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 June 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 August 5, 2024, the registrant had 42,114,070 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 219,972	$ 95,002
Marketable securities	21,106	41,966
Restricted cash	825	821
Accounts receivable, net	17,415	15,443
Inventories	7,442	5,673
Prepaid expenses and other current assets	12,208	10,281
Total current assets	278,968	169,186
Non-current assets:		
Property and equipment, net	580	689
Restricted deposit	175	225
Right of use assets	1,250	1,671
Marketable securities	203	4,502
Other non-current assets	673	2,038
Total Assets	$ 281,849	$ 178,311
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 23,754	$ 16,538
Employee related accrued expenses	6,849	10,814
Other current liabilities	3,620	3,860
Total current liabilities:	34,223	31,212
Non-current liabilities:		
Prepaid forward obligation	115,880	109,722
Long-term debt	97,813	98,551
Long-term lease liabilities	425	844
Uncertain tax positions liability	3,194	3,194
Total Liabilities	251,535	243,523
Commitments and Contingencies (Note 18)		
Shareholders' Equity (Deficit):		
Ordinary shares, NIS 0.01 par value, 100,000,000 shares authorized at June 30, 2024 and December 31, 2023; 41,169,954 and 32,490,119 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	112	89
Additional paid-in capital	775,270	614,035
Accumulated deficit	(745,037)	(679,348)
Accumulated other comprehensive income (loss)	(31)	12
Total Shareholders' Equity (Deficit)	30,314	(65,212)
Total Liabilities and Shareholders' Equity (Deficit)	$ 281,849	$ 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 June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ 21,848	$ 21,139	$ 40,629	$ 38,331
Cost of revenue	2,229	2,443	3,957	4,708
Gross profit	19,619	18,696	36,672	33,623
Operating expenses:				
Research and development expenses	15,402	11,584	30,896	24,082
Selling, general and administrative expenses	30,056	22,494	57,355	46,968
Operating loss	(25,839)	(15,382)	(51,579)	(37,427)
Financing on prepaid forward obligation	(5,773)	(5,344)	(11,433)	(10,568)
Interest expense on long-term debt	(3,461)	(3,761)	(5,908)	(7,314)
Interest and other income, net	1,708	405	3,323	1,035
Loss before income taxes	(33,365)	(24,082)	(65,597)	(54,274)
Income tax expense	(38)	(54)	(92)	(75)
Net Loss	$ (33,403)	$ (24,136)	$ (65,689)	$ (54,349)
Statements of Comprehensive Loss				
Net loss	$ (33,403)	$ (24,136)	$ (65,689)	$ (54,349)
Other comprehensive income (loss)				
Unrealized gain (loss) on investments	6	(109)	(43)	(47)
Comprehensive Loss	$ (33,397)	$ (24,245)	$ (65,732)	$ (54,396)
Net loss per ordinary share - basic and diluted	$ (0.91)	$ (1.03)	$ (1.87)	$ (2.33)
Weighted average number of shares outstanding used in computation of basic and diluted loss per ordinary share	36,821,915	23,462,016	35,106,524	23,371,878

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 loss	Total
Balance as of April 1, 2024	36,127,687	$ 99	$ 671,438	$ (711,634)	$ (37)	$ (40,134)
Changes During the Three Months Ended June 30, 2024						
Exercise of options into ordinary shares	42,267	—	135			135
Share-based compensation			3,560			3,560
Issuance of pre-funded warrants, net of issuance costs			18,641			18,641
Issuance of ordinary share, net of issuance costs	5,000,000	13	81,496			81,509
Other comprehensive income					6	6
Net loss				(33,403)		(33,403)
Balance as of June 30, 2024	41,169,954	$ 112	$ 775,270	$ (745,037)	$ (31)	$ 30,314
Balance as of April 1, 2023	23,440,521	$ 64	$ 490,744	$ (607,317)	(45)	$ (116,554)
Changes During the Three Months Ended June 30, 2023						
Exercise of options into ordinary shares	58,096	-	143			143
Share-based compensation			2,222			2,222
Other comprehensive loss					(109)	(109)
Net loss				(24,136)		(24,136)
Balance as of June 30, 2023	23,498,617	$ 64	$ 493,109	$ (631,453)	$ (154)	$ (138,434)

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 Six Months Ended June 30, 2024						
Exercise of options into ordinary shares	279,367	1	134			135
Share-based compensation			6,316			6,316
Issuance of pre-funded warrants, net of issuance costs			18,641			18,641
Issuance of ordinary share, net of issuance costs	8,400,468	22	136,144			136,166
Other comprehensive loss					(43)	(43)
Net loss				(65,689)		(65,689)
Balance as of June 30, 2024	41,169,954	$ 112	$ 775,270	$ (745,037)	$ (31)	$ 30,314
Balance as of January 1, 2023	23,129,953	$ 63	$ 487,787	$ (577,104)	$ (107)	$ (89,361)
Changes During the Six Months Ended June 30, 2023						
Exercise of options into ordinary shares	368,664	1	814			815
Share-based compensation			4,508			4,508
Other comprehensive loss					(47)	(47)
Net loss				(54,349)		(54,349)
Balance as of June 30, 2023	23,498,617	$ 64	$ 493,109	$ (631,453)	$ (154)	$ (138,434)

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)

	Six Months Ended June 30,	
	2024	**2023**
Cash Flows From Operating Activities		
Net loss	$ (65,689)	$ (54,349)
Adjustment to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	193	426
Accrued financing on prepaid forward obligation	5,939	5,982
(Accretion) on marketable securities	(481)	(664)
Share-based compensation	6,316	4,508
Amortization of discount on long-term debt	(738)	759
Amortization of right of use assets	421	440
Changes in operating assets and liabilities:		
Inventory	(1,769)	(663)
Accounts receivable, net	(1,972)	(2,801)
Prepaid expenses and other current assets	(1,927)	(1,622)
Other non-current assets	1,365	(77)
Accounts payable and accrued expenses	7,216	4,020
Employee related accrued expenses	(3,965)	(1,536)
Lease liabilities	(442)	(504)
Restricted deposit	50	—
Net cash used in operating activities	(55,483)	(46,081)
Cash Flows From Investing Activities		
Purchases of marketable securities	—	(24,176)
Maturities of marketable securities	25,600	34,204
Purchases of property and equipment	(84)	(38)
Net cash provided by investing activities	25,516	9,990
Cash Flows From Financing Activities		
Proceeds from exercise of options into ordinary shares	135	814
Proceeds from pre-funded warrant issuance, net of issuance costs	18,641	—
Proceeds from ordinary share issuance, net of issuance costs	136,166	—
Net cash provided by financing activities	154,942	814
Increase (Decrease) in Cash and Cash Equivalents	124,975	(35,277)
Cash, Cash Equivalents and Restricted Cash at Beginning of Period	95,822	56,220
Cash, Cash Equivalents and Restricted Cash at End of Period	$ 220,797	$ 20,943
Supplemental Disclosures of Non-Cash Activities		
Right of use assets obtained in exchange for new operating lease liabilities	$ —	$ 95

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

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

Note 1 – Business and Nature of Operations

Nature of Operations

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

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

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

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

Note 2 – Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with 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 $745.0 million and $679.3 million as of June 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 develop UGN-102.

Based on the Company's cash, cash equivalents and marketable securities as of June 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 $241.3 million as of June 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 with RTW Investments (the "RTW Transaction") in which the Company received funds to support the launch of *Jelmyto* and the development of UGN-102 in return for tiered, future cash payments based on net sales of *Jelmyto* and UGN-102, if approved by the FDA. The net proceeds received under the RTW Transaction were recognized as a long-term liability. The Company recognizes the current cash payable amounts under the arrangement within other current liabilities on the 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 evaluating the potential impact of the adoption of ASU 2023-07 on the Company’s financial disclosures.

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

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

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 June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024	December 31, 2023
Accounts payable	$ 8,317	$ 6,514
Accrued sales reserves	6,428	4,391
Accrued clinical expenses	1,469	1,246
Accrued research and development expenses	1,258	1,049
Accrued selling, general and administrative expenses	5,340	2,752
Accrued other expenses	942	586
Total accounts payable and accrued expenses	$ 23,754	$ 16,538

Interest and Other Income, Net

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Interest income	$ 1,722	$ 435	$ 3,332	$ 1,080
Other income (loss), net	(14)	(30)	(9)	(45)
Total interest and other income, net	$ 1,708	$ 405	$ 3,323	$ 1,035

Note 5 – Inventories

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

	June 30, 2024	December 31, 2023
Raw materials (1)	$ 3,785	$ 4,464
Finished goods	3,960	2,877
Total inventories	$ 7,745	$ 7,341

(1) $0.3 million and $1.7 million of raw materials are included within other non-current assets on the condensed consolidated balance sheets at June 30, 2024 and December 31, 2023, respectively. These raw materials are not expected to be manufactured and sold within the next 12 months. Changes in non-current 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 June 30, 2024 are as follows (in thousands):

		Fair Value Measurements Using	
	Balance as of June 30, 2024	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash equivalents			
Money market funds	$ 30,943	$ 30,943	$ —
Marketable securities			
U.S. government	12,999	12,999	—
Corporate bonds	5,063	—	5,063
Commercial paper	1,236	—	1,236
Certificates of deposit	2,010	—	2,010
Total marketable securities	21,308	12,999	8,309
Total assets at fair value	$ 52,251	$ 43,942	$ 8,309

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 June 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 June 30, 2024 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Assets:				
Cash equivalents				
Money market funds	$ 30,943	$ —	$ —	$ 30,943
Marketable securities:				
U.S. government	13,014	—	(15)	12,999
Corporate bonds	5,081	1	(19)	5,063
Commercial paper	1,236	—	—	1,236
Certificates of deposit	2,008	2	—	2,010
Total marketable securities	21,339	3	(34)	21,308
Total assets at fair value	$ 52,282	$ 3	$ (34)	$ 52,251

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

As of June 30, 2024, the aggregate fair value of investments held by the Company in an unrealized loss position was $15.9 million which consisted of 14 securities. The unrealized loss was primarily driven by minor fluctuations in the fair value of corporate bonds and U.S. government securities. 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 June 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 June 30, 2024 mature at various dates through January 2026. The fair values of investments by contractual maturity consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Maturities within one year	$ 52,048	$ 51,670
Maturities after one year through three years	203	4,502
Total investments	$ 52,251	$ 56,172

Note 8 – Property and Equipment

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

	June 30, 2024	December 31, 2023
Laboratory equipment	$ 464	$ 464
Computer equipment and software	2,373	2,293
Furniture	612	612
Leasehold improvements	621	617
Manufacturing equipment	655	655
	4,725	4,641
Less: accumulated depreciation and amortization	(4,145)	(3,952)
Property and equipment, net	$ 580	$ 689

Depreciation and amortization expense was $0.1 million and $0.2 million for the three and six months ended June 30, 2024 and $0.2 million and $0.4 million for the three and six months ended June 30, 2023.

Note 9 – Prepaid Forward Obligation

In March 2021, the Company entered into a prepaid forward agreement with RTW Investments ("RTW"). Under the terms of the RTW Transaction, the Company received $75.0 million ($72.4 million net of transaction costs) to support the launch of *Jelmyto* and the development of UGN-102. In return for the transferred funds, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of *Jelmyto* in an amount equal to: (i) 9.5% of annual net sales up to $200 million, (ii) 3.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 1.0% of annual net sales for annual net sales above $300 million. If certain revenue thresholds for *Jelmyto* aggregate worldwide annual net sales are not met, the future cash payments to RTW with respect to *Jelmyto* annual net sales up to $200 million will increase by 3.5%, and may decrease back to 9.5% dependent on the Company meeting certain subsequent *Jelmyto* aggregate worldwide annual net sales thresholds. The rate in effect for the six months ended June 30, 2024 for annual net sales up to $200 million was 13.0%.

In addition, subject to FDA approval of UGN-102, UGN-103 and UGN-104, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of UGN-102, UGN-103 and UGN-104 in an amount equal to: (i) 2.5% of annual net sales up to $200 million, (ii) 1.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 0.5% of annual net sales for annual net sales above $300 million. If the Company does not receive FDA approval for UGN-102 by a specified date, the future cash payments to RTW with respect to aggregate worldwide annual net sales of *Jelmyto* across all *Jelmyto* annual net sales tiers will increase by 1.5%.

In accordance with the prepaid forward agreement, the Company will be required to make payments of amounts owed to RTW each calendar quarter, through and until the quarter in which the aggregate cash payments received by RTW are equal to or greater than $300 million. As of June 30, 2024, the cumulative amounts paid and payable by the Company were $28.4 million. As security for the payment and fulfilment of these amounts throughout the arrangement, the Company has granted RTW a first priority security interest in *Jelmyto* and UGN-102, including the regulatory approvals, intellectual property, material agreements, proceeds and accounts receivable related to these products.

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

The following table shows the activity with respect to the carrying value of the prepaid forward liability for the year ended December 31, 2023 and for the six months ended June 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		11,433
Amounts paid and payable (1)		(5,275)
Carrying value of prepaid forward obligation as of June 30, 2024	$	115,880

(1) $2.8 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 June 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 accrues 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 is required to be drawn by September 30, 2024, subject to customary bring down conditions and deliverables. The fourth tranche of $75.0 million will become available at the Company's option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0 million tranche, (ii) receiving FDA approval of a new drug application (“NDA”) for UGN-102 no later than June 30, 2025 and (iii) 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. 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, 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
Interest expense	5,908
Amounts paid	(6,646)
Carrying value of Pharmakon loan as of June 30, 2024	$ 97,813

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 June 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 $0.9 million as of June 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 six months ended June 30, 2024 and 2023 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease cost	$ 225	$ 257	$ 450	$ 485
Sublease income	—	(56)	(42)	(112)
Variable lease cost	14	19	43	38
	$ 239	$ 220	$ 451	$ 411

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

	June 30, 2024	December 31, 2023
Right-of-use assets	$ 1,250	$ 1,671
Long-term lease liabilities	425	844
Other current liabilities	796	819

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

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

	Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 497	$ 587
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 95
Weighted-average remaining lease term of operating leases (in years)	1.51	2.23
Weighted-average discount rate of operating leases	10.26%	10.16%

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

	Operating Leases
Years ending December 31,	
Remainder of 2024	$ 435
2025	817
2026	57
Total future minimum lease payments	1,309
Less: Interest	(88)
Present value of lease liabilities	$ 1,221

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

	Operating Leases
Years ending December 31,	
Remainder of 2023	$ 581
2024	923
2025	811
2026	52
Total future minimum lease payments	2,367
Less: Interest	(248)
Present value of lease liabilities	$ 2,119

Note 12 – Revenue From Product Sales

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Jelmyto	$ 21,848	$ 21,139	$ 40,629	$ 38,331

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 June 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	5,871	2,143	4,499	12,513
Utilizations	(6,560)	—	(4,528)	(11,088)
Balance as of June 30, 2024	$ 373	$ 5,594	$ 1,429	$ 7,396

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 June 30, 2024 and December 31, 2023. The Company had 41.2 million and 32.5 million ordinary shares issued and outstanding as of June 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 June 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, 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 estimated offering expenses payable 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 of 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 of 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 of 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 of 450,000 shares to a total share reserve of 5,200,167 shares.

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

As of June 30, 2024, 4,149,388 ordinary shares are subject to outstanding awards under the Company's share-based compensation plans and 364,517 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expenses	$ 594	$ 496	$ 1,112	$ 1,021
Selling, general and administrative expenses	2,966	1,726	5,204	3,487
Total share-based compensation expense	$ 3,560	$ 2,222	$ 6,316	$ 4,508

The total unrecognized compensation cost of options and RSUs at June 30, 2024 is $18.4 million with a weighted average recognition period of 2.01 years.

Note 16 – **Income Taxes**

UroGen Pharma Ltd. is taxed under Israeli tax laws. As of June 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 six months ended June 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 June 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 June 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 six months ended June 30, 2024 or 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 June 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 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. 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 $0.5 million within selling, general and administrative expenses during the six months ended June 30, 2024 in relation to this arrangement.

Leases

See Note 11 for further discussion regarding lease commitments.

Note 19 – **Subsequent Events**

On July 18, 2024, the Company completed the sale of an additional 921,428 ordinary shares in its underwritten public offering pursuant to the exercise in full of the Underwriters' option to purchase additional shares, which resulted in additional gross proceeds to the Company from the offering of $16.1 million before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company of $1.0 million. See Note 14 – Shareholders' Equity for further discussion.

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 both monotherapy and combination therapy.

If approved, UGN-102 may become the first FDA-approved medicine for low-grade intermediate risk NMIBC. We estimate that the annual treatable patient population of low-grade UTUC in the United States is approximately 6,000 to 7,000 and the annual treatable population of low-grade intermediate risk NMIBC is approximately 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 (or hydrogel) 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 U.S. Food and Drug Administration ("FDA") approved our NDA for *Jelmyto* (mitomycin) for pyelocalyceal solution, formerly known as UGN-101, for the treatment of adult patients with low-grade UTUC. *Jelmyto* consists of mitomycin, an established chemotherapy, and sterile hydrogel, using our proprietary sustained release *RTGel* technology. It has been designed to prolong exposure of 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 were listed in the FDA's Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

Low-grade UTUC is a rare cancer that develops in the lining of the upper urinary tract, 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 80 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 have experienced a moderate decline in revenue during the third quarter from the preceding quarter. We believe this result is primarily attributable to the nature of low-grade disease, which does not require immediate treatment and therefore we believe there is an impact in the summer months. However,

it is too early to say with confidence whether this seasonality trend will continue in future periods. Moreover, our future *Jelmyto* revenue will be impacted by various factors and we expect our *Jelmyto* revenue to fluctuate quarter-to-quarter for the foreseeable future.

UGN-102 (mitomycin) for intravesical solution

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

UGN-102 is administered locally using the standard practice of intravesical instillation directly into the bladder via a 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 trans-urethral resection of bladder tumor ("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. Based on our agreement with the FDA, we expect to complete the submission of the rolling NDA for UGN-102 in the third quarter of 2024, with a potential FDA acceptance in the fourth quarter of 2024 and potential FDA approval in the first quarter of 2025 (assuming priority review) or the second quarter of 2025 (assuming standard review).

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.

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, we announced that the FDA has accepted our Investigational New Drug Application ("IND") for UGN-103. We have initiated a Phase 3 clinical study to support the NDA for UGN-103 in low-grade intermediate risk NMIBC, and plan to enroll approximately 87 patients. The first patients are expected to be dosed in the third quarter of 2024, with full enrollment anticipated by the first half of 2025. An NDA filing 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 early next year.

UGN-301 (zalifrelimab) intravesical solution

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

High-grade NMIBC is a highly aggressive form of bladder cancer. TURBT followed by adjuvant intravesical immunotherapy with 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. 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 believe that these combinations make local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effects.

In March 2022, we announced FDA clearance of our IND to begin a novel Phase 1 clinical study of UGN-301 in patients with recurrent NMIBC. The novel study design utilizes a Master Protocol that we believe is a more efficient and streamlined approach to development. It will provide more flexibility to add study arms as the trial progresses and is expected to increase efficiency and potentially reduce costs. We expect the Master Protocol will allow us to more quickly evaluate safety, tolerability and dosing of UGN-301 in combination with additional immunomodulators and chemotherapies, with the goal of developing optimized treatment regimens for patients. The multi-arm Phase 1 study, which is expected to support the development of UGN-301 in high-grade NMIBC, was initiated in April 2022 and is actively enrolling. Safety and dosing data from the first arm evaluating UGN-301 as monotherapy are expected 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 six months ended June 30, 2024, we recognized $21.8 million and $40.6 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:

	Six Months Ended June 30,	
(in thousands)	**2024**	**2023**
Personnel, facility and equipment, and other overhead costs	$ 8,296	$ 8,498
Clinical and other development costs	22,600	15,584
Total	$ 30,896	$ 24,082

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 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 June 30, 2024 and 2023

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

	Three Months Ended June 30,		
	2024	2023	Change
	(in thousands)		
Revenue	$ 21,848	$ 21,139	$ 709
Cost of revenue	2,229	2,443	(214)
Gross profit	19,619	18,696	923
Operating expenses:			
Research and development	15,402	11,584	3,818
Selling and marketing	18,872	13,930	4,942
General and administrative	11,184	8,564	2,620
Total operating expenses	45,458	34,078	11,380
Operating loss	(25,839)	(15,382)	(10,457)
Financing on prepaid forward obligation	(5,773)	(5,344)	(429)
Interest expense on long-term debt	(3,461)	(3,761)	300
Interest and other income, net	1,708	405	1,303
Loss before income taxes	(33,365)	(24,082)	(9,283)
Income tax expense	(38)	(54)	16
Net loss	$ (33,403)	$ (24,136)	$ (9,267)

Revenue

Revenue was $21.8 million and $21.1 million for the three months ended June 30, 2024 and 2023, respectively. The increase in revenue of $0.7 million primarily reflects the increased volume of sales of *Jelmyto*.

Cost of Revenue

Cost of revenue was $2.2 million and $2.4 million for the three months ended June 30, 2024 and 2023, respectively. The decrease of $0.2 million is primarily attributable to certain nonrecurring payments made in connection with our supply arrangement in the prior year.

Research and Development Expenses

Research and development expenses were $15.4 million and $11.6 million for the three months ended June 30, 2024 and 2023, respectively. The increase of $3.8 million is primarily attributable to higher costs related to manufacturing of UGN-102 which are recognized within research and development expenses prior to our product candidates receiving FDA approval as well as research and development expenses in connection with our initiation of a Phase 3 study 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 $18.9 million and $13.9 million for the three months ended June 30, 2024 and 2023, respectively. The increase in selling and marketing expenses of $5.0 million is primarily attributable to UGN-102 brand marketing costs as well as an increase in overall commercial operation costs including meetings, conferences, and trainings.

General and Administrative Expenses

General and administrative expenses were $11.2 million and $8.6 million for the three months ended June 30, 2024 and 2023, respectively. The increase in general and administrative expenses of $2.6 million is primarily attributable to higher compensation expenses, legal and compliance activities, pre-commercialization marketing 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 $5.8 million and $5.3 million for the three months ended June 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 $0.5 million was driven primarily by changes in underlying assumptions for remeasuring the effective rate.

Interest Expense on Long-term Debt

Interest expense was $3.5 million and $3.8 million for the three months ended June 30, 2024 and 2023, respectively. The decrease of $0.3 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 $1.7 million and $0.4 million for the three months ended June 30, 2024 and 2023, respectively. The increase of $1.3 million in interest and other income, net was primarily due to higher cash and investment balances.

Comparison of the six months ended June 30, 2024 and 2023

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

	Six Months Ended June 30,		
	2024	2023	Change
		(in thousands)	
Revenue	$ 40,629	$ 38,331	$ 2,298
Cost of revenue	3,957	4,708	(751)
Gross profit	36,672	33,623	3,049
Operating expenses:			
Research and development	30,896	24,082	6,814
Selling and marketing	35,972	28,073	7,899
General and administrative	21,383	18,895	2,488
Total operating expenses	88,251	71,050	17,201
Operating loss	(51,579)	(37,427)	(14,152)
Financing on prepaid forward obligation	(11,433)	(10,568)	(865)
Interest expense on long-term debt	(5,908)	(7,314)	1,406
Interest and other income, net	3,323	1,035	2,288
Loss before income taxes	(65,597)	(54,274)	(11,323)
Income tax expense	(92)	(75)	(17)
Net loss	$ (65,689)	$ (54,349)	$ (11,340)

Revenue

Revenue was $40.6 million and $38.3 million for the six months ended June 30, 2024 and 2023, respectively. The increase in revenue of $2.3 million primarily reflects the increased volume of sales of *Jelmyto*.

Cost of Revenue

Cost of revenue was $4.0 million and $4.7 million for the six months ended June 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 decrease in the *Jelmyto* unit cost.

Research and Development Expenses

Research and development expenses were $30.9 million and $24.1 million for the six months ended June 30, 2024 and 2023, respectively. The increase of $6.8 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 our initiation of a Phase 3 study 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 $36.0 million and $28.1 million for the six months ended June 30, 2024 and 2023, respectively. The increase in selling and marketing expenses of $7.9 million is primarily attributable to UGN-102 brand marketing costs as well as an increase in overall commercial operation costs including meetings, conferences, trainings and software costs.

General and Administrative Expenses

General and administrative expenses were $21.4 million and $18.9 million for the six months ended June 30, 2024 and 2023, respectively. The increase in general and administrative expenses of $2.5 million is primarily attributable to higher compensation expenses, legal and compliance activities, marketing communication expenses related to UGN-102, third-party advisory services, and ongoing managed services, partially offset by lower professional services.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation was $11.4 million and $10.6 million for the six months ended June 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 $0.8 million was driven primarily by changes in underlying assumptions for remeasuring the effective rate.

Interest Expense on Long-term Debt

Interest expense was $5.9 million and $7.3 million for the six months ended June 30, 2024 and 2023, respectively. The decrease of $1.4 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 $3.3 million and $1.0 million for the six months ended June 30, 2024 and 2023, respectively. The increase of $2.3 million in interest and other income, net was primarily due to higher cash and investment balances.

Liquidity and Capital Resources

As of June 30, 2024, we had $241.3 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 June 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 Cowen pursuant to which we may from time to time offer and sell our ordinary shares having an aggregate offering price of up to $100.0 million.

In the first quarter of 2024, we sold 3,400,468 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $56.1 million. The net proceeds to us after deducting sales commissions to TD Cowen were approximately $54.7 million. The remaining capacity under the ATM Sales Agreement was approximately $27.3 million as of June 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 UGN-102, if approved. In May 2021, following the receipt of necessary regulatory approvals, we received the $75.0 million prepaid forward payment ($72.4 million net of transaction costs) from RTW.

Pharmakon Loan Agreement

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

On March 13, 2024, we entered into an amended and restated loan agreement with Pharmakon for an additional third and fourth tranche of senior secured loan. The third tranche of $25.0 million is required to be drawn by September 30, 2024, subject to customary bring down conditions and deliverables. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0 million tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) 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 estimated offering expenses of $1.0 million.

We have incurred losses since our inception and negative cash flows from our operations, and as of June 30, 2024 we had an accumulated deficit of $744.4 million. We anticipate that we will continue to incur losses for the reasonably foreseeable future. Our primary uses of capital are, and we expect will continue to be, commercialization activities, research and development expense, including third-party clinical research and development services, laboratory and related supplies, clinical costs, including manufacturing costs, legal and other regulatory expense and general and administrative costs, partially offset by proceeds from sales of *Jelmyto*.

We routinely evaluate our liquidity needs, including assessment of our current financial condition, sources of liquidity including current cash and cash equivalents and marketable securities and management's cash flow projections. Our ability to continue as a going concern is expected to be impacted by our ability to raise additional capital to fund our operations, produce cash inflows from *Jelmyto* product sales and develop UGN-102. Based on our cash, cash equivalents and marketable securities as of June 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 $1.3 million as of June 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 is required to be drawn by September 30, 2024, subject to customary bring down conditions and deliverables. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0 million tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) 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. 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, the Company's 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 $0.5 million during the six months ended June 30, 2024 in relation to this arrangement.

Cash Flows

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

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (55,483)	$ (46,081)
Investing activities	25,516	9,990
Financing activities	154,942	814
Net change in cash and cash equivalents	$ 124,975	$ (35,277)

Operating Activities

Net cash used in operating activities was $55.5 million during the six months ended June 30, 2024, compared to $46.1 million during the six months ended June 30, 2023. The $9.4 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 and higher personnel related spend.

Investing Activities

Net cash provided by investing activities was $25.5 million during the six months ended June 30, 2024, compared to net cash provided by investing activities of $10.0 million during the six months ended June 30, 2023. The net change of $15.5 million is attributable primarily to less reinvestment of marketable securities in 2024 as compared to 2023.

Financing Activities

Net cash provided by financing activities was $155.0 million during the six months ended June 30, 2024, compared to $0.8 million during the six months ended June 30, 2023. The increase of $154.2 million is attributable primarily to proceeds from the issuance of ordinary shares under the ATM Sales Agreement and underwritten public offering.

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 June 30, 2024, we had $241.3 million in cash and cash equivalents and marketable securities. We invest our cash primarily in money market accounts, but from time to time may invest in commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. If a 10% change in interest rates were to have occurred on June 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 six months ended June 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 six months ended June 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 June 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 June 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 June 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. 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 Phase 3 ENVISION trial 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 UGN-301 if approved as a monotherapy or for any approved product that includes UGN-301. There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers, including single-source suppliers. Furthermore, our existing third-party subcontractors and single-source suppliers may not be able to meet the increased need for certain raw materials, compounds and components that may result from our commercialization efforts. This increases the risk that we will not have sufficient quantities of *Jelmyto*, UGN-102, UGN-103, UGN-104, UGN-201 or UGN-301 or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

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

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

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

- Our indebtedness resulting from our loan agreement 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 $33.4 million for the quarter ended June 30, 2024. As of June 30, 2024, we had an accumulated deficit of $745.0 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 June 30, 2024, we had cash and cash equivalents and marketable securities of $241.3 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 June 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 is required to be drawn by September 30, 2024, subject to customary bring down conditions and deliverables. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0 million tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) 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. We are required to draw the third tranche of $25.0 million by September 30, 2024. The fourth tranche of $75.0 million will become available at our option no later than August 29, 2025, subject to (i) having successfully drawn the immediately preceding $25.0 million tranche, (ii) receiving FDA approval of an NDA for UGN-102 no later than June 30, 2025 and (iii) the satisfaction of customary bring down conditions and deliverables. There is no assurance that the additional term loans will be funded as expected or at all.

The obligations of the Borrower under the loan agreement 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 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* and its proper administration, our efforts to successfully commercialize *Jelmyto* could be put in jeopardy, which would negatively impact our ability to generate product revenues.

There can be no assurance that our 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 began production of Adstiladrin, approved by the FDA for the treatment of high-risk BCG-unresponsive NMIBC, in the second half of 2023. We are also aware there are companies among this list conducting clinical trials in various phases in the same indications in which we are developing products. In addition, 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 we initiated the submission of a rolling NDA to the FDA for UGN-102 as a treatment for low-grade intermediate risk NMIBC in January 2024, there is no guarantee that the FDA will accept the NDA for filing once the rolling submission is complete or eventually approve UGN-102 for the indication and patient population that we request or approve the labeling that we believe is necessary or desirable for the successful commercialization of UGN-102, as the FDA has the authority to refuse to file or approve NDAs for a variety of reasons.

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

- the FDA's acceptance of our parameters for regulatory approval relating to UGN-102 and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways, and proposed labeling and packaging;
- our ability to successfully complete the FDA requirements related to CMC, for UGN-102 and our other product candidates, and if completed, their sufficiency to support an NDA;
- the FDA's timely acceptance of our INDs, for our product candidates and our inability to commence clinical trials in the United States without such IND acceptances;
- the FDA's acceptance of the design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from nonclinical studies or clinical trials;
- the FDA's acceptance of the population studied in our clinical trials being sufficiently large, broad and representative to assess efficacy and safety in the patient population for which we seek approval;
- our ability to successfully complete the clinical trials of our product candidates, including timely patient enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of the product candidates undergoing such clinical trials;
- our ability to demonstrate meaningful clinical or other benefits which outweigh any safety or other perceived risks, through the completion of our clinical trials for our product candidates;
- the FDA's need to schedule an advisory committee meeting, and to conduct such meeting, in a timely manner to evaluate and decide on the approval of our potential future NDA for UGN-102;
- if applicable, the recommendation of the FDA's advisory committee to approve our applications to market UGN-102 and our other product candidates in the United States, without limiting the approved labeling, specifications, distribution or use of the products, or imposing other restrictions;
- the FDA's determination of safety and efficacy of our product candidates;
- the FDA's determination that the Section 505(b)(2) 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 Phase 3 ENVISION trial 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 UGN-102 or the other product candidates in our pipeline, and we may be delayed in obtaining or failing to obtain such regulatory approvals and to commercialize our product candidates.*

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

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

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

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

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

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

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

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

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

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

These risks and uncertainties impact all of our nonclinical programs that we pursue. If we are unsuccessful in advancing our nonclinical product candidates into clinical trials in a timely fashion, our business may be harmed. Even if we are successful in advancing our nonclinical product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this 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 UGN-301 if approved as a monotherapy or for any approved product that includes UGN-301. There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers, including single-source suppliers. Furthermore, our existing third-party subcontractors and single-source suppliers may not be able to meet the increased need for certain raw materials, compounds and components that may result from our commercialization efforts. This increases the risk that we will not have sufficient quantities of Jelmyto, UGN-102, UGN-103, UGN-104, UGN-201 or UGN-301 or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.*

We currently rely on third party subcontractors and suppliers for certain compounds and components necessary to produce *Jelmyto* for commercial use and UGN-102, UGN-103, UGN-104, UGN-201 and UGN-301 for our nonclinical studies and clinical trials, and expect to rely on third party subcontractors and suppliers for commercial use for any of our drug candidates that receive regulatory approval. We currently depend on Teva Pharmaceuticals Industries Ltd, as our single-source supplier of mitomycin 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 purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development and commercialization of our product candidates or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of *Jelmyto* or any other approved products.

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

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

While we currently have over 12 months of mitomycin API and/or *Jelmyto* finished product on hand to continue our commercial and clinical operations as planned, we may face such delays or costs in future years. Although we believe we have sufficient quantities of bulk mitomycin API for planned manufacturing operations for 12 months, 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 June 30, 2024, we had 203 employees, of whom 40 are based in Israel and 163 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 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 will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to our Operations in Israel

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

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

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

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

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

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

Further, our operations could be disrupted by the obligations of our employees to perform military service. As of June 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 June 30, 2024, we had 203 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).
4.1	Form of June 2024 Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38079), filed with the SEC on June 18, 2024).
10.1*	UroGen Pharma Ltd. 2019 Inducement Plan, as amended.
10.2*	UroGen Pharma Ltd. 2024 Non-Employee Director and Officer Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 8, 2024).
10.3*	2017 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 8, 2024).
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

* Management contract or compensatory plan.

\# 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.

August 13, 2024 By: /s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer
(Principal Executive Officer)

August 13, 2024 By: /s/ Don Kim
Don Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)

UroGen Pharma Ltd.

2019 Inducement Plan

Adopted by the Board of Directors: May 21, 2019
Amendment Adopted by the Board of Directors: December 13, 2021
Amendment Adopted by the Board of Directors: June 14, 2024

1. General.

(a) Eligible Award Recipients. The only persons eligible to receive grants of Awards under this Plan are individuals who satisfy the standards for inducement grants under NASDAQ Marketplace Rule 5635(c)(4) or 5635(c)(3), if applicable, and the related guidance under NASDAQ IM 5635-1. A person who previously served as an Employee or Director will not be eligible to receive Awards under the Plan, other than following a *bona fide* period of non-employment. Persons eligible to receive grants of Awards under this Plan are referred to in this Plan as "***Eligible Employees***." These Awards must be approved by either a majority of the Company's "***Independent Directors***" (as such term is defined in NASDAQ Marketplace Rule 5605(a)(2)) or the Company's compensation committee, provided such committee comprises solely Independent Directors (the "***Independent Compensation Committee***") in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the NASDAQ Marketplace Rules. NASDAQ Marketplace Rule 5635(c)(4) and the related guidance under NASDAQ IM 5635-1 (and any analogous rules or guidance effective after the date hereof) are referred to in this Plan as the "***Inducement Award Rules***." An Israeli Sub-Plan has been established under the Plan in order to provide for additional terms for grants made to Participants in Israel.

(b) Available Awards. The Plan provides for the grant of the following types of Awards: (i) Nonstatutory Stock Options, (ii) Restricted Stock Unit Awards and (iii) Other Stock Awards.

(c) Purpose. This Plan, through the granting of Awards, is intended to provide (i) an inducement material for certain individuals to enter into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Marketplace Rules, (ii) incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and (iii) a means by which Eligible Employees may be given an opportunity to benefit from increases in value of the Ordinary Shares through the granting of Awards.

2. Administration.

(a) Administration by Board. The Board will administer the Plan; provided, however, that Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee. Subject to those constraints and the other constraints of the Inducement Award Rules, the Board may delegate some of its powers of administration of the Plan to a Committee, as provided in Section 2(c).

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan and the Inducement Award Rules:

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Ordinary Shares under the Award; (E) the number of Ordinary Shares subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to an Award; provided, however, that Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which an Award may be exercised or vest (or at which cash or Ordinary Shares may be issued).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not materially impair a Participant's rights under the Participant's then-outstanding Award without the Participant's written consent.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to nonqualified deferred compensation under Section 409A of the Code and/or to bring the Plan or Awards granted under the Plan into compliance therewith, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements (taking into account any permissible and effective opting out by the Company from such requirements), and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company shall seek stockholder approval for any amendment of the Plan. Except as provided above, rights under any Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Rule 16b-3 of Exchange Act or any successor rule.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more outstanding Awards. Except as otherwise provided in the Plan or an Award Agreement, no amendment of an outstanding Award will materially impair that Participant's rights

under his or her outstanding Award without his or her written consent. To be clear, unless prohibited by applicable law, the Board may amend the terms of an Award without the affected Participant's consent if necessary (A) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code, or (B) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by individuals who are foreign nationals or employed outside the United States.

(c) Delegation to Committee. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(d) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e) Repricing; Cancellation and Re-Grant of Awards. Neither the Board nor any Committee will have the authority to: (i) reduce the exercise, purchase or strike price of any outstanding Option, or (ii) cancel any outstanding Option that has an exercise price or strike price greater than the current Fair Market Value of an Ordinary Share in exchange for cash or other Awards under the Plan, unless the stockholders of the Company have approved such an action within twelve (12) months prior to such an event.

3. Shares Subject to the Plan.

(a) Share Reserve. Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of Ordinary Shares that may be issued pursuant to Awards from and after the Effective Date shall not exceed 1,800,000 shares. Shares may be issued under the terms of this Plan in connection with a merger or acquisition as permitted by NASDAQ Marketplace Rule 5635(c)(3), NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) Reversion of Shares to the Share Reserve. If an Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of Ordinary Shares that may be available for issuance under the Plan and the Ordinary Shares relating to such Award (or portion thereof) will again become available for issuance under the Plan. If any Ordinary Shares issued pursuant to an Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the Plan. Any shares reacquired by the Company in satisfaction of tax withholding obligations on an Award or as consideration for the exercise or purchase price of an Award will again become available for issuance under the Plan.

(c) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Ordinary Shares, including shares repurchased by the Company on the open market or otherwise.

4. Eligibility.

(a) Eligibility for Awards. Awards may only be granted to persons who are Eligible Employees described in Section 1(a) of the Plan, where the Award is an inducement material to the individual's entering into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the NASDAQ Marketplace Rules or is otherwise permitted pursuant to Rule 5635(c) of the NASDAQ Marketplace Rules, *provided however*, that Awards may not be granted to Eligible Employees who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Awards are granted pursuant to a corporate transaction such as a spin off transaction), or (ii) the Company, in consultation with its legal counsel, has determined that such Awards are otherwise exempt from or comply with the distribution requirements of Section 409A of the Code.

(b) Approval Requirements. All Awards must be granted either by a majority of the Company's independent directors or the Independent Compensation Committee.

5. Provisions relating to Options.

Each Option will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be Nonstatutory Stock Options. The provisions of separate Options need not be identical; *provided, however*, that each Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) Term. No Option will be exercisable after the expiration of 10 years from the date of its grant or such shorter period specified in the Award Agreement.

(b) Exercise Price. The exercise or strike price of each Option will not be less than 100% of the Fair Market Value of the Ordinary Shares subject to the Option on the date the Option is granted. Notwithstanding the foregoing, an Option may be granted with an exercise price lower than 100% of the Fair Market Value of the Ordinary Shares subject to the Option if such Option is granted pursuant to an assumption of or substitution for another option pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code.

(c) Purchase Price for Options. The purchase price of Ordinary Shares acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use

certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of Ordinary Shares;

(iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of Ordinary Shares issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Ordinary Shares will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are reduced to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Award Agreement.

(d) Transferability of Options. The Board may, in its sole discretion, impose such limitations on the transferability of Options as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options will apply:

(i) Restrictions on Transfer. An Option will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided herein, an Option may not be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option may be transferred pursuant to the terms of a domestic relations order or official marital settlement agreement or other divorce or separation instrument.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option and receive the Ordinary Shares or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant's estate will be entitled to exercise the Option and receive Ordinary Shares or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(e) Vesting Generally. The total number of Ordinary Shares subject to an Option may vest and become exercisable in periodic installments that may or may not be equal. The Option may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of performance goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options may vary. The provisions of this Section are subject to any Option provisions governing the minimum number of Ordinary Shares as to which an Option may be exercised.

(f) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date three months following the termination of the Participant's Continuous Service and (ii) the expiration of the term of the Option as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option within the applicable time frame, the Option will terminate.

(g) Extension of Termination Date. If the exercise of an Option following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of Ordinary Shares would violate the registration requirements under the Securities Act, then the Option will terminate on the earlier of (i) the expiration of a total period of three months (that need not be consecutive) after the termination of the Participant's Continuous Service during which the exercise of the Option would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Ordinary Shares received on exercise of an Option following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option will terminate on the earlier of (i) the expiration of a period of months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Ordinary Shares received upon exercise of the Option would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option as set forth in the applicable Award Agreement.

(h) Disability of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option (to the extent that the Participant was entitled to exercise such Option as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date 12 months following such termination of Continuous Service and (ii) the expiration of the term of the Option as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option within the applicable time frame, the Option (as applicable) will terminate.

(i) Death of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Award Agreement for exercisability after the termination of the Participant's Continuous Service for a reason other than death, then the Option may be exercised (to the extent the Participant was entitled to exercise such Option as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated to exercise the Option upon the Participant's death, but only within the period ending on the earlier of (i) the date 18 months following the date of death and (ii) the expiration of the term of such Option as set forth in the Award Agreement. If, after the Participant's death, the Option is not exercised within the applicable time frame, the Option will terminate.

(j) Termination for Cause. Except as explicitly provided otherwise in a Participant's Award Agreement, if a Participant's Continuous Service is terminated for Cause, the Option will terminate upon the date on which the event giving rise to the termination for Cause first occurred, and the Participant will be prohibited from exercising his or her Option from and after the date on which the event giving rise to the termination for Cause first occurred (or, if required by law, the date of termination of Continuous Service).

(k) Non-Exempt Employees. If an Option is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option will not be first exercisable for any Ordinary Shares until at least six (6) months following the date of grant of the Option (although the Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Award Agreement in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options may be exercised earlier than six months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Award will be exempt from the employee's regular rate of pay, the provisions of this Section will apply to all Awards and are hereby incorporated by reference into such Award Agreements.

6. Provisions of Awards Other than Options.

(a) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board deems appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each Ordinary Share subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each Ordinary Share subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of Ordinary Shares, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the Ordinary Shares (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(b) Other Stock Awards. Other forms of awards valued in whole or in part by reference to, or otherwise based on, Ordinary Shares, including the appreciation in value thereof may be granted either alone or in addition to Awards granted under Section 5 and this Section 6. Subject to the provisions of the Plan, the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of Ordinary Shares (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. Covenants of the Company.

(a) Availability of Shares. The Company will keep available at all times the number of Ordinary Shares reasonably required to satisfy then-outstanding Awards.

(b) Securities Law Compliance. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell Ordinary Shares upon exercise of the Stock Awards; *provided, however*, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any Ordinary Shares issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Ordinary Shares under the Plan, the Company will be relieved from any liability for failure to issue and sell Ordinary Shares upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Ordinary Shares pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award.

8. Miscellaneous.

(a) Use of Proceeds from Sales of Ordinary Shares. Proceeds from the sale of Ordinary Shares pursuant to Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement as a result of a clerical error in the papering of the Award Agreement, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement.

(c) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any Ordinary Shares subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares under, the Award pursuant to its terms, and (ii) the issuance of Ordinary Shares subject to such Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the articles of association of the Company or an Affiliate, and any applicable provisions of the corporate law of the jurisdiction in which the Company or the Affiliate is incorporated, as the case may be.

(e) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced.

(f) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Ordinary Shares under any Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Ordinary Shares subject to the Award for the Participant's own account and not with any present intention of selling or otherwise distributing Ordinary Shares. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Ordinary Shares under the Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of Ordinary Shares.

(g) Withholding Obligations. Unless prohibited by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding Ordinary Shares from the Ordinary Shares issued or otherwise issuable to the Participant in connection with the Award; *provided, however,* that no Ordinary Shares are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Award Agreement.

(h) Electronic Delivery. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Ordinary Shares or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(j) Compliance with Section 409A. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the Ordinary Shares are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six (6) months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

(k) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may

impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired Ordinary Shares or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company.

9. Adjustments upon Changes in Ordinary Shares; Other Corporate Events.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a); and (ii) the class(es) and number of securities and price per share of stock subject to outstanding Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Awards (other than Awards consisting of vested and outstanding Ordinary Shares not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the Ordinary Shares subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Award is providing Continuous Service; *provided, however*, that the Board may, in its sole discretion, cause some or all Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) Corporate Transaction. The following provisions will apply to Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of an Award. In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board will take one or more of the following actions with respect to Awards, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Award or to substitute a similar award for the Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Ordinary Shares issued pursuant to the Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Award (and, if applicable, the time at which the Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board will determine (or, if the Board will not determine such a date, to the date that is five days prior to the effective date of the Corporate Transaction), with such Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Award;

(v) cancel or arrange for the cancellation of the Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise. For clarity, this payment may be zero ($) if the value of the property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Company's Ordinary Shares in connection with the Corporate Transaction is delayed as a result of escrows, earn-outs, holdbacks or any other contingencies.

The Board need not take the same action or actions with respect to all Awards or portions thereof or with respect to all Participants.

(d) Change in Control. In the event of a Change in Control, the Board shall have the discretion to take any one or more of the actions set forth in Section 9(c)(i)-(vi) with respect to Awards, contingent upon the closing or completion of the Change in Control; *provided, however*, that for such purpose, the term "Corporate Transaction" in Section 9(c)(i)-(vi) will mean "Change In Control." An Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Award Agreement for such Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant.

10. Termination or Suspension of the Plan.

The Board may suspend or terminate the Plan at any time. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. Effective Date of the Plan.

The Plan will come into existence on the Effective Date. No Award may be granted prior to the Effective Date.

12. Choice of Law.

The Plan, all determinations made and actions taken pursuant hereto and, except as provided below or in an applicable subplan, each Award Agreement to a Participant shall be governed by the laws of the State of Israel, excluding matters that are subject to tax laws, regulations and rules, or conflicts or choice of law rule or principles, of any specific jurisdiction, which shall be governed by the respective laws, regulations and rules of such jurisdiction.

13. Definitions. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a)“ ***Affiliate***” means, at the time of determination, any “parent” or “subsidiary” of the Company as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which “parent” or “subsidiary” status is determined within the foregoing definition.

(b)“ ***Award***” means an Option, a Restricted Stock Unit Award or an Other Stock Award.

(c)“ ***Award Agreement***” means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(d)“ ***Board***” means the Board of Directors of the Company.

(e)“ ***Capitalization Adjustment***” means any change that is made in, or other events that occur with respect to, the Ordinary Shares subject to the Plan or subject to any Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company shall not be treated as a Capitalization Adjustment.

(f)“ ***Cause***” will have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant’s commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant’s attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant’s intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant’s unauthorized use or disclosure of the Company’s confidential information or trade secrets; or (v) such Participant’s gross misconduct. The determination that a termination of the Participant’s Continuous Service is either for Cause or without Cause will be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(g) “***Change in Control***” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company; (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company’s securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities; or (C) solely because the level of Ownership held by any Exchange Act Person (the “***Subject Person***”) exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the “***Incumbent Board***”) cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

For purposes of determining voting power under the term Change in Control, voting power shall be calculated by assuming the conversion of all equity securities convertible (immediately or at some future time) into shares entitled to vote, but not assuming the exercise of any warrant or right to subscribe to or purchase those shares. In addition, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, (B) the term Change in Control will not include a change in the voting power of any one or more stockholders as a result of the conversion of any class of the Company’s securities into another class of the Company’s securities having a different number of votes per share pursuant to the conversion provisions set forth in the Company’s Amended and Restated Certificate of Incorporation, and (C) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply. If required for compliance with Section 409A of the Code, in no event will a Change in Control be deemed to have occurred if such transaction is not also a “change in the ownership or effective control of” the Company or “a change in the ownership of a substantial portion of the assets of” the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board may, in its sole discretion and without a Participant’s consent, amend the definition of “Change in Control” to conform to the definition of “Change in Control” under Section 409A of the Code, and the regulations thereunder.

(h)" ***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(i)" ***Committee***" means a committee of one or more Independent Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(j)" ***Company***" means UroGen Pharma Ltd., an Israeli corporation.

(k)" ***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person.

(l)" ***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; *provided, however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(m)" ***Corporate Transaction***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) the consummation of a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) the consummation of a sale or other disposition of at least 50% of the outstanding securities of the Company;

(iii) the consummation of a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) the consummation of a merger, consolidation or similar transaction following which the Company is the surviving corporation but the Ordinary Shares outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

To the extent required for compliance with Section 409A of the Code, in no event will an event be deemed a Corporate Transaction if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(n) "***Director***" means a member of the Board. Directors are not eligible to receive Awards under the Plan with respect to their service in such capacity.

(o)" ***Disability***" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(p)" ***Effective Date***" means May 21, 2019.

(q)" ***Eligible Employee***" has the meaning set forth in Section 1(a).

(r)" ***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(s)" ***Entity***" means a corporation, partnership, limited liability company or other entity.

(t)" ***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(u)" ***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(v)" ***Fair Market Value***" means, as of any date, the value of the Ordinary Shares determined as follows:

(i) If the Ordinary Shares are listed on any established stock exchange or traded on any established market, the Fair Market Value of an Ordinary Share will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Ordinary Shares) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Ordinary Shares on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Ordinary Shares, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(w)" ***Independent Compensation Committee***" has the meaning set forth in Section 1(a).

(x)" ***Independent Directors***" has the meaning set forth in Section 1(a).

(y)" ***Inducement Award Rules***" has the meaning set forth in Section 1(a).

(z)" ***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(aa)" ***Nonstatutory Stock Option***" means any option granted pursuant to Section 5 of the Plan that does not qualify as an "incentive stock option" within the meaning of Section 422 of the Code.

(bb)" ***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(cc)" ***Option***" means a Nonstatutory Stock Option to purchase Ordinary Shares granted pursuant to the Plan.

(dd)" ***Option Agreement***" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(ee)" ***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(ff)" ***Ordinary Shares***" means the Ordinary Shares of the Company, par value NIS 0.01 per Ordinary Share.

(gg)" ***Other Stock Award***" means an award based in whole or in part by reference to the Ordinary Shares which is granted pursuant to the terms and conditions of Section 6(c).

(hh) "***Own,***" "***Owned,***" "***Owner,***" "***Ownership***" **A** person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ii)" ***Participant***" means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

(jj) "***Plan***" means this UroGen Pharma Ltd. 2019 Inducement Plan, as it may be amended.

(kk)" ***Restricted Stock Unit Award***" means a right to receive Ordinary Shares which is granted pursuant to the terms and conditions of Section 6(b).

(ll)" ***Restricted Stock Unit Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(mm)" ***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(nn)" ***Securities Act***" means the Securities Act of 1933, as amended.

(oo) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

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: August 13, 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, Don Kim, certify that:

1. I have reviewed this quarterly report on Form 10-Q of UroGen Pharma Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2024

By: /s/ Don Kim
Don Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of UroGen Pharma Ltd. (the "Company") on Form 10-Q for the period ended June 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: August 13, 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 June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Don Kim, 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: August 13, 2024

By: /s/ Don Kim

Don Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)