with respect hereto and thereto. Unless the context otherwise requires, the term "Agreement" as used in the Agreement shall be deemed to refer to the Agreement as amended hereby.

4. Governing Law. This Amendment shall be exclusively governed by, and construed in accordance with, the laws of the State of New York without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction.

5. Waiver. This Amendment shall not be deemed a waiver by any party of any of its rights or remedies under the Agreement, except to the extent expressly set forth in this Amendment.

6. Counterparts. This Amendment may be executed in any number of counterparts and by the parties hereto 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. Copies of executed counterparts transmitted by telecopy, facsimile or other similar means of electronic transmission, including "PDF," shall be considered original executed counterparts, provided receipt of such counterparts is confirmed.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

COMPANY
UroGen Pharma Ltd.

By: /s/ Molly Henderson
Name: Molly Henderson
Title: Chief Financial Officer

PAYER
RTW Investments ICAV for and on behalf of RTW Fund 2

By: /s/ Dermot Hanley
Name: Dermot Hanley
Title: Chairman

AMENDMENT NO. 2 TO
PRE-PAID FORWARD CONTRACT

This Amendment No. 2 to Pre-Paid Forward Contract ("Amendment"), dated August 14, 2024 (the "Amendment Date"), is between RTW Investments ICAV, an Irish Collective Asset- management Vehicle registered in Ireland as an umbrella fund with segregated liability between sub-funds (the "Payer"), for and on behalf of its sub-fund, RTW Fund 2, and UroGen Pharma Ltd., an Israel corporation with company registration number 513537621 (the "Company"), and amends that certain Pre-Paid Forward Contract by and between the Payer and the Company, dated as of March 18, 2021, as amended by that certain Amendment No. 1 to Pre-Paid Forward Contract, dated as of April 30, 2021 (collectively, the "Agreement").

WHEREAS, the parties mutually wish to amend the Agreement to clarify the definitions of Jelmyto and UGN-102 set forth therein; and

WHEREAS, Section 10.5 of the Agreement provides that the Agreement may be amended by a writing signed by each of the parties to the Agreement.

NOW THEREFORE, in consideration of the covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Payer hereby agree as follows:

1. Defined Terms. Capitalized terms that are used in this Amendment have the meaning set forth in the Agreement, unless otherwise defined in this Amendment.

2. Definition of Jelmyto. Effective as of the Amendment Date, the definition of Jelmyto in Section 1.1 of the Agreement is amended to read in its entirety as follows:

> "Jelmyto" means (a) the pharmaceutical product known as JELMYTO® (mitomycin) (and foreign-named equivalents) for pyelocalyceal solution, (b) the pharmaceutical product known as UGN-104 (mitomycin) (and foreign-named equivalents) for pyelocalyceal solution for the treatment of upper tract urothelial cancer, (c) 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 (d) any pharmaceutical product that contains any of the foregoing, in each case of (a)–(d), in any dosage form, dosing regimen, strength, or route of administration.

3. Definition of UGN-102. Effective as of the Amendment Date, the definition of UGN-102 in Section 1.1 of the Agreement is amended to read in its entirety as follows:

> "UGN-102" means (a) the pharmaceutical product known as UGN-102 (mitomycin) for intravesical solution, (b) the pharmaceutical product known as UGN-103 (mitomycin) for intravesical solution for the treatment of bladder cancer, (c) 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 (d) any pharmaceutical product that contains any of the foregoing, in each case of (a)–(d), in any dosage form, dosing regimen, strength, or route of administration.

4. Diligence. Effective as of the Amendment Date, Section 6.10(b) of the Agreement is amended to read in its entirety as follows:

> (b) The Company shall use Commercially Reasonable Efforts to (i) complete clinical development, (ii) prepare, execute, deliver and file any and all agreements, documents or instruments that are necessary or desirable to secure and maintain all Marketing Approval required to Commercialize the Products in the Territory, (iii) not withdraw or abandon, or fail to take any action necessary to prevent the withdrawal or abandonment of, any such Marketing Approvals, and (iv) Commercialize (either directly or through Licensees) at least two Products in the Territory, including (A) at least one pharmaceutical product (1) under clause (a) or
>
> (b) of the definition of "Jelmyto" or (2) under clause (d) of the definition of "Jelmyto" solely with respect to any pharmaceutical product that contains any of the pharmaceutical products described under clause (a) or (b) of the definition of "Jelmyto" and (B) at least one pharmaceutical product (1) under clause (a) or (b) of the definition of "UGN-102" or (2) under clause (d) of the definition of "UGN-102" solely with respect to any pharmaceutical product that contains any of the pharmaceutical products described under clause (a) or (b) of the definition of "UGN-102". For clarity, solely with respect to clause (iv), the Company shall have no obligation to Commercialize in the Territory (x) more than one pharmaceutical product meeting the requirement under clause (A) above in any given period of time or (y) more than one pharmaceutical product meeting the requirement under clause (B) above in any given period of time.

5. Entire Agreement. The provisions of this Amendment supersede all provisions of the Agreement that are inconsistent with the provisions of this Amendment. The Agreement, as modified by this Amendment, remains in full force and effect and, with the Exhibits annexed thereto and the Disclosure Schedule constitute the entire understanding between the parties hereto with respect to the subject matter hereof and thereof and supersede all other understandings and negotiations with respect hereto and thereto. Unless the context otherwise requires, the term "Agreement" as used in the Agreement shall be deemed to refer to the Agreement as amended hereby.

6. Governing Law. This Amendment shall be exclusively governed by, and construed in accordance with, the laws of the State of New York without giving effect to any choice or conflict of law provision or rule that would cause the application of the laws of any other jurisdiction.

7. Waiver. This Amendment shall not be deemed a waiver by any party of any of its rights or remedies under the Agreement, except to the extent expressly set forth in this Amendment.

8. Counterparts. This Amendment may be executed in any number of counterparts and by the parties hereto 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. Copies of executed counterparts transmitted by telecopy, facsimile or other similar means of electronic transmission, including "PDF," shall be considered original executed counterparts, provided receipt of such counterparts is confirmed.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

COMPANY

UroGen Pharma Ltd.

By: /s/ Don Kim
Name: Don Kim
Title: Chief Financial Officer

[Signature Page to Amendment No. 2 to Pre-Paid Forward Contract]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed and delivered by their respective representatives thereunto duly authorized as of the date first above written.

PAYER

RTW INVESTMENTS JCAV FOR AND ON BEHALF OF RTWFUND2

By: /s/ Dermot Hanley
Name: Dermot Hanley
Title: Chairman

[Signature Page to Amendment No. 2 to Pre-Paid Forward Contract]

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: November 6, 2024

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, Chris Degnan, 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: November 6, 2024

By: /s/ Chris Degnan
Chris Degnan
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 September 30, 2024 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: November 6, 2024

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 September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Chris Degnan, 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: November 6, 2024

By: /s/ Chris Degnan
Chris Degnan
Chief Financial Officer
(Principal Financial and Accounting Officer)