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, 2023

OR

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

For the transition period from to

Commission file number: 001-38079

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

Israel	**98-1460746**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification 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 7, 2023, the registrant had 30,282,880 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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 20,127	$ 55,408
Marketable securities	27,174	44,556
Restricted cash	816	813
Accounts receivable	15,505	12,704
Inventories	4,988	4,325
Prepaid expenses and other current assets	12,723	11,101
Total current assets	81,333	128,907
Non-current assets:		
Property and equipment, net	910	1,297
Restricted deposit	224	223
Right of use assets	2,107	2,452
Marketable securities	7,970	—
Other non-current assets	2,817	2,740
Total Assets	$ 95,361	$ 135,619
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 16,403	$ 12,383
Employee related accrued expenses	6,721	8,257
Other current liabilities	3,641	3,276
Total current liabilities:	26,765	23,916
Non-current liabilities:		
Prepaid forward obligation	104,507	98,923
Long-term debt	98,296	97,537
Long-term lease liabilities	1,209	1,586
Uncertain tax positions liability	3,018	3,018
Total Liabilities	233,795	224,980
Commitments and Contingencies (Note 18)		
Shareholders' Deficit:		
Ordinary shares, NIS 0.01 par value, 100,000,000 shares authorized at June 30, 2023 and December 31, 2022; 23,498,617 and 23,129,953 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	64	63
Additional paid-in capital	493,109	487,787
Accumulated deficit	(631,453)	(577,104)
Accumulated other comprehensive loss	(154)	(107)
Total Shareholders' Deficit	(138,434)	(89,361)
Total Liabilities and Shareholders' Deficit	$ 95,361	$ 135,619

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,	
	2023	2022	2023	2022
Revenue	$ 21,139	$ 16,604	$ 38,331	$ 30,168
Cost of revenue	2,443	1,846	4,708	3,371
Gross profit	18,696	14,758	33,623	26,797
Operating expenses:				
Research and development expenses	11,584	12,640	24,082	25,336
Selling, general and administrative expenses	22,494	20,833	46,968	42,133
Operating loss	(15,382)	(18,715)	(37,427)	(40,672)
Financing on prepaid forward obligation	(5,344)	(5,833)	(10,568)	(11,659)
Interest expense on long-term debt	(3,761)	(2,239)	(7,314)	(2,521)
Interest and other income (expense), net	405	128	1,035	126
Loss before income taxes	(24,082)	(26,659)	(54,274)	(54,726)
Income tax expense	(54)	(32)	(75)	(357)
Net Loss	$ (24,136)	$ (26,691)	$ (54,349)	$ (55,083)
Statements of Comprehensive Loss				
Net loss	$ (24,136)	$ (26,691)	$ (54,349)	$ (55,083)
Other comprehensive loss				
Unrealized gain (loss) on investments	(109)	13	(47)	(31)
Comprehensive Loss	$ (24,245)	$ (26,678)	$ (54,396)	$ (55,114)
Net loss per ordinary share - basic and diluted	$ (1.03)	(1.18)	$ (2.33)	$ (2.43)
Weighted average number of shares outstanding used in computation of basic and diluted loss per ordinary share	23,462,016	22,703,572	23,371,878	22,667,825

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

UroGen Pharma Ltd.
Condensed Consolidated Statements of Shareholders' 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, 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)
Balance as of April 1, 2022	22,682,221	$ 62	$ 478,646	$ (495,713)	(69)	$ (17,074)
Changes During the Three Months Ended June 30, 2022						
Exercise of options into ordinary shares	45,670	-	16			16
Share-based compensation			2,823			2,823
Other comprehensive income					13	13
Net loss				(26,691)		(26,691)
Balance as of June 30, 2022	22,727,891	$ 62	$ 481,485	$ (522,404)	$ (56)	$ (40,913)

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

UroGen Pharma Ltd.
Condensed Consolidated Statements of Shareholders' 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 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)
Balance as of January 1, 2022	22,462,995	$ 61	$ 475,698	$ (467,321)	(25)	$ 8,413
Changes During the Six Months Ended June 30, 2022						
Exercise of options into ordinary shares	264,896	1	15			16
Share-based compensation			5,772			5,772
Other comprehensive loss					(31)	(31)
Net loss				(55,083)		(55,083)
Balance as of June 30, 2022	22,727,891	$ 62	$ 481,485	$ (522,404)	$ (56)	$ (40,913)

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

	Six Months Ended June 30,	
	2023	**2022**
Cash Flows From Operating Activities		
Net loss	$ (54,349)	$ (55,083)
Adjustment to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	426	449
Inventory Obsolescence	—	265
Accrued financing on prepaid forward obligation	5,982	8,359
Amortization (accretion) on marketable securities	(664)	169
Share-based compensation	4,508	5,772
Amortization of discount on long-term debt	759	403
Amortization of right of use assets	440	483
Changes in operating assets and liabilities:		
Inventory	(663)	(480)
Accounts receivable	(2,801)	122
Prepaid expenses and other current assets	(1,622)	(2,958)
Other non-current assets	(77)	(444)
Accounts payable and accrued expenses	4,020	(3,454)
Employee related accrued expenses	(1,536)	(520)
Other current liabilities	—	(704)
Lease liabilities	(504)	(574)
Net cash used in operating activities	(46,081)	(48,195)
Cash Flows From Investing Activities		
Purchases of marketable securities	(24,176)	—
Maturities of marketable securities	34,204	13,533
Purchases of property and equipment	(38)	(88)
Net cash provided by investing activities	9,990	13,445
Cash Flows From Financing Activities		
Proceeds from exercise of options into ordinary shares	814	16
Proceeds from issuance of long-term debt	—	70,793
Issuance cost related to at-the-market issuances	—	(144)
Net cash provided by financing activities	814	70,665
Increase (Decrease) in Cash and Cash Equivalents	(35,277)	35,915
Cash, Cash Equivalents and Restricted Cash at Beginning of Period	56,220	45,586
Cash, Cash Equivalents and Restricted Cash at End of Period	$ 20,943	$ 81,501
Supplemental Disclosures of Non-Cash Activities		
Right of use assets obtained in exchange for new operating lease liabilities	$ 95	$ 1,419

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

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

Note 1 – Business and Nature of Operations

Nature of Operations

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

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

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

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

Note 2 – Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of the Company's management, the accompanying condensed consolidated financial statements contain all adjustments (consisting of normal recurring accruals and adjustments) necessary for fair statement of its financial position, results of operations and cash flows of the Company at the dates and for the periods indicated. Interim results are not necessarily indicative of results for the full fiscal year. The year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States. The unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and the notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the U.S. Securities and Exchange Commission ("SEC") on March 24, 2023.

The Company has experienced net losses since its inception and has an accumulated deficit of $631.5 million and $577.1 million as of June 30, 2023 and December 31, 2022, respectively. The Company expects to incur losses and have negative net cash flows from operating activities as it executes on its strategy including engaging in further research and development activities, particularly conducting non-clinical studies and clinical trials. The success of the Company depends on the ability to successfully commercialize its technologies to support its operations and strategic plan.

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.

On July 26, 2023, the Company entered into a private placement transaction with certain institutional and other accredited investors pursuant to which the Company agreed to sell its ordinary shares and pre-funded warrants to purchase ordinary shares to the investors, for aggregate gross proceeds of $120.0 million. See Note 19 for further discussion regarding the private placement transaction.

Based on the Company's cash, cash equivalents and marketable securities as of June 30, 2023, together with management's cash flow projections and the net proceeds to the Company from its private placement transaction in July 2023, the Company believes that it has sufficient cash and cash equivalents to fund its operations beyond one year from the issuance of these financial statements. The Company will need to raise additional capital in the future. There can be no assurances that the Company will be able to secure such additional financing if at all, or on terms that are satisfactory to the Company, and that it will be sufficient to meet its needs. In the event the Company is not successful in obtaining sufficient funding, this could force us to delay, limit, or reduce our product development, commercialization efforts or other operations.

Note 3 – **Significant Accounting Policies**

Principles of Consolidation

The 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 (expense), 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 $55.3 million as of June 30, 2023. The Company accounts for its investments, which include cash equivalents and marketable securities, as available-for-sale in accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 320, “Investments — Debt and Equity Securities”. Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported in other comprehensive income/loss within shareholders’ equity. Realized gains and losses are recorded as a component of interest and other income (expense), net. The cost of securities sold is based on the specific-identification method.

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

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

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

Concentration of Credit Risk

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

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

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

Income Taxes

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

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. After concluding that a particular filing position can be recognized (i.e., has a more-likely-than-not chance of being sustained), ASC 740-10-30-7 requires that the amount of benefit recognized be measured using a methodology based on the concept of cumulative probability. Under this methodology, the amount of benefit recorded represents the largest amount of tax benefit that is greater than 50% likely to be realized upon settlement with a taxing authority that has full knowledge of all relevant information. See Note 16 for further discussion related to income taxes.

Inventory

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

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

Property and Equipment

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

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

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

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

Prepaid Forward Obligation

The Company is party to a transaction with RTW Investments (the “RTW Transaction”) in which the Company received funds to support the continued launch of *Jelmyto* and the development of UGN-102 in return for tiered, future cash payments based on net sales of *Jelmyto* and UGN-102, if approved by the FDA. The net proceeds received under the RTW Transaction were recognized as a long-term liability. The 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 arrangement with a single customer, a third-party national specialty distributor. Net revenue recognized includes gross revenue and management’s estimate of returns, consideration paid to the customer, chargebacks relating to differences between the wholesale acquisition cost and the contracted price offered to the end consumer, chargebacks relating to 340b drug pricing programs and other government sponsored programs, Medicaid drug rebate programs, the Company’s copay assistance program, and Medicare refund 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. The fair value of options is determined using the Black-Scholes option-pricing model. The fair value of a restricted stock unit (“RSU”) equaled the closing price of the Company’s ordinary shares on the grant date. The Company accounts for forfeitures as they occur in accordance with ASC Topic 718, “Compensation—Stock Compensation”.

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

Net Loss per Ordinary Share

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

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

Recently Adopted Issued Pronouncements

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

Note 4 – **Other Financial Information**

Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following as of June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023	December 31, 2022
Accounts payable	$ 4,659	$ 5,527
Accrued sales reserves	2,721	618
Accrued clinical expenses	2,054	2,853
Accrued research and development expenses	1,003	1,285
Accrued selling, general and administrative expenses	2,836	1,609
Accrued other expenses	3,130	491
Total accounts payable and accrued expenses	$ 16,403	$ 12,383

Interest and Other Income (Expense), Net

Interest and other income (expense), net consisted of the following as of June 30, 2023 and 2022 (in thousands):

	Six Months Ended June 30,	
	2023	2022
Interest income	$ 1,080	$ 28
Other income (expense), net	(45)	98
Total interest and other income (expense), net	$ 1,035	$ 126

Note 5 – **Inventories**

Inventories consisted of the following as of June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023	December 31, 2022
Raw materials (1)	$ 5,363	$ 4,676
Finished goods	2,072	2,019
Total inventories	$ 7,435	$ 6,695

(1) $2.4 million and $2.4 million of raw materials are included within other non-current assets on the condensed consolidated balance sheets at June 30, 2023 and December 31, 2022, respectively. 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, 2023 are as follows (in thousands):

		Fair Value Measurements Using	
	Balance as of June 30, 2023	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Assets:			
Cash equivalents			
Money market funds	$ 596	$ 596	$ —
Marketable securities			
U.S. government	18,915	18,915	—
Corporate bonds	6,485	—	6,485
Commercial paper	2,011	—	2,011
Certificates of deposit	7,733	—	7,733
Total marketable securities	35,144	18,915	16,229
Total assets at fair value	$ 35,740	$ 19,511	$ 16,229

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

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

The Company's investments in U.S. government bonds and money market funds are measured based on publicly available quoted market prices for identical securities as of June 30, 2023 and December 31, 2022. The Company's investments in corporate bonds, commercial paper and certificates of deposits are measured based on quotes from market makers for similar items in active markets.

Note 7 – **Investments**

The following table summarizes the Company's investments as of June 30, 2023 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Assets:				
Cash equivalents				
Money market funds	$ 596	$ -	$ —	$ 596
Marketable securities:				
U.S. government	$ 18,991	$ —	$ (76)	$ 18,915
Corporate bonds	6,548	—	(63)	6,485
Commercial paper	2,014	—	(3)	2,011
Certificates of deposit	7,745	1	(13)	7,733
Total marketable securities	$ 35,298	$ 1	$ (155)	$ 35,144
Total assets at fair value	$ 35,894	$ 1	$ (155)	$ 35,740

The Company classifies its investments as available-for-sale, and they consist entirely of debt securities. As of June 30, 2023, the amortized cost of investments included an immaterial amount of accrued interest. As of June 30, 2023, 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, 2023, the aggregate fair value of investments held by the Company in an unrealized loss position was $33.9 million which consisted of 38 securities. The unrealized loss was primarily driven by rising interest rates. The Company does not expect to settle the debentures at a price less than the amortized cost basis of the investment; the Company expects to recover the entire amortized cost basis of the security. In accordance with the Company's general investment strategy, the Company does not intend to sell the investments before maturity. As of June 30, 2023, the Company believes the cost basis for its marketable securities were recoverable in all material aspects and no allowance for credit losses were recognized in the period.

The Company's investments as of June 30, 2023 mature at various dates through January 2026. The fair values of investments by contractual maturity consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Maturities within one year	$ 27,770	$ 44,556
Maturities after one year through three years	7,970	—
Total investments	$ 35,740	$ 44,556

Note 8 – **Property and Equipment**

Property and equipment, consists of the following as of June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023	December 31, 2022
Laboratory equipment	$ 456	$ 452
Computer equipment and software	2,195	2,168
Furniture	610	602
Leasehold improvements	617	617
Manufacturing equipment	607	608
	4,485	4,447
Less: accumulated depreciation and amortization	(3,575)	(3,150)
Property and equipment, net	$ 910	$ 1,297

Depreciation and amortization expense was $0.2 million and $0.4 million for the three and six months ended June 30, 2023 and $0.2 million and $0.4 million for the three and six months ended June 30, 2022.

Note 9 – **Prepaid Forward Obligation**

In March 2021, the Company entered into a prepaid forward agreement with RTW Investments ("RTW"). Under the terms of the RTW Transaction, the Company received $75.0 million ($72.4 million net of transaction costs) to support the continued launch of *Jelmyto* and the development of UGN-102. In return for the transferred funds, RTW is entitled to receive tiered, future cash payments based on aggregate worldwide annual net product sales of *Jelmyto* in an amount equal to: (i) 9.5% of annual net sales up to $200 million, (ii) 3.0% of annual net sales for annual net sales between $200 million and $300 million, and (iii) 1.0% of annual net sales for annual net sales above $300 million. If certain revenue thresholds for *Jelmyto* aggregate worldwide annual net sales are not met, the future cash payments to RTW with respect to *Jelmyto* annual net sales up to $200 million will increase by 3.5%, and may decrease back to 9.5% dependent on the Company meeting certain subsequent *Jelmyto* aggregate worldwide annual net sales thresholds. The rate in effect for the six months ended June 30, 2023 for annual net sales up to $200 million was 13.0%.

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

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

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

The following table shows the activity with respect to the carrying value of the prepaid forward liability for the year ended December 31, 2022 and for the six months ended June 30, 2023, in thousands:

Carrying value of prepaid forward obligation as of December 31, 2021	$	85,713
Financing on prepaid forward obligation		21,559
Amounts paid and payable (1)		(8,349)
Carrying value of prepaid forward obligation as of December 31, 2022		98,923
Financing on prepaid forward obligation		10,568
Amounts paid and payable (1)		(4,984)
Carrying value of prepaid forward obligation as of June 30, 2023	$	104,507

(1) $2.7 million and $2.3 million of the Amounts paid and payable are included as current portion of the prepaid forward obligation within other current liabilities on the condensed consolidated balance sheets as of June 30, 2023 and December 31, 2022, 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. The facility will mature five years from initial funding and can be prepaid in whole at the Company's discretion, at any time, subject to prepayment premiums and make-whole amounts. The loan will require interest-only payments for the first 48 months followed by principal and interest payments with interest accruing using 3-month London Inter-Bank Offered Rate (“LIBOR”) (with a 1.25% floor) plus 8.25%. On June 29, 2023, the loan agreement with Pharmakon was amended to replace the benchmark governing the interest rate with a rate based on the secured overnight financing rate ("SOFR") published by the Federal Reserve Bank of New York. Effective July 2023, the loan will accrue interest using a benchmark rate of 3-month SOFR plus a 0.26161% adjustment. The Company is not required to maintain any financial covenants.

The Company incurred financing expenses of $4.2 million which are recognized as a direct offset to the long-term debt on the Company's 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:

Long-term debt at closing of Pharmakon loan	$	100,000
Capitalized costs and discounts		(4,217)
Interest expense		8,438
Amounts paid		(6,685)
Carrying value of Pharmakon loan as of December 31, 2022		97,537
Interest expense		7,314
Amounts paid		(6,555)
Carrying value of Pharmakon loan as of June 30, 2023	$	98,296

Note 11 – Leases

Operating Leases

The Company had the following office and laboratory facility leases as of June 30, 2023:

- In April 2016, UPL signed an addendum to its November 2014 lease agreement for the Company’s offices located in Israel, in order to increase the office space rented and to extend the rent period for an additional three years until August 2022. In July 2022, the Company signed a lease extension agreement for the Company’s offices located in Israel, extending the term of the lease through September 2025. The Company's remaining contractual obligation under this lease is approximately $0.6 million as of June 30, 2023.

- In April 2018, UPI entered into a new lease agreement for an office in Los Angeles, California. The lease commencement date was July 10, 2018 and terminates in March 2024. The landlord provided a tenant allowance for leasehold improvements of $0.2 million that was accounted for as a lease incentive. The Company’s remaining contractual obligation under this lease is approximately $0.2 million as of June 30, 2023. In November 2019, UPI entered into a sublease for this office space, with a lease commencement date of January 1, 2020 and continuing until the end of the lease term in March 2024. The subtenants exercised their early access clause and moved into the premises at the end of November 2019. The remaining rental payments to be received over the lease term is approximately $0.2 million as of June 30, 2023. The Company accounts 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 $1.5 million as of June 30, 2023.

In addition, the Company has other operating office equipment and vehicle leases. The Company’s operating leases may require minimum rent payments, contingent rent payments adjusted periodically for inflation, or rent payments equal to the greater of a minimum rent or contingent rent. The Company’s leases do not contain any residual value guarantees or material restrictive covenants. The Company’s leases expire at various dates from 2023 through 2026, with varying renewal and termination options.

The components of lease cost for the three and six months ended June 30, 2023 and 2022 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating lease cost	$ 257	$ 257	$ 485	$ 516
Sublease income	(56)	(56)	(112)	(112)
Variable lease cost	19	19	38	36
	$ 220	$ 220	$ 411	$ 440

The amounts recognized as of June 30, 2023 and December 31, 2022 were as follows (in thousands):

	June 30, 2023	December 31, 2022
Right-of-use assets	$ 2,107	$ 2,452
Long-term lease liabilities	1,209	1,586
Other current liabilities	910	941

As of June 30, 2023, no impairment losses have been recognized.

Supplemental information related to leases for the six months ended June 30, 2023 and 2022 is as follows (in thousands, except for lease terms and discount rate amounts):

	Six Months Ended June 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	587	590
Right-of-use assets obtained in exchange for new operating lease liabilities	95	1,419
Weighted-average remaining lease term of operating leases (in years)	2.23	3.01
Weighted-average discount rate of operating leases	10.16%	9.93%

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
2027 and thereafter	—
Total future minimum lease payments	$ 2,367
Less: Interest	(248)
Present value of lease liabilities	$ 2,119

Subleases

As of June 30, 2023, undiscounted cash flows to be received under the Company's operating sublease on an annual basis were as follows (in thousands):

	Operating Leases
Years ending December 31,	
Remainder of 2023	$ 126
2024	49
2025 and thereafter	—
	$ 175

Note 12 – **Revenue From Product Sales**

Net product sales consist of the following for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Jelmyto	$ 21,139	$ 16,604	$ 38,331	$ 30,168

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 refund 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, 2023 (in thousands):

	Reserves related to government sponsored programs	Other reserves	Total accrued sales reserves
Balance as of December 31, 2022	$ 590	$ 847	$ 1,437
Accruals	5,392	6,052	11,444
Utilizations	(5,182)	(3,756)	(8,938)
Balance as of June 30, 2023	$ 800	$ 3,143	$ 3,943

Note 13 – **License and Collaboration Agreements**

Agenus Agreement

In November 2019, the Company entered into a license agreement with Agenus Inc., pursuant to which Agenus granted to the Company an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary 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").

MD Anderson Agreement

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

Note 14 – **Shareholders' Equity**

The Company had 100.0 million ordinary shares authorized for issuance as of June 30, 2023 and December 31, 2022. The Company had 23.5 million and 23.1 million ordinary shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively. Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors (the "Board"). Since its inception, the Board has not declared any dividends.

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

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

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

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

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

As of June 30, 2023, 3,493,724 ordinary shares are subject to outstanding awards under the Company's share-based compensation plans and 941,759 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,	
	2023	2022	2023	2022
Research and development expenses	$ 496	$ 673	$ 1,021	$ 1,398
Selling, general and administrative expenses	1,726	2,150	3,487	4,374
Total share-based compensation expense	$ 2,222	$ 2,823	$ 4,508	$ 5,772

The total unrecognized compensation cost of options and RSUs at June 30, 2023 is $12.6 million with a weighted average recognition period of 2.0 years.

Note 16 – **Income Taxes**

UroGen Pharma Ltd. is taxed under Israeli tax laws. As of June 30, 2023, 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 2022, 2021 and 2020, and for the six months ended June 30, 2023. 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 $3.0 million as of June 30, 2023, for tax positions relating to transfer pricing between affiliated entities. The Company recognizes interest accrued and penalties related to uncertain tax positions as a component of income tax expense. As of June 30, 2023, the Company's liability for uncertain tax positions includes $1.1 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, 2023 or 2022.

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, 2023 and December 31, 2022. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Leases

See Note 11 for further discussion regarding lease commitments.

Note 19 – **Subsequent Events**

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 12,579,156 ordinary shares of the Company ("Shares") (or in lieu of Shares, pre-funded warrants to purchase ordinary shares of the Company) at a purchase price of $9.54 per Share (or $9.539 for each ordinary share underlying a pre-funded warrant), in a private placement transaction (the "Private Placement") for aggregate gross proceeds of $120.0 million, before deducting fees to placement agents and financial advisors and before other expenses payable 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 payable by the Company to placement agents and financial advisors is $3.6 million, plus the reimbursement of certain expenses.

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.

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, 2022 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, 2022 ("Annual Report"), which was filed with the SEC on March 24, 2023. 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 in combination therapy.

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

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

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

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

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

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

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

Jelmyto

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

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

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

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

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

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

We are committed to helping patients access *Jelmyto*. Our market access teams have laid the foundation for coverage and reimbursement, meeting multiple times with payors. Medicare patients 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 an agreement with a major national specialty pharmacy under which the pharmacy, following receipt of a patient prescription, prepares and dispenses the *Jelmyto* admixture on our behalf. In September 2022, the FDA authorized an extension of the in-use period for Jelmyto admixture from eight hours to 96 hours (four days) following reconstitution of the product, adding convenience and flexibility in managing patient care.

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

In the first two full fiscal years following 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.

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

In December 2022 we presented new data from a follow up study to the OPTIMA II study designed to obtain long-term data on UGN-102 that shows median duration of response of 24.4 months based on available data for 15 out of 25 patients who achieved a complete response 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 transurethral resection of the bladder tumors or fulguration.

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

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

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

On July 27, 2023, we announced topline data from our Phase 3 trials, ATLAS and ENVISION. In the ATLAS trial, UGN-102 met its primary endpoint of disease-free survival, reducing risk of recurrence, progression, or death by 55%. UGN-102 also showed a 64.8% complete response rate at three months for patients who only received UGN-102, compared to a 63.6% complete response rate at three months for patients who only received a TURBT. The ENVISION trial met its primary endpoint by demonstrating that patients treated with UGN-102 had a 79.2% rate of complete response at 3-months following the initial treatment. Additional data evaluating the secondary endpoint of duration of response from ENVISION is anticipated in 2024. In both trials, UGN-102 was generally well-tolerated, with a side effect profile similar to that of 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 instillation were performed by a properly trained and qualified home health professional. The primary endpoints of the study include safety and tolerability, discontinuations from at home study treatment and feedback from patients, home health professionals and investigators via standardized questionnaires. The study completed enrollment with a total of eight patients across four centers and all study visits for these enrolled patients have been completed. Preliminary results were reported through a press release in February 2023, finding that UGN-102 was suitable to administer at home by a visiting nurse under the supervision of a treating physician and resulted in 75% of patients achieving a complete response, defined as no detectable disease three months after starting treatment. Patients, nurses and investigators also completed home instillation feasibility questionnaires. These standardized feasibility questionnaires highlighted that all eight patients preferred at-home to in-office treatment, and five of six patients recommended UGN-102 home instillation instead of TURBT. Home instillation was reported as feasible for visiting nurses, and three of four investigators considered at-home treatment “not different” than in-office treatment. We believe establishing the precedent for a convenient at home solution may facilitate access to care and address quality of life issues that certain patients may face with the current standard of care.

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

High-grade non-muscle invasive bladder cancer ("high-grade NMIBC") is a highly aggressive form of bladder cancer. TURBT followed by adjuvant intravesical immunotherapy with Bacillus of Calmette and Guerin ("BCG") is the current standard of care therapy for high-grade NMIBC. However, the high rates of recurrence and significant risk of progression to muscle-invasive tumors are particularly dangerous.

Radical cystectomy, or bladder removal is strongly advocated in patients with BCG-unresponsive NMIBC (i.e., patients with BCG-refractory and BCG-relapsing tumors in whom further BCG therapy is not recommended) or for patients who cannot tolerate BCG.

The first combination we are seeking to investigate clinically involves the sequential use of UGN-201 (imiquimod), a toll-like receptor-7 ("TLR 7") agonist, and UGN-301 in high-grade NMIBC. UGN-201 is a liquid formulation of imiquimod for intravesical administration that has been optimized for delivery in the urinary tract. We believe that UGN-201 may elicit an innate immune response in the presence of released bladder cancer antigens, which may translate into a long lasting acquired immune response. We believe the combination of UGN-301 and UGN-201 could elicit an innate as well as adaptive immune response and potentially represent a valid post-TURBT adjuvant treatment of high-grade NMIBC. UGN-301 is delivered using our proprietary *RTGel* technology, which has been designed to significantly improve the effectiveness of certain intravesical therapy. In November 2019, we entered into a worldwide license agreement with Agenus Inc. to develop and commercialize zalifrelimab via intravesical delivery for the treatment of urinary tract cancers, initially in high-grade NMIBC. We believe that the combination of UGN-301 and UGN-201 makes local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effects.

In March 2022, we announced FDA clearance of our Investigational New Drug application ("IND") to begin a novel Phase 1 clinical study of UGN-301 in patients with recurrent NMIBC. The novel study design 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.

Our Research and Development and License Agreements

Agenus Agreement

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

MD Anderson Agreement

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

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

Components of Operating Results

Revenue

During the three and six months ended June 30, 2023, we recognized $21.1 million and $38.3 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 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 pre-commercialization and commercialization activities related to *Jelmyto,* formerly known as UGN-101.

General and Administrative Expenses

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

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation is comprised of financing expense related to the RTW Transaction (see Note 9 to our 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 (Expense), Net

Interest and other income (expense), 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 $419.1 million as of December 31, 2022. 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, 2023 and 2022

The following table sets forth our results of operations for the three months ended June 30, 2023 and 2022.

	Three Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
Revenue	$ 21,139	$ 16,604	$ 4,535
Cost of revenue	2,443	1,846	597
Gross profit	18,696	14,758	3,938
Operating expenses:			
Research and development	11,584	12,640	(1,056)
Selling and marketing	13,930	12,841	1,089
General and administrative	8,564	7,992	572
Total operating expenses	34,078	33,473	605
Operating loss	(15,382)	(18,715)	3,333
Financing on prepaid forward obligation	(5,344)	(5,833)	489
Interest expense on long-term debt	(3,761)	(2,239)	(1,522)
Interest and other income (expense), net	405	128	277
Loss before income taxes	(24,082)	(26,659)	2,577
Income tax expense	(54)	(32)	(22)
Net loss	$ (24,136)	$ (26,691)	$ 2,555

Revenue

Revenue was $21.1 million and $16.6 million for the three months ended June 30, 2023 and 2022, respectively. The increase in revenue of $4.5 million primarily reflects the increased volume of sales of *Jelmyto*.

Cost of Revenue

Cost of revenue was $2.4 million and $1.8 million for the three months ended June 30, 2023 and 2022, respectively. In periods prior to receiving FDA approval for *Jelmyto*, we recognized inventory and related costs associated with the manufacture of *Jelmyto* as research and development expenses. The overall increase of $0.6 million is primarily attributable to the full depletion of inventories that we had expensed prior to receiving FDA approval and increased volume of sales of our product *Jelmyto*.

Research and Development Expenses

Research and development expenses were $11.6 million and $12.6 million for the three months ended June 30, 2023 and 2022, respectively. The overall decrease of $1.0 million is primarily attributable to lower research and development expenses due to the conclusion of the ATLAS trial and lower cost related to the Phase 3 ENVISION trial for UGN-102, partially offset by higher research and development expenses related to our Phase 1 study for UGN-301. Additionally, research and development expenses decreased due to the ending of our collaboration with MD Anderson, lower cost incurred related to research into ingredient scale-up and production efficiency for *Jelmyto* and lower clinical compensation expenses.

Selling and Marketing Expenses

Selling and marketing expenses were $13.9 million and $12.8 million for the three months ended June 30, 2023 and 2022, respectively. The increase in selling and marketing expenses of $1.1 million is primarily attributable to brand marketing related expenses and commercial operation advertisement, data management and trainings, partially offset by lower market research related expenses.

General and Administrative Expenses

General and administrative expenses were $8.6 million and $8.0 million for the three months ended June 30, 2023 and 2022, respectively. The increase in general and administrative expenses of $0.6 million resulted primarily from professional services and ongoing managed services.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation was $5.3 million and $5.8 million for the three months ended June 30, 2023 and 2022, respectively. The measurement of financing on prepaid forward obligation is an accounting estimate under the "imputed interest method" of accounting (see Note 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 decrease 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 $3.8 million and $2.2 million for the three months ended June 30, 2023 and 2022, respectively. The increase was primarily driven by increase in interest rates related to the Pharmakon loan and the funding of the second tranche of the Pharmakon loan in December 2022.

Interest and Other Income (Expense), Net

Interest and other income (expense), net was $0.4 million and $0.1 million for the three months ended June 30, 2023 and 2022, respectively. The increase in interest and other income (expense), net was primarily due to interest earned on investments due to changes in the overall interest rate environment.

Comparison of the six months ended June 30, 2023 and 2022

The following table sets forth our results of operations for the six months ended June 30, 2023 and 2022.

	Six Months Ended June 30,		
	2023	2022	Change
		(in thousands)	
Revenue	$ 38,331	$ 30,168	$ 8,163
Cost of revenue	4,708	3,371	1,337
Gross profit	33,623	26,797	6,826
Operating expenses:			
Research and development	24,082	25,336	(1,254)
Selling and marketing	28,073	26,192	1,881
General and administrative	18,895	15,941	2,954
Total operating expenses	71,050	67,469	3,581
Operating loss	(37,427)	(40,672)	3,245
Financing on prepaid forward obligation	(10,568)	(11,659)	1,091
Interest expense on long-term debt	(7,314)	(2,521)	(4,793)
Interest and other income (expense), net	1,035	126	909
Loss before income taxes	(54,274)	(54,726)	452
Income tax expense	(75)	(357)	282
Net loss	$ (54,349)	$ (55,083)	$ 734

Revenue

Revenue was $38.3 million and $30.2 million for the six months ended June 30, 2023 and 2022, respectively. The increase in revenue of $8.1 million primarily reflects the increased volume of sales of *Jelmyto*.

Cost of Revenue

Cost of revenue was $4.7 million and $3.4 million for the six months ended June 30, 2023 and 2022, respectively. In periods prior to receiving FDA approval for *Jelmyto*, we recognized inventory and related costs associated with the manufacture of *Jelmyto* as research and development expenses. The overall increase of $1.3 million is primarily attributable to the full depletion of inventories that we had expensed prior to receiving FDA approval and increased volume of sales of our product *Jelmyto*.

Research and Development Expenses

Research and development expenses were $24.1 million and $25.3 million for the six months ended June 30, 2023 and 2022, respectively. The overall decrease of $1.2 million is primarily attributable to lower research and development expenses due to the conclusion of the ATLAS trial and lower cost related to the Phase 3 ENVISION trial for UGN-102, partially offset by higher research and development expenses related to our Phase 1 study for UGN-301. Additionally, research and development expenses decreased due to the ending of our collaboration with MD Anderson, lower cost incurred related to research into ingredient scale-up and production efficiency for *Jelmyto* and lower clinical compensation expenses.

Selling and Marketing Expenses

Selling and marketing expenses were $28.1 million and $26.2 million for the six months ended June 30, 2023 and 2022, respectively. The increase in selling and marketing expenses of $1.9 million is primarily attributable to brand marketing related expenses and commercial operation advertisement, data management and trainings, partially offset by lower market research related expenses.

General and Administrative Expenses

General and administrative expenses were $18.9 million and $15.9 million for the six months ended June 30, 2023 and 2022, respectively. The increase in general and administrative expenses of $3.0 million resulted primarily from third-party advisory providers, professional services, and ongoing managed services.

Financing on Prepaid Forward Obligation

Financing on prepaid forward obligation was $10.6 million and $11.7 million for the six months ended June 30, 2023 and 2022, respectively. The measurement of financing on prepaid forward obligation is an accounting estimate under the "imputed interest method" of accounting (see Note 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 decrease in financing on prepaid forward obligation of $1.1 million was driven primarily by changes in underlying assumptions for remeasuring the effective rate.

Interest Expense on Long-term Debt

Interest expense was $7.3 million and $2.5 million for the six months ended June 30, 2023 and 2022, respectively. The cost in 2023 relates to interest expense on the Pharmakon loan for two full quarters versus the prior year given the loan closed in March 2022. In addition, the increase was attributable to increase in interest rates related to the Pharmakon loan and the funding of the second tranche of the Pharmakon loan in December 2022.

Interest and Other Income (Expense), Net

Interest and other income (expense), net was $1.0 million and $0.1 million for the six months ended June 30, 2023 and 2022, respectively. The increase in interest and other income (expense), net was primarily due to interest earned on investments due to changes in the overall interest rate environment.

Liquidity and Capital Resources

As of June 30, 2023, we had $55.3 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, 2023, we funded our operations primarily through public equity offerings, private placements of equity securities and our funding arrangements with RTW and Pharmakon.

In December 2019, we entered into a sales agreement (the “ATM Sales Agreement”) with Cowen and Company, LLC (“Cowen”) pursuant to which we may from time to time offer and sell our ordinary shares having an aggregate offering price of up to $100.0 million. The remaining capacity under the ATM Sales Agreement is approximately $83.4 million as of June 30, 2023. The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 filed with the SEC on November 15, 2022, which was declared effective on November 29, 2022.

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

On March 7, 2022, we entered into a loan agreement ("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. The Pharmakon loan will mature five years from initial funding and can be prepaid in whole at our discretion, at any time, subject to prepayment premiums and make-whole amounts. The Pharmakon loan will require interest-only payments for the first 48 months followed by principal and interest payments with interest accruing using 3-month LIBOR (with a 1.25% floor) plus 8.25%. On June 29, 2023, the Loan Agreement was amended to replace the benchmark governing the interest rate with a rate based on the secured overnight financing rate ("SOFR") published by the Federal Reserve Bank of New York. Effective July 2023, the loan will accrue interest using a benchmark rate of 3-month SOFR plus a 0.26161% adjustment.

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 (the “Private Placement”) for aggregate gross proceeds of $120.0 million, before deducting fees to placement agents and financial advisors and before other expenses payable by us. 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 payable by us to placement agents and financial advisors is $3.6 million, plus the reimbursement of certain expenses.

We have incurred losses since our inception and negative cash flows from our operations, and as of June 30, 2023 we had an accumulated deficit of $631.5 million. We anticipate that we will continue to incur losses for the reasonably foreseeable future. Our primary uses of capital are, and we expect will continue to be, commercialization activities, research and development expense, including third-party clinical research and development services, laboratory and related supplies, clinical costs, including manufacturing costs, legal and other regulatory expense and general and administrative costs, partially offset by proceeds from sales of *Jelmyto*.

We routinely evaluate our liquidity needs, including assessment of our current financial condition, sources of liquidity including current cash and cash equivalents and marketable securities and management’s cash flow projections. Our ability to continue as a going concern is expected to be impacted by our ability to raise additional capital to fund our operations, produce cash inflows from *Jelmyto* product sales and develop UGN-102.

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

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

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

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

For more information as to the risks associated with our future funding needs, see 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 April 2018, we entered into a new lease agreement for an office in Los Angeles, CA. The lease commencement date was July 10, 2018 and terminates in March 2024. In November 2019, we subleased our offices in Los Angeles, CA. The lease commencement date was January 1, 2020 and terminates in March 2024. The subtenants exercised their early access clause and moved into the premises at the end of November 2019.

Also, in November 2019, we entered into a new lease agreement, dated effective October 31, 2019, for an office in Princeton, NJ. The lease commencement date was November 29, 2019 and the lease term is 38 months. 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 $2.4 million as of June 30, 2023. See Note 11 to the condensed consolidated financial statements appearing elsewhere in this Quarterly Report for further information.

In March 2022, UroGen Pharma Ltd., UroGen Pharma, Inc., as the borrower ("Borrower"), and certain direct and indirect subsidiaries of the Company party thereto from time to time, as guarantors ("Guarantors" and, collectively with UroGen Pharma Ltd. and Borrower, "Credit Parties"), entered into the Loan Agreement with funds managed by Pharmakon Advisors, L.P., including BPCR Limited Partnership (as a "Lender"), BioPharma Credit Investments V (Master) LP (as a "Lender"), and BioPharma Credit PLC, as collateral agent for the Lenders (in such capacity, "Collateral Agent"), pursuant to which the Lenders agreed to make the Term Loans to the Borrower in an aggregate principal amount of up to $100.0 million to be funded in two tranches: (i) the Tranche A Loan of $75.0 million was advanced in March 2022 and (ii) the Tranche B Loan of $25.0 million was advanced in December 2022. The Term Loans will mature on the fifth-year anniversary of the Tranche A Closing Date (the “Maturity Date”). The Term Loans bear interest at 8.25% plus three-month LIBOR per annum with a LIBOR floor of 1.25%. On June 29, 2023, the Loan Agreement was amended ("Amended Loan Agreement") to replace the benchmark governing the interest rate with a rate based on the SOFR published by the Federal Reserve Bank of New York. Effective July 2023, the loan will accrue interest using a benchmark rate of 3-month SOFR plus a 0.26161% adjustment as described in the Amended Loan Agreement. Interest is payable quarterly in arrears. Repayment of outstanding principal of the Term Loans will be made in four equal quarterly payments of principal commencing after the 17th-quarter anniversary of the Tranche A Closing Date. The obligations of the Borrower under the Loan Agreement are guaranteed on a full and unconditional basis by UroGen Pharma Ltd. and the other Guarantor and are secured by substantially all of the respective Credit Parties’ tangible and intangible assets and property, including intellectual property, subject to certain exceptions.

Cash Flows

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

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (46,081)	$ (48,195)
Investing activities	9,990	13,445
Financing activities	814	70,665
Net change in cash and cash equivalents	$ (35,277)	$ 35,915

Operating Activities

Net cash used in operating activities was $46.1 million during the six months ended June 30, 2023, compared to $48.2 million during the six months ended June 30, 2022. The $2.1 million decrease was attributable primarily to timing of certain accruals, as well as increase in net sales of our product *Jelmyto* during 2023, partially offset by increase in interest on long-term debt.

Investing Activities

Net cash provided by investing activities was $10.0 million during the six months ended June 30, 2023, compared to $13.5 million during the six months ended June 30, 2022. The net change of $3.5 million is attributable primarily to more reinvestment of marketable securities in 2023 as compared to 2022.

Financing Activities

Net cash provided by financing activities was $0.8 million during the six months ended June 30, 2023, compared to $70.7 million during the six months ended June 30, 2022. The decrease of $69.9 million is attributable primarily to proceeds from the Pharmakon loan in the prior year.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Fluctuation Risk

Some of the securities in which we invest have market risk in that a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. As of June 30, 2023, we had $55.3 million in cash, 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, 2023, 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 three and six months ended June 30, 2023 or 2022.

Foreign Currency Exchange Risk

The U.S. dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in the New Israeli Shekel ("NIS"). As a result, we are exposed to the risk that 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 2022 by a total of 11.9%. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future. If a 10% change in NIS-to-Dollar exchange rates were to have occurred during the three months ended June 30, 2023, 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, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

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, 2023, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

Changes in our internal control over financial reporting may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes. There were no changes in our internal control over financial reporting during the quarter ended June 30, 2023 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.

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

Item 1A. Risk Factors.

Risk Factor Summary

Below is a summary of the 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 U.S. Securities and Exchange Commission ("SEC") before making investment decisions regarding our ordinary shares.

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

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

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

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

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

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

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

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

- 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 shares of 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 $109.8 million for the year ended December 31, 2022 and a net loss of $24.1 million for the quarter ended June 30, 2023. As of June 30, 2023, we had an accumulated deficit of $631.5 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our ability to ultimately achieve recurring revenues and profitability is dependent upon our ability to successfully complete the development of our product candidates and obtain necessary regulatory approvals for and successfully manufacture, market and commercialize our products.

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

Our future capital requirements depend on many factors, including:

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

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

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

We are not profitable and have had negative cash flow from operations since our inception. Since our inception, almost all our resources have been dedicated to the nonclinical and clinical development of our first commercial product, *Jelmyto*, and our lead product candidate UGN-102. As of June 30, 2023, we had cash and cash equivalents and marketable securities of $55.3 million. This amount does not include the proceeds from our $120.0 million private placement of ordinary shares and pre-funded warrants, $115.0 million of which closed on August 2, 2023 and the remaining $5.0 million of which closed on August 9, 2023. Fees to placement agents and financial advisors for the private placement are 3.0% of the gross proceeds, plus the reimbursement of certain expenses. 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 March 2021, we announced a transaction with RTW Investments ("RTW") totaling $75 million in funding for our company, which was received in May 2021, to support the launch of *Jelmyto* and the development of UGN-102. In return for the upfront cash payment, RTW is entitled to receive tiered future payments based on global annual net product sales of *Jelmyto* and UGN-102, if approved. In March 2022, we entered into the Loan Agreement, pursuant to which the Lenders agreed to make the Term Loans to Borrower in an aggregate principal amount of up to $100 million to be funded in two tranches. 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.

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

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

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

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

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

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

On March 7, 2022, UroGen Pharma Ltd., UroGen Pharma, Inc., as the borrower ("Borrower"), and certain direct and indirect subsidiaries of the Company party thereto from time to time, as guarantors ("Guarantors") and, collectively with UroGen Pharma Ltd. and Borrower ("Credit Parties") entered into a loan agreement ("Loan Agreement") with funds managed by Pharmakon Advisors, L.P., including BPCR Limited Partnership (as a "Lender"), BioPharma Credit Investments V (Master) LP (as a "Lender"), and BioPharma Credit PLC, as collateral agent for the Lenders (in such capacity, "Collateral Agent"), pursuant to which the Lenders agreed to make term loans to the Borrower in an aggregate principal amount of up to $100 million ("Term Loans"), to be funded in two tranches: (i) the first tranche ("Tranche A Loan") was advanced in the amount of $75 million, in March 2022 ("Tranche A Closing Date") and (ii) the second tranche ("Tranche B Loan") of $25 million was advanced in December 2022.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Business and Strategy

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

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

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

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

In addition, our ongoing commercial launch of *Jelmyto* and subsequent commercialization efforts could be hindered by pandemics, epidemics or public health emergencies, although we are currently not able to predict or quantify any such potential impact with any degree of certainty.

If the launch or commercialization of *Jelmyto* is unsuccessful or perceived as disappointing, our share price could decline significantly and the long-term success of the product and our company could be harmed.

Jelmyto has only been studied in a limited number of patients and in limited populations. Following the initiation of our commercial launch in June 2020, Jelmyto is now available to a much larger number of patients and in broader populations, and we do not know whether the results of Jelmyto use in such larger number of patients and broader populations will be consistent with the results from our clinical studies.*

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

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

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

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

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

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

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

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

Cancer therapies are sometimes characterized as first-line, second-line or third-line. When cancer is detected early enough, first-line therapy, often chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life. Second- and third-line therapies are administered to patients when prior therapy is not or is no longer effective. For urothelial cancers, the current first-line standard of care is surgery designed to remove one or more tumors. Chemotherapy is currently used in treating urothelial cancer only as an adjuvant, or supplemental therapy, after tumor resection. We are designing our lead product candidate UGN-102 as an alternative to surgery as the standard of care for certain urothelial cancers. However, there is no guarantee that this product candidate will be approved or that we will not have to conduct additional clinical trials. Even if approved, the market opportunity for UGN-102 may be smaller than we anticipate or limited to those patients who are ineligible for established therapies or for whom prior therapies have failed. Our other or future product candidates 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, physicians may choose to only use it to treat tumors in the renal pelvis and not tumors in the ureter, which would limit the degree of physician adoption and market acceptance of *Jelmyto*. Even if we obtain significant market share, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including the use of the products as first- or second-line therapy. For example, low-grade UTUC is a rare malignant tumor of the cells lining the urinary tract and there is limited scientific literature or other research on the incidence and prevalence of low-grade UTUC. If our estimates of the incidence and prevalence of low-grade UTUC are incorrect, *Jelmyto*'s commercial viability may prove to be limited, which may negatively affect our financial results.

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

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

- the clinical indications for which the product is approved;
- the safety and efficacy data from the clinical trial(s) supporting the approved clinical indications;
- the approved labeling and packaging for our products, including the degree of product preparation and administration convenience and ease of use that is afforded to physicians by the approved labeling and product packaging;
- the prevalence and severity of adverse side effects and the level of benefit/risk observed in our clinical trials;
- sufficient patient satisfaction with the results and administration of our products and overall treatment experience, including relative convenience, ease of use and avoidance of, or reduction in, adverse side effects;
- the extent to which physicians recommend our products to patients;
- physicians' and patients' willingness to adopt new therapies in lieu of other products or treatments, including willingness to adopt *Jelmyto*, and our lead product candidate UGN-102 as locally-administered drug replacements to current surgical standards of care;
- the cost of treatment, safety and efficacy of our products in relation to alternative treatments, including the recurrence rate of our treatments;
- the extent to which the costs of our products are covered and reimbursed by third-party payors, including the availability of a physician reimbursement code for our treatments, and patients' willingness to pay for our products;
- whether treatment with our products, including the treatment of low-grade UTUC with *Jelmyto* and the treatment of low-grade intermediate risk NMIBC with UGN-102, if approved, will be deemed to be an elective procedure by third- party payors; if so, the cost of treatment would be borne by the patient and would be less likely to be broadly adopted;
- proper education of physicians or nurses for the skillful administration of our approved product, *Jelmyto*, and UGN-102, if approved, and development of a broad experiential knowledge base of aggregated clinician feedback from which we can refine appropriate procedures for product administration, without which there could be a risk of adverse events;
- 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., Ferring Pharmaceuticals, FKD Therapies Oy, GSK, ImmunityBio, Janssen, Merck Sharp & Dohme Corp, Roche, Samyang Biopharma, Seagen Inc., Steba Biotech Ltd., SURGE Therapeutics, Viralytics Limited and Vyriad. We are aware that Ferring Pharmaceuticals plans to begin production of its Adstiladrin, approved by the FDA for the treatment of high-risk BCG-unresponsive NMIBC, in the second half of 2023. In January 2023, SURGE Therapeutics received FDA clearance on an IND to proceed with a Phase 1/2a study of its SURGERx platform with resiquimod for prevention of recurrence and/or progression after TURBT in patients previously diagnosed with high-grade NMIBC that experience recurrence. We are aware of a company called Steba Biotech with an IND granted in December 2020 which has initiated a Phase 3 study of padeliporfin ImPACT for the treatment of adult patients with low-grade and unifocal high-grade UTUC in the first quarter of 2021. We have also entered into a Phase 1 study to support the development of UGN-301 in high-grade NMIBC. We are also aware that other companies, such as Janssen and Lipac are conducting, or have recently conducted clinical trials for product candidates for the treatment of low-grade intermediate risk NMIBC. Outside of these indications where we are developing products, we are aware of other companies doing work in both bladder and upper tract cancers, but these are with agents or on targets in high-grade, metastatic, or muscle invasive cancers. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing products that are more effective, easier to administer or less costly than our product candidates.

In addition, we face competition from existing standards of treatment, surgical tumor resection procedures. If we are not able to demonstrate that our product candidates are at least as safe and effective as such courses of treatment, medical professionals may not adopt our product candidates in replacement of the existing standard of care. Generic mitomycin injectable drug products, while approved by FDA for gastric and pancreatic cancers, are neither approved for low-grade UTUC nor reconstituted with hydrogel 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-201 and UGN-301 for the treatment of various forms of bladder cancer. The FDA and other applicable regulatory agencies will restrict our ability to market or advertise our products to the scope of the approved label for the applicable product and for no other indications, which could limit physician and patient adoption. We may attempt to develop and, if approved, promote and commercialize new treatment indications for our products in the future, but we cannot predict when or if we will receive the regulatory approvals required to do so. Failure to receive such approvals will prevent us from promoting or commercializing new treatment indications. In addition, we would be required to conduct additional clinical trials or studies to support approvals for additional indications, which would be time consuming and expensive, and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

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

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

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

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

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

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

- the FDA's acceptance of our parameters for regulatory approval relating to UGN-102 and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways, and proposed labeling and packaging;
- our ability to successfully complete the FDA requirements related to chemistry, manufacturing and controls ("CMC"), for UGN-102 and our other product candidates, and if completed, their sufficiency to support an NDA;
- the FDA's timely acceptance of our INDs, for our product candidates 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 finished product from third-party suppliers for product candidates, including UGN-102, if approved;
- our ability to obtain, maintain, protect and enforce our intellectual property rights with respect to our product candidates;
- the extent to which the costs of our products, once approved, are covered and reimbursed by third-party payors, including the availability of a physician reimbursement code for our treatments, and patients' willingness to pay for our products; and
- our ability to properly train physicians or nurses for the skillful preparation and administration of any of our product candidates that receive approval, including UGN-102, and our ability to develop a broad experiential knowledge base of aggregated clinician feedback from which we can refine appropriate procedures for product administration, without which there could be a risk of adverse events.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Although we have received FDA approval of *Jelmyto* for pyelocalyceal solution, for the treatment of adult patients with low-grade UTUC, and we plan to devote a substantial portion of our resources to the continued clinical testing and potential approval 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-201 and UGN-301 for nonclinical studies and clinical trials, and expect to continue to do so to support commercial scale production of UGN-102 and UGN-201, if approved, as well as UGN-301 if approved as a monotherapy or for any approved product that includes UGN-301. There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers, including single-source suppliers. Furthermore, our existing third-party subcontractors and single-source suppliers may not be able to meet the increased need for certain raw materials, compounds and components that may result from our commercialization efforts. This increases the risk that we will not have sufficient quantities of Jelmyto, UGN-102, UGN-201 or UGN-301 or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.*

We currently rely on third party subcontractors and suppliers for certain compounds and components necessary to produce *Jelmyto* for commercial use and UGN-102, UGN-201 and UGN-301 for our nonclinical studies and clinical trials, and expect to rely on third party subcontractors and suppliers for commercial use for any of our drug candidates that receive regulatory approval. We currently depend on Teva Pharmaceuticals Industries Ltd ("Teva"), as our single-source supplier of mitomycin active pharmaceutical ingredient ("API") for *Jelmyto* and UGN-102. We rely on Cenexi-Laboratories Thissen s.a., and Isotopia Molecular Imaging Ltd. as our single contracted suppliers for the mitomycin and gel contained in *Jelmyto* and UGN-102, respectively. We also currently depend on a single source supplier for imiquimod for UGN-201 and zalifrelimab for UGN-301. Because there are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce *Jelmyto* for commercial sale and our product candidates for our clinical trials and their subsequent commercial sale, if approved. Even if we are able to engage alternate suppliers on reasonable terms, we may face delays or increased costs in our supply chain that could jeopardize the commercialization of *Jelmyto* 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 also rely on a single third-party manufacturer to produce our proprietary drug product, or final mitomycin formulation, necessary for our clinical trial and commercial requirements. We plan to continue to rely on third parties for the production of mitomycin API, the gel contained in *Jelmyto,* UGN-102 and UGN-301, and for imiquimod for UGN-201, and for zalifrelimab for UGN-301, as well as for the raw materials, compounds and components necessary to produce our product candidates and for nonclinical studies and clinical trials.

Even though we are approved as a commercial supplier of *Jelmyto*, we have limited experience as a company in the commercial supply of drugs and may never be successful as a commercial supplier of drug products containing mitomycin. In addition, cost-overruns, unexpected delays, equipment failures, logistics breakdowns, labor shortages, natural disasters, power failures, production failures or product recalls, and numerous other factors could prevent us from realizing the intended benefits of our sales strategy and have a material adverse effect on our business. Further, although we commercially supply *Jelmyto*, further build-out is required and establishing such commercial-scale supply capabilities requires additional investment, is time-consuming and may be subject to delays, including because of shortage of labor, compliance with regulatory requirements or receipt of necessary regulatory approvals. In addition, building out our *Jelmyto* commercial supply capabilities may cost more than we currently anticipate, and delays or problems may adversely impact our ability to provide sufficient quantities of *Jelmyto* to support our 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 mitomycin API for planned manufacturing operations during 2023, 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, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture and distribute *Jelmyto* for commercial sales and our product candidates for our clinical trials and research and development operations.

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

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

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

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

We rely on third party transportation to deliver materials to our facilities and ship products to our customers. Transport operators are exposed to various risks, such as extreme weather conditions, natural disasters, work stoppages, personnel shortages, and operating hazards, as well as interstate and international transportation requirements. In addition, transport operators 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 a resurgence of COVID-19 or other 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. For example, we have entered into an exclusive license agreement with Neopharm Ltd. ("Neopharm"), pursuant to which Neopharm is leading the process for seeking regulatory approval of *Jelmyto* in Israel. Neopharm initiated the regulatory approval process in June 2021 and the Israeli Ministry of Health has issued a registration certificate for the product. Additional analytical testing of proposed commercial materials is required to be completed before full clearance to market. Even if *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 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, 2023, we had 193 employees, of whom 41 are based in Israel and 152 are based in the United States. We will need to continue to expand our development, quality, managerial, operational, finance, marketing, sales and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

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

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

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

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

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

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

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

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

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

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

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

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

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fake, 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 (such as credential stuffing), 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, and other similar threats.

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

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

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business. Additionally, our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employee’s, personnel’s, or vendor’s 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. 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, but we may be unable to detect and remediate all vulnerabilities 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 but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business.

Additionally, applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. 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. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security 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.

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 New Israeli Shekels ("NIS"), which is the lawful currency of the State of Israel. As a result, we are exposed to the risks that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. For example, the dollar appreciated against the NIS during 2022 by a total of 11.9%. 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, including a resurgence of COVID-19, poses the risk that we or our employees, contractors, suppliers, customers, and other partners may be prevented from conducting certain business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. 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, including a resurgence of COVID-19, could disrupt the supply chain of material needed for our product candidates and our approved product, *Jelmyto*, interrupt healthcare services, delay coverage decisions from Medicare and third party payors, delay ongoing and planned clinical trials involving our product candidates and have a material adverse effect on our business, financial condition and results of operations. In addition, we and many of our potential customers and partners worldwide have in the past and may in the future be subject to stay-at-home orders as a result of COVID-19 or future pandemics, epidemics or public health emergencies, including a resurgence of COVID-19. In addition, our ongoing commercial launch of *Jelmyto* and subsequent commercialization activities could be hindered by a pandemic, epidemic or other public health emergency, including a resurgence of COVID-19, although we are currently not able to predict or quantify any such potential impact with any degree of certainty. The worldwide spread of the COVID-19 virus previously resulted in and a future pandemic, epidemic or public health emergency, including a resurgence of COVID-19, may in the future result in a varying degree of interruption or slowdown of economic activity, thereby impacting demand for a broad variety of goods and services, including potentially for *Jelmyto*, while also disrupting sales channels and marketing activities for an unknown period of time.

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

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

To the extent any future pandemics, epidemics or public health emergencies, including a resurgence of COVID-19, 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, such as the Phase 3 ATLAS trial, are operated outside of the United States, including in the Ukraine and Russia. We continue to follow patients in ATLAS, in the region. However, due to the ongoing war, we have experienced difficulty in following up with patients in the region, and we may not have the ability to continue follow up of these patients. The failure to identify and operationalize any alternative clinical sites may have an adverse effect on patient enrollment, and could result in delays in enrolling, carrying out, and/or completing our clinical trials. If we experience delays in achieving our development objectives within a timeframe that meets our prospective customers' expectations, our business, prospects, financial results and reputation could be harmed.

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

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

We currently dedicate certain resources to comply with numerous laws and regulations in each jurisdiction in which we operate outside of the 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 intellectual property and proprietary technologies, our products and their uses, as well as our ability to operate without infringing upon the proprietary rights of others. We rely upon a combination of patents, trade secret protection and confidentiality agreements, assignment of invention agreements and other contractual arrangements to protect the intellectual property related to hydrogel-based pharmaceutical compositions for optimal delivery of a drug in internal cavities such as the bladder, the method for treating 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, pending patent applications and trademarks covering our proprietary *RTGel* technology, the pharmaceutical compositions, methods of use and manufacturing aspects of our product candidates. In the United States, we currently hold approximately 19 granted patents that are directed to protect our approved product, *Jelmyto* and our lead product candidate, UGN-102, a proprietary *RTGel* technology, local compositions comprising different active ingredients, inter alia compositions comprising a Botulinum Toxin, UGN-201, the sequential use of UGN-201 and UGN-301, and our future product candidates that are under company research. These IP rights relate to certain aspects of cancer treatment. These issued patents are set to expire between 2024 and 2037. In total, our IP portfolio includes 42 granted patents worldwide, and more than 45 pending patent applications filed in the U.S., Europe, Israel, Japan, Canada, China, Mexico and Australia that are directed to cover various methods, systems and compositions for treating cancer locally, by intravesical means, utilize various active ingredients and the combinations thereof. These patent applications, if issued, are set to expire between 2031 and 2041.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our trade secrets may not have sufficient intellectual property protection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We filed applications for trademarks (*Jelmyto*®, *RTGel*®, 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. If we file an infringement action against such a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

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

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

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

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

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

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

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

A significant portion of our intellectual property has been developed by our employees during their employment. 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.

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

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

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

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

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

Additionally, there have been several recent U.S. presidential executive orders, Congressional inquiries and proposed and enacted legislation at the federal and state levels designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, for example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, on November 15, 2021, President Biden signed into law the Infrastructure Investment and Jobs Act. Beginning on January 1, 2023, manufacturers will be required to pay quarterly refunds to CMS for discarded amounts of certain single-dose container and single-use package drugs payable under part B of the Medicare program. Refunds are based on the discarded volume above 10% of the total allowed amount. However, in unique circumstances, CMS will increase the applicable threshold to 35%. At this time, CMS has determined that *Jelmyto* fits within this unique circumstance classification. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We are subject to stringent and changing U.S. and foreign laws, regulations, rules, contractual obligations, 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, "processing") proprietary, confidential, and sensitive data, including personal data, intellectual property, and trade secrets (collectively, "sensitive information"). Our data processing activities 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 and the California Consumer Privacy Act of 2018 (“CCPA”) applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights related to their personal data. The CCPA provides for civil penalties for noncompliance (up to $7,500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the California Privacy Rights Act of 2020 (“CPRA”), expands the CCPA’s requirements, including by adding a new right for individuals to correct their personal information and establishing a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states, such as Virginia, Colorado, Utah and Connecticut, have also passed comprehensive privacy laws, which have taken effect or will become effective in 2023, and additional similar laws are being considered at the federal, state, and local levels. While these laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts and increase legal risk and compliance costs for us, the third parties upon whom we rely. 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 EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 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 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 and UK’s standard contractual clauses, the UK’s International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework (which allows for transfers for 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 at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Inability to import personal data from Europe to the United States may limit our ability to conduct clinical trial activities in Europe, limit our ability to collaborate with contract research organizations, service providers, contractors and other entities subject to European data protection laws, adversely impact our operations, product development and ability to provide our products, and require us to increase our data processing capabilities in Europe at significant expense. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR’s cross-border data transfer limitations.

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

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

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

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

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

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of *Jelmyto*, UGN-102 and our other product candidates, if approved, will depend on the coverage and reimbursement policies of third-party payors, like government authorities, private health insurers, and managed care organizations. Third-party payors decide which medications they will cover and separately establish reimbursement levels. In October 2020, a Medicare C-Code was issued for *Jelmyto* and we have obtained pass-through status for two years, no more than three. CMS has established a permanent and product-specific J-code for *Jelmyto* that took effect on January 1, 2021. Our existing pass-through status is set to expire in the fourth quarter of 2023. Loss of pass-through status may result in Medicare beneficiaries losing access to *Jelmyto* in the hospital outpatient setting and *Jelmyto* becomes packaged into a comprehensive ambulatory payment classification. This loss of pass-through status could adversely affect our *Jelmyto* revenues.

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 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. 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 Cowen, acting as sales agent or principal, in any manner deemed to be an “at-the market offering”. As of June 30, 2023, $83.4 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.

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, 2022. 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. 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 facilities are located in Ra’anana, Israel. If these or any future facilities in Israel were to be damaged, destroyed or otherwise unable to operate, whether due to war, acts of hostility, earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, pandemic, power outages or otherwise, or if performance of our research and development is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved and we choose to manufacture all or any part of them internally, jeopardize our ability to manufacture our products as promptly as our prospective customers will likely expect, or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our prospective customers’ expectations, our business, prospects, financial results and reputation could be harmed.

Political, economic and military conditions in Israel may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, Hamas (an Islamist militia and political group that controls the Gaza Strip) and Hezbollah (an Islamist militia and political group based in Lebanon). In addition, several countries, principally in the Middle East, restrict doing business with Israel, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise. Any hostilities involving Israel, terrorist activities, political instability or violence in the region or the interruption or curtailment of trade or transport between Israel and its trading partners could adversely affect our operations and results of operations and adversely affect the market price of our ordinary shares.

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, 2023, we had 41 employees based in Israel. Of these employees, some may be military reservists, and may be called upon to perform military reserve duty of up to 36 days per year (and in some cases more) until they reach the age of 40 (and in some cases, up to the age of 45 or older). Additionally, they may be called to active duty at any time under emergency circumstances. In response to increased tension and hostilities in the region, there have been, at times, call-ups of military reservists, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of these employees due to military service. Such disruption could harm our business and operating results.

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

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

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

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

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

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

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

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

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

Risks Related to Our Management and Employees

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

Our success depends upon the continued service and performance of our executive officers who are essential to our growth and development. The loss of one or more of our executive officers could delay or prevent the continued successful implementation of our growth strategy, could affect our ability to manage our company effectively and to carry out our business plan, or could otherwise be detrimental to us. As of June 30, 2023, we had 193 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. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have implemented a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, there is no guarantee that such programs will be sufficient. Additionally, 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.

While we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations as a result of the matters relating to SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

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 stock price.

The global credit and financial markets have experienced extreme volatility and disruptions in the past, including due to recent bank failures. 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 current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our portfolio of corporate and government bonds could also be adversely impacted. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

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

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

Item 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 July 2023 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 July 27, 2023).
10.1+	Manufacturing and Supply Agreement - Amendment No. 2, dated May 19, 2023, by and between the Registrant and Isotopia Molecular Imaging Ltd.
10.2	Amendment to Loan Agreement, dated June 29, 2023, by and among the Company, UroGen Pharma, Inc., as the borrower, and certain direct and indirect subsidiaries of the Company party thereto from time to time, as guarantors, BPCR Limited Partnership, as a lender, BioPharma Credit Investments V (Master) LP, as a lender, and BioPharma Credit PLC, as collateral agent for the lenders.
10.3	Securities Purchase Agreement, dated July 26, 2023, by and among UroGen Pharma Ltd. and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38079), filed with the SEC on July 27, 2023).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2#	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL

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

+ Certain portions of this exhibit are omitted because they are not material and are the type that the Registrant treats as private and confidential.

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 10, 2023 By: /s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer
(Principal Executive Officer)

August 10, 2023 By: /s/ Don Kim
Don Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Execution Version

MANUFACTURING AND SUPPLY AGREEMENT – AMENDMENT NO. 2

Whereas, **UroGen Pharma Ltd.**, with a principal place of business or an office at 9 HaTa'asiya Street, Ra'anana 4365007, Israel (the "**Buyer**") and **Isotopia Molecular Imaging Ltd.** with its principal place of business located at Alexander Yanai 39 Street Segula Industrial Park Petach Tikva 49277, Israel. (the "**Supplier**") (hereinafter referred to individually as a "**Party**" and collectively as the "**Parties**") entered a Manufacturing and Supply Agreement with an Effective Date of May 26, 2020 (the "**Original Agreement**"); and

Whereas, the Parties to the Original Agreement entered into a first amendment to the Original Agreement with an effective date of July 1, 2022, extending the term of the Original Agreement and providing for certain additional amendments to the Original Agreement ("**Amendment No. 1**"); and

Whereas, the Parties agree that the "Original Agreement", together with "Amendment No. 1", hereinafter shall collectively be referred to as the "Agreement"; and

Whereas, the Parties desire to enter into this amendment ("**Amendment No. 2**") of the Agreement providing for the pre-payment by Buyer of certain future fees due Supplier under the Agreement, Buyer's right to certain off-invoice discounts as provided herein, and providing for certain other amendments to the Agreement, as set forth in more detail below.

Now, therefore, in consideration of the mutual promises and covenants contained herein, the parties hereby agree as follows:

1. **Interpretation**

Capitalized terms contained herein shall have the meaning ascribed to them in this Amendment No. 2. Capitalized terms which are not defined herein shall have the same meaning ascribed to them in the Agreement.

2. **Amendments to the Agreement**

2.1. New Section 10.5 shall be added to the Agreement. It shall provide as follows:

"10.5. **Pre-payment of Future Fees Due under the Agreement**. On the effective date of this Amendment No. 2, Buyer shall deliver to Supplier via wire transfer [***] (the "**Pre-Payment**"), constituting Buyer's pre-payment of future fees that will become due under the Agreement."

2.2. New Section 10.6 shall be added to the Agreement. It shall provide as follows:

"10.6 **Off-Invoice Cumulative Discount to Buyer.** Supplier shall provide a discount to Buyer under the Agreement with a cumulative total of ILS [***]. (the "**Cumulative Discount**"). Commencing on the Effective Date of Amendment No. 2 and continuing to the end of the Term or until the Cumulative Discount has been satisfied in full, whichever is sooner, each Supplier invoices delivered to Buyer, except for invoices referring to payments made by Supplier to third parties in relation to Manufacturing (including Raw Materials and Services), shall include and shall reflect, without offset or a lesser discount percentage for any reason, a [***] discount off the fee otherwise payable by Buyer to Supplier under the Agreement, excluding Transfer Taxes (the "**Individual Invoice Discount**"). If any portion of the Cumulative Discount has not been fully satisfied by the sum of the Individual Invoice Discounts prior to the end of the Term, then Supplier shall pay via Wire Transfer prior to the end of the Term the unsatisfied balance of the Cumulative Discount that is owed to Buyer. By mutual prior written agreement, the Parties may elect to exempt certain Supplier invoices from the Individual Invoice Discount, except that [***] batch invoices and annual retainer invoices are not eligible for mutual exemption."

2.3. New Section 10.7 shall be added to the Agreement. It shall provide as follows: "10.7 **Exclusive Dedication of Pre-Payment to Improvements**. Supplier undertakes to dedicate 100% the Pre-Payment exclusively toward the reasonable and necessary costs of certain mutually agreed capital equipment ([***]) and other improvements required by the applicable Regulatory Authority according to the Improvements Plan attached hereto as Exhibit A (collectively, the "**Improvements**"), that are intended for the Facility. Supplier agrees to complete the Improvements at the Facility no later than July 23, 2023. For clarity, Supplier shall be solely responsible for the costs of such Improvements and all payments to vendors and suppliers relating to such Improvements at the Facility."

2.4. New Section 13.3 shall be added to the Agreement. It shall provide as follows: "13.3. **Buyer's Right to Receive Audited Financial Statements and to Audit Supplier's Financial Good Standing**. For the period commencing January 1, 2023, through the end of the Term, Supplier shall provide Buyer with copies of its semiannual (e.g., quarterly) and annual audited financial statements (the "**Financial Statements**"). Such Financial Statements shall be delivered to Supplier within three (3) business days of Supplier's receipt of such Financial Statements. For clarity, on or before the Effective Date of Amendment No. 2, Supplier shall provide Buyer with its Financial Statement for the first quarter (Q1) of 2023. In addition, Buyer (or any third party designated by Buyer), during the Term and at reasonable times and upon reasonable advance notice to Supplier, may audit the Books and Records and other mutually agreed financial records of Supplier to ensure Supplier is and remains in good financial standing sufficient to meet its commitments under and compliance with the Agreement; provided, however, that such audits by Buyer may not be conducted more than twice in any twelve (12)-month period, unless during a previous audit during such twelve (12)-month period Buyer identified and disclosed to Supplier a material risk relating to Supplier's financial good standing. Buyer (or, as applicable, Buyer's third-party designee) will be allowed to interview key Supplier employees, including its Chief Financial Officer, with respect to Supplier's financial good standing and have access to, and be permitted to examine and copy (without charge), the Books and Records and mutually agreed financial records maintained by Supplier for the purposes of conducting such audit. The reasonable

costs for any such audit of Supplier's Financial Good Standing shall be borne by Supplier. Notwithstanding, as of July 31, 2023, Buyer (or any third party designated by Buyer), at its dole discretion and at reasonable times and upon reasonable advance notice to Supplier, may audit the Books and Records, Financial Statements and other mutually agreed financial records of Supplier to verify Supplier's dedication of and use of the Pre-Payment solely for the Improvements."

2.5. New Section 18.8.1 shall be added to the Agreement. It shall provide as follows: "18.8.1 **Additional Change of Control Protections for Buyer.** Without limiting section 18.8 of the Agreement, or any of Buyer's rights under the Agreement (e.g., Buyer's right to deny consent to any assignment of the Agreement) or any of Supplier's duties under the Agreement, or any of the protections or rights afforded Buyer under applicable law in the event of a change of control, in the event Supplier enters a transaction leading to a change of control of the Facility during the Term, then Supplier agrees that the written terms of such change of control agreement with such acquirer shall expressly provide for (i) the duly authorized assignment of the Agreement and the properly financed continuation of Manufacturing at the Facility and the continued, uninterrupted Manufacturing and supply of Product to Buyer consistent with the terms of the Agreement; (ii) written notice within ten (10) business days of the close of such transaction from acquirer to Buyer confirming the continuation of manufacturing at the Facility and confirming acquirer's obligations under and performance under the Agreement; and (iii) receipt of Buyer's prior written consent to such change of control agreement, which shall not be unreasonably withheld."

2.6. Section 4.4 of the Agreement shall be amended. As amended, it shall provide as follows: "4.4 **Prompt Notification of Potential Product Supply Instability, Forecast Adjustment and Purchase Order Lead Time Adjustment**. Supplier shall notify Buyer in writing immediately upon learning any issue or event (e.g., Audit of the Facility; any Regulatory Authority action; material decrease in production capacity; material decrease in customer product orders/forecasts) that (i) may result in a Product supply interruption of greater than thirty (30) days; or (ii) may result in Supplier's inability, financial or otherwise, to perform certain of its obligations under the Agreement; or (iii) may result in Supplier's default under the Agreement; or (iv) may result in Supplier's liquidation, whether voluntarily or otherwise, or its entering into any arrangement with its creditors or the appointment of a receiver ("**Instability Notification**"). Without limiting Buyer's rights under Section 4.5 of the Agreement or Section 7 of the Agreement, following Buyer's receipt of any such Instability Notification from Supplier, Buyer shall have the right (i) to request an increase in its then current "Safety Stock" of Raw Materials, without limitation, and Supplier shall order and maintain the requested increase in the "Safety Stock" of Raw Materials; (ii) to issue a new Forecast for Product; and (iii) to issue Purchase Orders for Product with delivery date lead times of thirty (30) or more calendar days after the date of the Purchase Order, or such other lead time as may be mutually agreed between Supplier and Buyer."

2.7. New Section 4.6 shall be added to the Agreement. It shall provide as follows: "4.6 **Prioritization of the Facility and Supplier's Manufacture of the Product at the Facility.** Without limiting any of Buyer's rights or Supplier's duties under the Agreement, in the event Supplier elects during the Term to terminate, downsize, or reduce capacity at one or more of its various facilities or its Manufacturing activities at such facilities, either on account of financial hardship, market slowdowns, or for other business reasons, then Supplier agrees to prioritize the survival of and continued operation of the Facility and the Manufacture of Buyer's Product at the Facility, at the expense of Supplier's other facilities and operations therein."

2.8. Exhibit D to the Agreement (the "**Quote**") shall be amended. As amended, the Quote is set forth as Exhibit B to this Amendment No. 2.

2.9. Except as amended above, all other terms of and exhibits to the Agreement shall remain unchanged.

3. **Remaining Provisions**

3.1. Unless specifically stated otherwise in this Amendment No. 2, the remainder of the terms under the Agreement shall remain in full force and effect, *mutatis mutandis*. In any inconsistency between this Amendment No. 2 and the Agreement, this Amendment No. 2 shall prevail.

3.2. This Amendment No. 2 and the Agreement, together with all exhibits and schedules thereto, constitutes the full and entire understanding and agreements between the parties regarding the subject matters hereof and thereof, and the Agreement and Amendment No. 2 supersede all prior written or oral, and all contemporaneous written or oral, agreements, understandings and negotiations with respect to the subject matter hereof. No rights, duties or obligations hereunder may be waived, amended, modified or assigned, in any way, in whole or in part, including by operation of law, without the prior written consent of the parties and such rights, duties and obligations shall inure to the benefit of and be binding upon the successors, assigns and personal representatives of each of the parties hereto.

3.3. In case any provision of this Amendment No. 2 shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions of this Amendment No. 2 shall not in any way be affected or impaired thereby.

3.4. This Amendment No. 2 may be executed by separate signature pages or in any number of counterparts (including by facsimile or PDF attachment to e-mail), and each of such counterparts shall, for all purposes, constitute one agreement binding on the Parties, notwithstanding that the Parties are not signatories to the same counterpart.

4. **Effective Date of Amendment No. 2.**

4.1. The effective date for this Amendment No. 2 shall be May 22, 2023.

IN WITNESS WHEREOF, this Amendment No. 2 has been signed by the following authorized representatives of the Parties hereto:

UROGEN PHARMA LTD.
By: /s/ Keren Stotzky
Name: Keren Stotzky
Title: VP Manufacturing & Supply Chain
Date: 5/18/2023

ISOTOPIA MOLECULAR IMAGING LTD.
By: /s/ Tzachi Levy
Name: Tzachi Levy
Title: Head Of Sterile Plant
Date: 5/19/2023-

Exhibit 10.2
Execution Version

FIRST AMENDMENT TO LOAN AGREEMENT

This FIRST AMENDMENT TO LOAN AGREEMENT (this "**Amendment**"), dated and effective as of June 29, 2023 (the "**First Amendment Effective Date**"), is made by and among UROGEN PHARMA, INC., a Delaware corporation (as "**Borrower**" and a Credit Party), UROGEN PHARMA LTD., a company incorporated in Israel with company registration number 513537621 (as "**Parent**" and a Credit Party), BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales with company number 10443190 (as the "**Collateral Agent**"), BPCR LIMITED PARTNERSHIP, a limited partnership established under the laws of England and Wales with registration number LP020944 (as a "**Lender**"), and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership acting by its general partner, BioPharma Credit Investments V GP LLC (as a "**Lender**").

RECITALS

A. Collateral Agent, Lenders and Borrower have entered into that certain Loan Agreement dated as of March 7, 2022 (the "Loan Agreement").

B. In accordance with Section 11.5 of the Loan Agreement, Borrower (acting for its own behalf and on behalf of the other Credit Parties other than Parent), Collateral Agent and Lenders desire to amend the Loan Agreement on the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, IN CONSIDERATION OF THE FOREGOING RECITALS AND OTHER GOOD AND VALUABLE CONSIDERATION, THE RECEIPT AND ADEQUACY OF WHICH IS HEREBY ACKNOWLEDGED, AND INTENDING TO BE LEGALLY BOUND, THE PARTIES HERETO AGREE AS FOLLOWS:

1. Definitions. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement. The rules of interpretation set forth in the first paragraph of Section 13.1 of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

2. Amendments to Loan Agreement. With immediate effect from and as of the First Amendment Effective Date:

a. The Loan Agreement shall be amended by adding as the fourth paragraph in Section 1 of the Loan Agreement the following:

"The Collateral Agent does not warrant or accept responsibility for, and shall not have any liability with respect to (a) the continuation of, administration of, submission of, calculation of or any other matter related to the Term SOFR Reference Rate, Adjusted Term SOFR or Term SOFR, or any component definition thereof or rates referred to in the definition thereof, or any alternative, successor or replacement rate thereto (including any Benchmark Replacement), including whether the composition or characteristics of any such alternative, successor or replacement rate (including any Benchmark Replacement) will be similar to, or produce the same value or economic equivalence of, or have the same volume or liquidity as, the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR or any other Benchmark prior to its discontinuance or unavailability, or (b) the effect, implementation or composition of any Conforming Changes. The Collateral Agent and its affiliates or other related entities may engage in transactions that affect the calculation of the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR, any alternative, successor or replacement rate (including any Benchmark Replacement) or any relevant adjustments thereto, in each case, in a manner adverse to the Borrower. The Collateral Agent may select information sources or services in its reasonable discretion to ascertain the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR or any other Benchmark, in each case pursuant to the terms of this Agreement, and shall have no liability to Borrower, any Lender or any other Person for damages of any kind, including direct or indirect, special, punitive, incidental or consequential damages, costs, losses or expenses (whether in tort, contract or otherwise and whether at law or in equity), for any error or calculation of any such rate (or component thereof) provided by any such information source or service."

b. The Loan Agreement shall be amended by deleting in their entirety Section 2.2(b)(ii) of the Loan Agreement and replacing it as follows:

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

c. The Loan Agreement shall be amended by deleting in its entirety Section 2.2(c)(ii) of the Loan Agreement and replacing it as follows:

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

d. The Loan Agreement shall be amended by deleting in its entirety Section 2.2(g) of the Loan Agreement and replacing it as follows:

"(g) Any Makewhole Amount or Prepayment Premium payable as a result of any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall be presumed to be the liquidated

damages sustained by each applicable Lender as the result of the early redemption and repayment of such Term Loan Notes and Borrower agrees that it is reasonable under the circumstances currently existing. BORROWER EXPRESSLY WAIVES (TO THE FULLEST EXTENT IT MAY LAWFULLY DO SO) THE PROVISIONS OF ANY PRESENT OR FUTURE REQUIREMENTS OF LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF ANY MAKEWHOLE AMOUNT OR PREPAYMENT PREMIUM IN CONNECTION WITH ANY SUCH PREPAYMENT OR ACCELERATION OR OTHERWISE. Borrower expressly agrees that (to the fullest extent it may lawfully do so) that: (i) each Makewhole Amount and Prepayment Premium is reasonable and is the product of an arm's-length transaction among sophisticated business people, ably represented by counsel; (ii) each Makewhole Amount and Prepayment Premium shall be payable notwithstanding the then-prevailing market rates at the time payment thereof is made; (iii) there has been a course of conduct among Lenders and Borrower giving specific consideration in this transaction for such agreement to pay each Makewhole Amount and Prepayment Premium; and (iv) Borrower shall be estopped hereafter from claiming differently than as agreed to in this Section 2.2(g) and Section 8.6. Borrower expressly acknowledges that its agreement to pay the Makewhole Amount and Prepayment Premium, as the case may be, to applicable Lenders as herein described is a material inducement to such Lenders to make any Credit Extension. Without affecting any of any Lender's rights or remedies hereunder or in respect hereof, if Borrower fails to pay the applicable Makewhole Amount or Prepayment Premium when due, then the amount thereof shall thereafter bear interest until paid in full at the Default Rate."

e. The Loan Agreement shall be amended by deleting in its entirety Section 2.3(a)(i) of the Loan Agreement and replacing it as follows:

"(i) Subject to Section 2.3(b) below, the principal amount outstanding under each Term Loan shall accrue interest at a *per annum* rate equal to Adjusted Term SOFR for the Interest Period therefor *plus* the Applicable Margin (the "**Term Loan Rate**"), which interest shall be payable quarterly in arrears in accordance with this Section 2.3."

f. The Loan Agreement shall be amended by deleting in its entirety Section 2.3(e) of the Loan Agreement and replacing it as follows:

"(e) Conforming Changes. In connection with the use or administration of Term SOFR, the Collateral Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Loan Document. The Collateral Agent will promptly notify Borrower and Lenders of the effectiveness of any Conforming Changes in connection with the use or administration of Term SOFR."

g. The Loan Agreement shall be amended by adding as Section 2.3(f) of the Loan Agreement the following:

"(f) Benchmark Replacement Setting.

(i) Benchmark Replacement. Notwithstanding anything to the contrary herein or in any other Loan Document, if a Benchmark Transition Event and its related Benchmark Replacement Date have occurred prior any setting of the then-current Benchmark, then (x) if a Benchmark Replacement is determined in accordance with clause (a) of the definition of "Benchmark Replacement" for such Benchmark Replacement Date, such Benchmark Replacement will replace such Benchmark for all purposes hereunder and under any Loan Document in respect of such Benchmark setting and subsequent Benchmark settings without any amendment to, or further action or consent of any other party to, this Agreement or any other Loan Document and (y) if a Benchmark Replacement is determined in accordance with clause (b) of the definition of "Benchmark Replacement" for such Benchmark Replacement Date, such Benchmark Replacement will replace such Benchmark for all purposes hereunder and under any Loan Document in respect of any Benchmark setting at or after 5:00 p.m. (New York City time) on the fifth (5th) Business Day after the date notice of such Benchmark Replacement is provided to Borrower and the Lenders without any amendment to, or further action or consent of any other party to, this Agreement or any other Loan Document so long as the Collateral Agent has not received, by such time, written notice of objection to such Benchmark Replacement from Lenders comprising the Required Lenders. If the Benchmark Replacement is Daily Simple SOFR, all interest payments will be payable on a quarterly basis.

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

(iii) Notices; Standards for Decisions and Determinations. The Collateral Agent will promptly notify Borrower and the Lenders of (A) the implementation of any Benchmark Replacement and (B) the effectiveness of any Conforming Changes in connection with the use, administration, adoption or implementation of a Benchmark Replacement. The Collateral Agent will notify Borrower of (x) the removal or reinstatement of any tenor of a Benchmark pursuant to sub-clause (iv) below and (y) the commencement of any Benchmark Unavailability Period. Any determination, decision or election that may be made by the Collateral Agent or, if applicable, any Lender (or group of Lenders) pursuant to this Section 2.3(f), including any determination with respect to a tenor, rate or adjustment or of the occurrence or non-occurrence of an event, circumstance or date and any decision to take or refrain from taking any action, will be conclusive and binding absent manifest error and may be made in its or their sole discretion and without consent from any other party to this Agreement or any other Loan Document, except, in each case, as expressly required pursuant to this Section 2.3(f).

(iv) Unavailability of Tenor of Benchmark. Notwithstanding anything to the contrary herein or in any other Loan Document, at any time (including in connection with the implementation of a Benchmark Replacement), (A) if the then-current Benchmark is a term rate (including the Term SOFR Reference Rate) and either (1) any tenor for such Benchmark is not displayed on a screen or other information service that publishes such rate from time to time as selected by the Collateral Agent in its reasonable discretion or (2) the regulatory supervisor for the administrator of such Benchmark has provided a public statement or publication of information announcing that any tenor for such Benchmark is not or will not be representative, then the Collateral Agent may modify the definition of "Interest Period" (or any similar or analogous definition) for any Benchmark settings at or after such time to remove such unavailable or non-representative tenor and (B) if a tenor that was removed pursuant to sub-clause (A) above either (1) is subsequently displayed on a screen or information service for a Benchmark (including a Benchmark Replacement) or (2) is not, or is no longer, subject to an announcement that it is not or will not be representative for a Benchmark (including a Benchmark Replacement), then the Collateral Agent may modify the definition of "Interest Period" (or any similar or analogous definition) for all Benchmark settings at or after such time to reinstate such previously removed tenor."

h. The Loan Agreement shall be amended by deleting the phrase "…the United States or any state thereof..." in Section 2.6(d)(i) of the Loan Agreement and replacing it with the phrase "…the United States…"

i. The Loan Agreement shall be amended by deleting Section 2.6(f) of the Loan Agreement in its entirety and replacing it as follows:

"(f) Tax Status of Borrower. Borrower is currently treated as a corporation for U.S. federal income tax purposes. Borrower shall provide the Required Lenders with a prior written notice as promptly as practicable, and in any event not less than ten (10) days, before taking any affirmative action (including making any election under Section 301.7701-3(c) of the Treasury Regulations (or any successor provision) by way of filing an IRS Form 8832) to change its U.S. entity tax classification."

j. The Loan Agreement shall be amended by deleting in its entirety Section 8.1(f) of the Loan Agreement and replacing it as follows:

"(f) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. With respect to any and all Intellectual Property owned or held by any Credit Party and included in Collateral, each Credit Party hereby grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, as of the Tranche A Closing Date: (i) an irrevocable, non-exclusive, assignable, royalty-free license or other right to use (and for its agents or representatives to use), without charge, including the right to sublicense, use and practice, any and all such Intellectual Property in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral, and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; and (ii) in connection with the Collateral Agent's exercise of its rights or remedies under this Section 8.1 (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral), each Credit Party's rights under all licenses and all franchise Contracts inure to the benefit of all Secured Parties;"

k. The Loan Agreement shall be amended by deleting in its entirety Section 8.6 of the Loan Agreement and replacing it as follows:

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

l. The Loan Agreement shall be amended by deleting in its entirety the Collateral Agent's notice details in Section 9 of the Loan Agreement and replacing them as follows:

"BioPharma Credit Plc
c/o Link Group, Company Matters Ltd.
6th Floor
65 Gresham Street
London EC2V 7NQ
United Kingdom
Attn: Company Secretary
Tel: +44 01 392 477 500
Fax: +44 01 392 438 288
Email: biopharmacreditplc@linkgroup.co.uk

with copies (which shall not constitute notice) to:

Pharmakon Advisors, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Fax: +1 (917) 210-4048
Email: pharmakon@pharmakonadvisors.com

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: +1 (212) 872-8081
Fax: +1 (212) 872-1002
Email: gsecol@akingump.com"

m. The Loan Agreement shall be amended by deleting in its entirety Section 11.2(a) of the Loan Agreement and replacing it as follows:

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

n. The Loan Agreement shall be amended by deleting in its entirety Section 11.12 of the Loan Agreement and replacing it as follows:

"11.12 Electronic Execution of Documents

. The words "execution," "execute," "signed," "signature," and words of like import in this Agreement and the other Loan Documents shall be deemed to include electronic signatures or electronic records, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any Requirements of Law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act."

o. The Loan Agreement shall be amended by deleting in its entirety each of the definitions of Available Tenor, Benchmark, Benchmark Replacement, Benchmark Transition Event, CCPA, Daily Simple SOFR, Data Protection Laws, Floor, Governmental Authority, Health Care Laws, Indemnified Liabilities, Interest Date, Interest Period, Lender Expenses, SOFR, Term SOFR, Tranche A Closing Date and Tranche B Closing Date in Section 13.1 of the Loan Agreement and replacing them, in alphabetical order, as follows:

""**Adjusted Term SOFR**" means, for purposes of any calculation, the rate per annum equal to (a) Term SOFR for such calculation plus (b) the Term SOFR Adjustment; provided that if Adjusted Term SOFR as so determined shall ever be less than the Floor, then Adjusted Term SOFR shall be deemed to be the Floor."

""**Available Tenor**" means, as of any date of determination and with respect to the then-current Benchmark, as applicable, (a) if such Benchmark is a term rate, any tenor for such Benchmark (or component thereof) that is or may be used for determining the length of an interest period pursuant to this Agreement or (b) otherwise, any payment period for interest calculated with reference to such Benchmark (or component thereof) that is or may be used for determining any frequency of making payments of interest calculated with reference to such Benchmark pursuant to this Agreement, in each case, as of such date and not including, for the avoidance of doubt, any tenor for such Benchmark that is then-removed from the definition of "Interest Period" pursuant to Section 2.3(e)."

""**Benchmark**" means, initially, the Term SOFR Reference Rate; provided that if a Benchmark Transition Event has occurred with respect to the Term SOFR Reference Rate or the then-current Benchmark, then "Benchmark" means the applicable Benchmark Replacement to the extent that such Benchmark Replacement has replaced such prior benchmark rate pursuant to Section 2.3(e)."

""**Benchmark Replacement**" means, with respect to any Benchmark Transition Event, the first alternative set forth in the order below that can be determined by the Collateral Agent for the applicable Benchmark Replacement Date:

(a) the sum of (i) Daily Simple SOFR and (ii) 0.26161% (26.161 basis points); or

(b) the sum of: (i) the alternate benchmark rate that has been selected by the Collateral Agent giving due consideration to (A) any selection or recommendation of a replacement benchmark rate or the mechanism for determining such a rate by the Relevant Governmental Body or (B) any evolving or then-prevailing market convention for determining a benchmark rate as a replacement to the then-current Benchmark for Dollar-denominated syndicated credit facilities and (ii) the related Benchmark Replacement Adjustment;

provided that, if the Benchmark Replacement as determined pursuant to clause (a) or (b) above would be less than the Floor, the Benchmark Replacement will be deemed to be the Floor for the purposes of this Agreement and the other Loan Documents."

""**Benchmark Transition Event**" means the occurrence of one or more of the following events with respect to the then-current Benchmark:

(a) a public statement or publication of information by or on behalf of the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that such administrator has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof), permanently or indefinitely; provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof);

(b) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof), the Federal Reserve Board, the Federal Reserve Bank of New York, an insolvency official with jurisdiction over the administrator for such Benchmark (or such component), a resolution authority with jurisdiction over the administrator for such Benchmark (or such component) or a court or an entity with similar insolvency or resolution authority over the administrator for such Benchmark (or such component), which states that the administrator of such Benchmark (or such component) has ceased or will cease to provide

all Available Tenors of such Benchmark (or such component thereof) permanently or indefinitely; provided that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof); or

(c) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that all Available Tenors of such Benchmark (or such component thereof) are not, or as of a specified future date will not be, representative.

For the avoidance of doubt, a "Benchmark Transition Event" will be deemed to have occurred with respect to any Benchmark if a public statement or publication of information set forth above has occurred with respect to each then-current Available Tenor of such Benchmark (or the published component used in the calculation thereof)."

""**CCPA**" means the provisions of the California Consumer Privacy Act, as amended by the California Privacy Rights Act and codified at Cal. Civ. Code § 1798.100 et seq., with any implementing regulations."

""**Daily Simple SOFR**" means, for any day, SOFR, with the conventions for this rate (which will include a lookback) being established by the Collateral Agent in accordance with the conventions for this rate recommended by the Relevant Governmental Body for determining "Daily Simple SOFR" for Dollar-denominated bilateral business loans; provided, that if the Collateral Agent decides that any such convention is not administratively feasible for the Collateral Agent, then the Collateral Agent may establish another convention in its reasonable discretion."

""**Data Protection Laws**" means any and all applicable foreign or domestic (including U.S. federal, state and local), statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to privacy, security, notification of breaches, or confidentiality of Personal Data that are applicable to the Parent or any of its Subsidiaries, including, to the extent applicable, HIPAA, Section 5 of the FTC Act and other consumer protection laws, Israeli Data Protection Law, GDPR, CCPA and other comprehensive state privacy laws, CMIA and other U.S. state medical information privacy laws and genetic testing laws."

""**Floor**" means a rate of interest equal to 1.25% *per annum*."

""**Governmental Authority**" means any nation or government, any state or other political subdivision thereof, any agency (including Regulatory Agencies and data protection authorities), government department, authority, instrumentality, regulatory body, commission, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization."

""**Health Care Laws**" means, collectively: (a) applicable federal, state or local laws, rules, regulations, codes, orders, ordinances, statutes and requirements issued under or in connection with Medicare, Medicaid or any other Government Payor Program; (b) applicable federal and state laws and regulations governing the privacy, security, confidentiality, or notification of breaches regarding health information, including HIPAA and Section 5 of the FTC Act; (c) applicable federal, state and local fraud and abuse laws of any Governmental Authority, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code and the regulations promulgated pursuant to such statutes; (d) the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173) and the regulations promulgated thereunder; (e) the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h); (f) any applicable reporting and disclosure requirements, including any arising under Section 603 of the Veteran's Health Care Act (Quarterly and Annual Non-Federal Average Manufacturer Price and Federal Ceiling Price), Best Price, Federal Supply Schedule Contract Prices and Tricare Retail Pharmacy Refunds, and Medicare Part D; (g) health care laws, rules, codes, statutes, regulations, orders, ordinances and requirements pertaining to Medicare or Medicaid; (h) federal, state or local laws, rules, regulations, ordinances, statutes and requirements relating to (x) the regulation of managed care, third party payors and Persons bearing the financial risk for the provision or arrangement of health care services, (y) billings to insurance companies, health maintenance organizations and other Managed Care Plans or otherwise relating to insurance fraud and (z) any insurance, health maintenance organization or managed care Requirements of Law; (i) the interoperability, information blocking, and health information technology certification regulations promulgated under the 21st Century Cures Act (to the extent effective); (j) CDC regulations (including regulations implemented by the CDC Division of Select Agents and Toxins ("DSAT") or otherwise relating to the Federal Select Agent Program ("FSAP"), such as 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73); and (k) any other applicable domestic or foreign health care laws, rules, codes, regulations, manuals, orders, ordinances, and statutes relating to the research, development, testing, approval, licensure, post-approval or post-licensure monitoring, post-approval or post-licensure requirements, post-approval or post-licensure commitments, reporting, manufacture, production, packaging, labeling, use, commercialization, marketing, promotion, advertising, importing, exporting, storage, transport, offer for sale, distribution or sale of or payment for Product."

""**Indemnified Liabilities**" means, collectively, any and all liabilities, obligations, losses, damages (including natural resource damages), penalties, claims, actions, judgments, suits, costs, reasonable and documented out-of-pocket fees, expenses and disbursements of any kind or nature whatsoever (including the reasonable and documented fees, expenses and disbursements of one counsel for Indemnified Persons plus, as applicable, one local legal counsel in each relevant material jurisdiction and one intellectual property legal counsel, and in the case of an actual or perceived conflict of interest, one additional counsel for such affected Indemnified Persons, in connection with any investigative, administrative or judicial proceeding or hearing commenced or threatened in writing by any Person, whether or not any such Indemnified Person shall have commenced such proceeding or hearing or be designated as a party or a potential party thereto, and any fees or expenses incurred by Indemnified Persons in enforcing any indemnity hereunder) whether direct, indirect or consequential and whether based on any federal, state or foreign laws, statutes, rules or regulations, on common law or equitable cause or on contract or otherwise, that may be imposed on, incurred by, or asserted against any such Indemnified Person, in any manner relating to or arising out of this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby (including any Lender's agreement to make Credit Extensions or the use or intended use of the proceeds thereof, or any enforcement of any of the Loan Documents (including any sale of, collection from, or other realization upon any of the Collateral or the enforcement of any guaranty of the Obligations))."

""**Interest Date**" means the last day of each calendar quarter, commencing with the last day of the calendar quarter during which the First Amendment Effective Date occurs."

""**Lender Expenses**" means, collectively:

(a) all reasonable and documented out-of-pocket fees and expenses of the Collateral Agent and, as applicable, each Lender (and their respective successors and assigns) and their respective Related Parties (including the reasonable and documented out-of-pocket fees, expenses and

disbursements of any legal counsel, manufacturing consultants or intellectual property experts (it being agreed that such consultant or expert fees, expenses and disbursements shall be limited to one such consultant and one such expert for the Collateral Agent, Lenders and such Related Parties, taken as a whole and in the case of an actual or perceived conflict of interest, one additional legal counsel for such affected Indemnified Person) therefor, (i) incurred in connection with developing, preparing, negotiating, syndicating, executing and delivering, and interpreting, investigating and administering, the Loan Documents (or any term or provision thereof), any commitment, proposal letter, letter of intent or term sheet therefor or any other document prepared in connection therewith, (ii) incurred in connection with the consummation and administration of any transaction contemplated therein, (iii) incurred in connection with the performance of any obligation or agreement contemplated therein, (iv) incurred in connection with any modification or amendment of any term or provision of, or any supplement to, or the termination (in whole or in part) of, any Loan Document, (v) incurred in connection with internal audit reviews and Collateral audits, or (vi) otherwise incurred with respect to the Credit Parties in connection with the Loan Documents, including any filing or recording fees and expenses; and

(b) all reasonable and documented out-of-pocket costs and expenses incurred by the Collateral Agent and each Lender (and their respective successors and assigns) and their respective Related Parties (including the reasonable and documented out-of-pocket fees, expenses and disbursements of any legal counsel therefor for the Collateral Agent, Lenders and such Related Parties taken as a whole and in the case of an actual or perceived conflict of interest, one additional legal counsel for such affected Indemnified Person) in connection with (i) any refinancing or restructuring of the credit arrangements provided hereunder in the nature of a "work-out," (ii) the enforcement or protection or preservation of any right or remedy under any Loan Document, any Obligation, with respect to any of the Collateral or any other related right or remedy, or (iii) the commencement, defense, conduct of, intervention in, or the taking of any other action with respect to, any proceeding (including any Insolvency Proceeding) related to any Credit Party or any Subsidiary of any Credit Party in respect of any Loan Document or Obligation, or otherwise in connection with any Loan Document or Obligation (or the response to and preparation for any subpoena or request for document production relating thereto); provided, that, except with respect to an Insolvency Proceeding, to the extent such enforcement entails the Collateral Agent or any Lender commencing legal action of any sort against Borrower, any fees and expenses incurred in connection therewith shall only be payable by Borrower to the extent the Collateral Agent or any Lender is successful in such legal action."

""**SOFR**" means a rate equal to the secured overnight financing rate as administered by the SOFR Administrator."

""**Term SOFR**" means, for any day in any calendar month, the Term SOFR Reference Rate for a tenor of three (3) months on the day (such day, the "**Periodic Term SOFR Determination Day**") that is two (2) U.S. Government Securities Business Days' prior to the first day of such Interest Period, as such rate is published by the Term SOFR Administrator; provided, however, that if as of 5:00 p.m. (New York City time) on any Periodic Term SOFR Determination Day the Term SOFR Reference Rate for the applicable tenor has not been published by the Term SOFR Administrator and a Benchmark Replacement Date with respect to the Term SOFR Reference Rate has not occurred, then Term SOFR will be the Term SOFR Reference Rate for such tenor as published by the Term SOFR Administrator on the first preceding U.S. Government Securities Business Day for which such Term SOFR Reference Rate for such tenor was published by the Term SOFR Administrator so long as such first preceding U.S. Government Securities Business Day is not more than three (3) U.S. Government Securities Business Days prior to such Periodic Term SOFR Determination Day."

""**Tranche A Closing Date**" means the date on which the Tranche A Loan is advanced by Lenders, which is March 16, 2022."

""**Tranche B Closing Date**" means the date on which the Tranche B Loan is advanced by Lenders, which is December 16, 2022."

p. The Loan Agreement shall be amended by deleting in its entirety each of the definitions of Early Opt-in Effective Date, Early Opt-in Election, Interest Rate Determination Date and LIBOR Rate in Section 13.1 of the Loan Agreement.

q. The Loan Agreement shall be amended by adding, in alphabetical order, each of the following definitions to Section 13.1 of the Loan Agreement:

""**Applicable Margin**" means, for any day, as to any Term Loan, a rate *per annum* equal to eight and one-quarter percent (8.25%)."

""**Benchmark Replacement Adjustment**" means, with respect to any replacement of the then-current Benchmark with an Unadjusted Benchmark Replacement, the spread adjustment, or method for calculating or determining such spread adjustment, (which may be a positive or negative value or zero) that has been selected by the Collateral Agent and Borrower giving due consideration to (a) any selection or recommendation of a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of such Benchmark with the applicable Unadjusted Benchmark Replacement by the Relevant Governmental Body or (b) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of such Benchmark with the applicable Unadjusted Benchmark Replacement for Dollar-denominated syndicated credit facilities at such time."

""**Benchmark Replacement Date**" means a date and time determined by the Collateral Agent in its reasonable discretion, which date shall be no later than the earliest to occur of the following events with respect to the then-current Benchmark:

(a) in the case of clause (a) or (b) of the definition of "Benchmark Transition Event," the later of (i) the date of the public statement or publication of information referenced therein and (ii) the date on which the administrator of such Benchmark (or the published component used in the calculation thereof) permanently or indefinitely ceases to provide all Available Tenors of such Benchmark (or such component thereof); and

(b) in the case of clause (c) of the definition of "Benchmark Transition Event," the first date on which such Benchmark (or the published component used in the calculation thereof) has been determined and announced by the regulatory supervisor for the administrator of such Benchmark (or such component thereof) to be non-representative; provided that such non-representativeness will be determined by reference to the most recent statement or publication referenced in such clause (c) and even if any Available Tenor of such Benchmark (or such component thereof) continues to be provided on such date.

For the avoidance of doubt, the "Benchmark Replacement Date" will be deemed to have occurred in the case of clause (a) or (b) above with respect to any Benchmark upon the occurrence of the applicable event or events set forth therein with respect to all then-current Available Tenors of such Benchmark (or the published component used in the calculation thereof)."

""**Benchmark Unavailability Period**" means, the period (if any) (a) beginning at the time that a Benchmark Replacement Date has occurred if, at such time, no Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Loan

Document in accordance with Section 2.3(e) and (b) ending at the time that a Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Loan Document in accordance with Section 2.3(e).”

““**CMIA**” means the California Confidentiality of Medical Information Act, codified at Cal. Civ. Code pt. 2.6 § 56 et seq.”

““**Conforming Changes**” means, with respect to either the use or administration of Term SOFR or the use, administration, adoption or implementation of any Benchmark Replacement, any technical, administrative or operational changes (including changes to the definition of “Business Day,” the definition of “U.S. Government Securities Business Day,” the definition of “Interest Period” or any similar or analogous definition (or the addition of a concept of “interest period”), timing and frequency of determining rates and making payments of interest, timing of borrowing requests or prepayment, conversion or continuation notices, the applicability and length of lookback periods and other technical, administrative or operational matters) that the Collateral Agent decides (after consultation with Borrower) may be appropriate to reflect the adoption and implementation of any such rate or to permit the use and administration thereof by the Collateral Agent in a manner substantially consistent with market practice (or, if the Collateral Agent decides that adoption of any portion of such market practice is not administratively feasible or if the Collateral Agent determines that no market practice for the administration of any such rate exists, in such other manner of administration as the Collateral Agent decides is reasonably necessary in connection with the administration of this Agreement and the other Loan Documents).”

““**First Amendment Effective Date**” means June __, 2023.”

““**Periodic Term SOFR Determination Day**” has the meaning specified in the definition of Term SOFR.”

““**SOFR Administrator**” means the Federal Reserve Bank of New York (or a successor administrator of the secured overnight financing rate).”

““**Term SOFR Adjustment**” means a percentage equal to 0.26161% *per annum*.”

““**Term SOFR Administrator**” means CME Group Benchmark Administration Limited (CBA) (or a successor administrator of the Term SOFR Reference Rate selected by the Collateral Agent in its reasonable discretion).”

““**Term SOFR Reference Rate**” means the forward-looking term rate based on SOFR.”

““**U.S. Government Securities Business Day**” means any day except for (a) a Saturday, (b) a Sunday or (c) a day on which the Securities Industry and Financial Markets Association recommends that the fixed income departments of its members be closed for the entire day for purposes of trading in United States government securities.”

r. The Loan Agreement shall be amended by deleting in its entirety the notice details of each Lender in Exhibit D of the Loan Agreement and replacing them as follows:

“BPCR LIMITED PARTNERSHIP
c/o Link Group, Company Matters Ltd.
6th Floor
65 Gresham Street
London EC2V 7NQ
United Kingdom
Attn: Company Secretary
Tel: +44 01 392 477 500
Fax: +44 01 392 438 288
Email: biopharmacreditplc@linkgroup.co.uk

with copies (which shall not constitute notice) to:

PHARMAKON ADVISORS, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Fax: +1 (917) 210-4048
Email: pharmakon@pharmakonadvisors.com

and

AKIN GUMP STRAUSS HAUER & FELD LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: +1 (212) 872-8081
Fax: +1 (212) 872-1002
Email: gsecol@akingump.com”

“BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP
c/o BioPharma Credit Investments V GP LLC
c/o Walkers Corporate Limited
190 Elgin Avenue,
George Town, Grand Cayman KY1-9008
Attn: Pedro Gonzalez de Cosio

with copies (which shall not constitute notice) to:

PHARMAKON ADVISORS, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: +1 (212) 883-2296
Fax: +1 (917) 210-4048
Email: pharmakon@pharmakonadvisors.com

and

AKIN GUMP STRAUSS HAUER & FELD LLP
One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: +1 (212) 872-8081
Fax: +1 (212) 872-1002
Email: gsecol@akingump.com"

s. The Loan Agreement shall be amended by deleting in its entirety Exhibits B-1 and B-2 to the Loan Agreement and replacing them with Exhibits B-1 and B-2 attached to this Amendment.

3. Representations and Warranties; Reaffirmation; Covenant to Deliver.

a. Borrower hereby represents and warrants to each Lender and the Collateral Agent as follows:

i. Borrower has all requisite power and authority to enter into this Amendment and to carry out the transactions contemplated hereby.

ii. This Amendment has been duly executed and delivered by Borrower and is the legally valid and binding obligation of such Person, enforceable against such Person in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by general principles of equity.

iii. The execution, delivery and performance by Borrower of this Amendment have been duly authorized and do not and will not: (A) contravene the terms of such Person's Operating Documents; (B) violate any Requirements of Law, except to the extent that such violation could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change; (C) conflict with or result in any breach or contravention of, or require any payment to be made under any provision of any security issued by such Person or of any agreement, instrument or other undertaking to which such Person is a party or affecting such Person or the assets or properties of such Person or any of its Subsidiaries or any order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which such Person or any of its properties or assets are subject, except to the extent that such conflict, breach, contravention or payment could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change; (D) require any Governmental Approval, or other action by, or notice to, or filing with, any Governmental Authority (except such Governmental Approvals or other actions, notices and filings which have been duly obtained, taken, given or made on or before the First Amendment Effective Date and are in full force and effect), except for those approvals, consents, exemptions, authorizations or other actions, notices or filings, the failure of which to obtain or make could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change; (E) require any approval, consent, exemption or authorization, or other action by, or notice to, or filing with, any Person other than a Governmental Authority, including such Person's stockholders, members or partners, (except such approvals, consents, exemptions, authorizations, actions, notices and filings which have been or will be duly obtained, taken, given or made on or before the First Amendment Effective Date and are in full force and effect), except for those approvals, consents, exemptions, authorizations or other actions, notices or filings, the failure of which to obtain or make could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change; or (F) constitute a material breach of or a material default under (which such default has not been cured or waived) or an event of default (or the equivalent thereof, however described) under, or could reasonably be expected to give rise to the cancellation, termination or invalidation of or the acceleration of such Person's or any Subsidiary's obligations under, any Material Contract.

iv. Both before and immediately after giving effect to this Amendment, no Event of Default or Default has occurred and is continuing.

b. Borrower hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Amendment, except as expressly provided herein. By executing this Amendment, Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

c. Borrower hereby agrees to deliver to the Collateral Agent, within two (2) Business Days of the First Amendment Effective Date, originally-signed copies of the Amended and Restated Tranche A Notes and the Amended and Restated Tranche B Notes, in the forms attached as Exhibit B-1 and Exhibit B-2 hereto, respectively (collectively, the "***Replacement Notes***"), in replacement of the Tranche A Notes, dated March 16, 2022, and the Tranche B Notes, dated December 16, 2022, issued by Borrower to each Lender (the "***Existing Notes***") whereupon the Lenders shall return all copies of the Existing Notes to Borrower to be destroyed and the Existing Notes shall from that moment be treated as cancelled and of no further force or effect. Failure of Borrower to deliver the Replacement Notes in accordance with this paragraph constitutes an Event of Default for all purposes under the Loan Agreement.

4. References to and Effect on Loan Agreement. Except as specifically set forth herein, this Amendment shall not modify or in any way affect any of the terms, conditions, covenants, representations and warranties contained in the Loan Agreement, or any of the rights of the Lenders and the Collateral Agent therein, which shall remain in full force and effect and are hereby ratified and confirmed in all respects. Except as specifically set forth herein, the execution, delivery and effectiveness of this Amendment shall not directly or indirectly (i) constitute a consent or waiver of any past, present or future breaches, violations or defaults of or under any provisions of the Loan Agreement nor constitute a novation of any of the Obligations under the Loan Agreement, (ii) amend, modify or operate as a waiver of any provision of the Loan Agreement or any right, power or remedy of any Lender or the Collateral Agent, or (iii) constitute a course of dealing or other basis for altering the Loan Agreement or any other Loan Document. Except as set forth herein, each of the Lenders and the Collateral Agent reserves all of its rights, powers, and remedies under the Loan Documents and Requirements of Law. On and after the First Amendment Effective Date, all references in the Loan Agreement to "this Agreement," "hereto," "hereof," "hereunder," or words of like import shall mean the Loan Agreement as amended by this Amendment.

5. Successors and Assigns. This Amendment binds and is for the benefit of Borrower, the other Credit Parties, Lenders and Collateral Agent and each of their respective successors and permitted assigns.

6. Governing Law; Venue; Jury Trial Waiver. This Amendment shall be construed in accordance with and governed by the law of the State of New York. The provisions of Section 10 (*Choice of law, Venue and Jury Trial Waiver Etc*.) of the Loan Agreement shall apply hereto as if more fully set forth herein as if references therein to "this Agreement" were references to this Amendment.

7. Counterparts. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Amendment. The words "execution," "signed," "signature," and words of like import in this Amendment shall be deemed to include electronic signatures or electronic records, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for under any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the undersigned hereto have caused this Amendment to be executed as of the date first written above by each of their officers thereunto duly authorized.

UROGEN PHARMA, INC.,
as Borrower and a Credit Party on its own behalf and on behalf of each other Credit Party (other than Parent)

By /s/ Don Kim
Name: Don Kim
Title: Chief Financial Officer

UROGEN PHARMA LTD.,
as Parent and a Credit Party

By /s/ Don Kim
Name: Don Kim
Title: Chief Financial Officer

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BPCR LIMITED PARTNERSHIP,
as a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP,
as Lender

By: BioPharma Credit Investments V GP LLC,
its general partner

By: Pharmakon Advisors, LP,
its Investment Manager

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: CEO and Managing Member

EXHIBIT B-1

THIS TRANCHE A NOTE HAS BEEN ISSUED WITH "ORIGINAL ISSUE DISCOUNT" (WITHIN THE MEANING OF SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED). HOLDERS OF THIS TRANCHE A NOTE SHOULD CONTACT MOLLY HENDERSON, CHIEF FINANCIAL OFFICER, UROGEN PHARMA, 400 ALEXANDER PARK DRIVE, PRINCETON, NEW JERSEY 08540 IN WRITING TO OBTAIN (1) THE ISSUE PRICE AND ISSUE DATE OF THIS TRANCHE A NOTE, (2) THE AMOUNT OF ORIGINAL ISSUE DISCOUNT ON THIS TRANCHE A NOTE AND (3) THE YIELD TO MATURITY OF THIS TRANCHE A NOTE.

AMENDED AND RESTATED SECURED TRANCHE A LOAN PROMISSORY NOTE

$37,500,000.00 Dated: June __, 2023

FOR VALUE RECEIVED, the undersigned, UROGEN PHARMA, INC., a private limited company incorporated under the laws of England and Wales and limited by shares ("**Borrower**"), HEREBY PROMISES TO PAY to [BPCR LIMITED PARTNERSHIP] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of THIRTY-SEVEN MILLION FIVE HUNDRED THOUSAND DOLLARS AND NO CENTS ($37,000,000.00), plus interest on the aggregate unpaid principal amount of this Amended and Restated Secured Tranche A Loan Promissory Note (this "**Tranche A Note**") at a *per annum* rate equal to Adjusted Term SOFR *plus* the Applicable Margin, and in accordance with the terms of the Loan Agreement dated as of March 7, 2022 by and among Borrower, Lender, BioPharma Credit PLC, as Collateral Agent, the other Lenders from time to time party thereto and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date. This Amended and Restated Secured Tranche A Loan Promissory Note amends and restates in its entirety that certain Secured Tranche A Loan Promissory Note, dated March 16, 2022, in the aggregate principal amount of Thirty-Seven Million and Five Hundred Thousand Dollars and Zero Cents ($37,500,000.00). Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Borrower shall make four (4) equal quarterly payments of principal of the Tranche A Loan commencing on the first Payment Date that occurs during or immediately after the 17th calendar quarter following the Tranche A Closing Date and continuing through the Term Loan Maturity Date; provided, however, that if any such date is not a Business Day, the applicable principal shall be due and payable on the first Business Day immediately following such date. All unpaid principal with respect to the Tranche A Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date. Interest shall accrue on this Tranche A Note commencing on, and including, the date of this Tranche A Note, and shall accrue on this Tranche A Note, or any portion thereof, for the day on which this Tranche A Note or such portion is paid. Interest on this Tranche A Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche A Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche A Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche A Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche A Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche A Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche A Note are hereby waived.

THIS TRANCHE A NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche A Note shall be registered on a record of ownership maintained by Borrower pursuant to Section 2.8(a) of the Loan Agreement. Notwithstanding anything else in this Tranche A Note to the contrary, the right to the principal of, and stated interest on, this Tranche A Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche A Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche A Note on the part of any other Person.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Tranche A Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

UROGEN PHARMA, INC.,
as Borrower

By: _____

Name: _____

Title: _____

EXHIBIT B-2

AMENDED AND RESTATED SECURED TRANCHE B LOAN PROMISSORY NOTE

$12,500,000.00 Dated: June __, 2023

FOR VALUE RECEIVED, the undersigned, UROGEN PHARMA, INC., a private limited company incorporated under the laws of England and Wales and limited by shares ("**Borrower**"), HEREBY PROMISES TO PAY to [BPCR LIMITED PARTNERSHIP] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of TWELVE MILLION FIVE HUNDRED THOUSAND DOLLARS AND NO CENTS ($12,500,000.00), plus interest on the aggregate unpaid principal amount of this Amended and Restated Secured Tranche B Loan Promissory Note (this "**Tranche B Note**") at a *per annum* rate equal to Adjusted Term SOFR *plus* the Applicable Margin, and in accordance with the terms of the Loan Agreement dated as of March 7, 2022 by and among Borrower, Lender, BioPharma Credit PLC, as Collateral Agent, the other Lenders from time to time party thereto and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date. This Amended and Restated Secured Tranche B Loan Promissory Note amends and restates in its entirety that certain Secured Tranche B Loan Promissory Note, dated December 16, 2022, in the aggregate principal amount of twelve million five hundred thousand dollars and zero cents ($12,500,000.00). Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Borrower shall make four (4) equal quarterly payments of principal of the Tranche B Loan commencing on the first Payment Date that occurs during or immediately after the 17th calendar quarter following the Tranche A Closing Date and continuing through the Term Loan Maturity Date; provided, however, that if any such date is not a Business Day, the applicable principal shall be due and payable on the first Business Day immediately following such date. All unpaid principal with respect to the Tranche B Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date; provided, however, that if such date is not a Business Day, the applicable principal (and any and all other outstanding amounts payable under the Loan Documents) shall be due and payable on the first Business Day immediately following such date.. Interest shall accrue on this Tranche B Note commencing on, and including, the date of this Tranche B Note, and shall accrue on this Tranche B Note, or any portion thereof, for the day on which this Tranche B Note or such portion is paid. Interest on this Tranche B Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche B Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche B Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche B Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche B Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche B Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche B Note are hereby waived.

THIS TRANCHE B NOTE SHALL BE GOVERNED BY, AND CONSTRUED AND INTERPRETED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche B Note shall be registered on a record of ownership maintained by Borrower pursuant to Section 2.8(a) of the Loan Agreement. Notwithstanding anything else in this Tranche B Note to the contrary, the right to the principal of, and stated interest on, this Tranche B Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche B Note (as recorded on such

record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche B Note on the part of any other Person.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Tranche B Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

UROGEN PHARMA, INC.,
as Borrower

By: _____

Name: _____

Title: _____

Exhibit 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 10, 2023

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 10, 2023

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, 2023 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 10, 2023

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, 2023 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 10, 2023

By: /s/ Don Kim

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