UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2020

OR

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

For the transition period from__________ to __________

Commission file number: 001-38079

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

Israel	**98-1460746**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Alexander Park Drive, Princeton, New Jersey	**08540**
(Address of principal executive offices)	**(Zip Code)**

(646) 768-9780

Registrant's telephone number, including area code

N/A

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Ordinary Shares, par value NIS 0.01 per share	URGN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 4, 2020, the registrant had 22,093,054 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”, “we,” “us” and “our” refer to UroGen Pharma Ltd. and its subsidiary, UroGen Pharma, Inc. The Company has registered trademarks for UroGen and Jelmyto. The Company has trademark applications for RTGel and Cystoject. This Quarterly Report on Form 10-Q, or this Quarterly Report, contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such 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 rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

UROGEN PHARMA LTD.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited; in thousands, except share amounts and par value)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 24,565	$ 49,688
Marketable securities	95,058	97,389
Restricted cash	1,224	523
Accounts receivable	2,810	—
Inventory	1,346	—
Prepaid expenses and other current assets	4,335	1,034
Total current assets	129,338	148,634
Non-current assets:		
Property and equipment, net	1,725	977
Restricted deposit	223	223
Right of use asset	2,652	3,735
Marketable securities	5,900	48,555
Other non-current assets	55	264
TOTAL ASSETS	$ 139,893	$ 202,388
Liabilities and Shareholder's equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,492	$ 11,186
Employee related accrued expenses	7,791	6,711
Other current liabilities	1,335	1,585
Total current liabilities:	17,618	19,482
Non-current liabilities:		
Long-term lease liability	1,748	2,604
TOTAL LIABILITIES	19,366	22,086
Commitments and contingencies (Note 14)		
Shareholders' equity:		
Ordinary shares, NIS 0.01 par value; 100,000,000 shares authorized at September 30, 2020 and December 31, 2019; 22,071,432 and 21,026,184 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	60	57
Additional paid-in capital	445,950	407,986
Accumulated deficit	(325,975)	(228,017)
Accumulated other comprehensive income	492	276
TOTAL SHAREHOLDERS' EQUITY	120,527	180,302
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 139,893	$ 202,388

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

UROGEN PHARMA LTD.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited; in thousands, except share and per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	$ 3,461	$ —	$ 3,833	$ 18
Cost of revenues	309	—	357	—
Gross profit	3,152	—	3,476	18
Operating expenses:				
Research and development expenses	10,211	9,481	34,905	29,203
Selling, general and administrative expenses	22,065	13,972	68,056	40,454
Operating loss	(29,124)	(23,453)	(99,485)	(69,639)
Interest and other income, net	308	1,201	1,527	3,466
NET LOSS	$ (28,816)	$ (22,252)	$ (97,958)	$ (66,173)
STATEMENTS OF COMPREHENSIVE LOSS				
Net loss	$ (28,816)	$ (22,252)	$ (97,958)	$ (66,173)
Other comprehensive income				
Unrealized (loss) gain on marketable securities	(268)	22	216	303
COMPREHENSIVE LOSS	$ (29,084)	$ (22,230)	$ (97,742)	$ (65,870)
Net loss per ordinary share basic and diluted	$ (1.31)	$ (1.06)	$ (4.52)	$ (3.25)
Weighted average number of shares outstanding used in computation of basic and diluted loss per ordinary share	22,058,343	20,916,780	21,657,712	20,373,070

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

UROGEN PHARMA LTD.
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(unaudited; in thousands, except share amounts)

	Ordinary Shares		Additional paid-in capital	Accumulated Deficit	Other comprehensive income	Total
	Number of Shares	Amount	Amounts			
BALANCE AS OF JUNE 30, 2020	22,001,296	$ 60	$ 438,999	$ (297,159)	$ 760	$ 142,660
CHANGES DURING THE THREE MONTHS ENDED SEPTEMBER 30, 2020						
Exercise of options into ordinary shares	70,136	—	188			188
Share-based compensation			6,763			6,763
Other comprehensive income					(268)	(268)
Net loss				(28,816)		(28,816)
BALANCE AS OF SEPTEMBER 30, 2020	22,071,432	$ 60	$ 445,950	$ (325,975)	$ 492	$ 120,527
BALANCE AS OF JUNE 30, 2019	20,849,515	$ 57	$ 391,233	$ (166,792)	281	$ 224,779
CHANGES DURING THE THREE MONTHS ENDED SEPTEMBER 30, 2019						
Exercise of options into ordinary shares	94,735	-	1,124			1,124
Share-based compensation			7,243			7,243
Other comprehensive income					22	22
Net loss				(22,252)		(22,252)
BALANCE AS OF SEPTEMBER 30, 2019	20,944,250	$ 57	$ 399,600	$ (189,044)	$ 303	$ 210,916

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

	Ordinary Shares		Additional paid-in capital	Accumulated Deficit	Other comprehensive income	Total
	Number of Shares	Amount	Amounts			
BALANCE AS OF JANUARY 1, 2020	21,026,184	$ 57	$ 407,986	$ (228,017)	$ 276	$ 180,302
CHANGES DURING THE NINE MONTHS ENDED SEPTEMBER 30, 2020						
Exercise of options into ordinary shares	345,248	1	690			691
Share-based compensation			21,499			21,499
Issuance of ordinary shares, net of issuance expenses	700,000	2	15,775			15,777
Other comprehensive income					216	216
Net loss				(97,958)		(97,958)
BALANCE AS OF SEPTEMBER 30, 2020	22,071,432	$ 60	$ 445,950	$ (325,975)	$ 492	$ 120,527
BALANCE AS OF JANUARY 1, 2019	16,214,883	$ 44	$ 212,921	$ (122,871)	$ —	$ 90,094
CHANGES DURING THE NINE MONTHS ENDED SEPTEMBER 30, 2019						
Exercise of options into ordinary shares	522,050	2	3,341			3,343
Share-based compensation			21,902			21,902
Issuance of ordinary shares in public offering, net of issuance expenses	4,207,317	11	161,436			161,447
Other comprehensive income					303	303
Net loss				(66,173)		(66,173)
BALANCE AS OF SEPTEMBER 30, 2019	20,944,250	$ 57	$ 399,600	$ (189,044)	$ 303	$ 210,916

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

UROGEN PHARMA LTD.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW
(unaudited; in thousands)

	Nine Months Ended September 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (97,958)	$ (66,173)
Adjustment to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	295	188
Amortization/Accretion on marketable securities	386	(497)
Stock-based compensation	21,499	21,902
Amortization of right of use asset	1,134	736
Lease liability	(1,157)	(620)
Changes in operating assets and liabilities:		
Inventory	(1,346)	—
Accounts receivable	(2,810)	—
Prepaid expenses and other current assets	(3,261)	(520)
Accounts payable and accrued expenses	(2,506)	(190)
Employee related accrued expenses	1,080	157
Net cash used in operating activities	(84,644)	(45,017)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Change in restricted deposit	—	(4)
Purchase of marketable securities	(29,687)	(168,852)
Maturities of marketable securities	74,503	14,100
Purchases of property and equipment	(1,043)	(133)
Net cash provided by (used in) investing activities	43,773	(154,889)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of options into ordinary shares	651	3,343
Issuance of ordinary shares, net of issuance expenses	15,853	161,662
Issuance cost related to at-the-market issuances	(55)	—
Net cash provided by financing activities	16,449	165,005
DECREASE IN CASH AND CASH EQUIVALENTS	(24,422)	(34,901)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE PERIOD	50,211	101,571
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE PERIOD	$ 25,789	$ 66,670
SUPPLEMENTAL DISCLOSURES OF NON-CASH ACTIVITIES:		
Non-cash new lease liabilities	$ 51	$ —
Exercise of options	$ 40	$ —

The accompanying notes are an integral part of these 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 biopharmaceutical company focused on developing and commercializing novel therapies designed to change the standard of care for urological pathologies. 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, preparing for the commercial launch of our first commercial product, Jelmyto (mitomycin) for pyelocalyceal solution, formerly known as UGN-101, and its product candidate 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 (“LG-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. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information. 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, 2019, as filed with the Securities and Exchange Commission (“SEC”) on March 2, 2020.

The consolidated financial statements include the accounts of UPL and its wholly owned subsidiary UPI. All material intercompany balances and transactions have been eliminated during consolidation.

The Company has experienced net losses since its inception and has an accumulated deficit of $326.0 million and $228.0 million as of September 30, 2020 and December 31, 2019, respectively. The Company expects to incur losses and have negative net cash flows from operating activities as it continues its commercial launch of Jelmyto, and expands its portfolio and engages in further research and development activities, particularly conducting non-clinical studies and clinical trials.

The success of the Company depends on its ability to develop its technologies to the point of FDA approval and subsequent revenue generation and, the Company must raise enough capital to finance these efforts. Based on management’s cash flow projections, the Company believes that its cash and cash equivalents and marketable securities are sufficient to fund the Company’s planned operations for at least the next 12 months. However, in the future, the Company may need to raise additional capital to finance the continued operating and capital requirements of the Company. There can be no assurances that the Company will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs. If the Company cannot obtain adequate working capital, it may be forced to reevaluate its planned business operations.

NOTE 3-SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with 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 revenues and expenses during the reporting period. Actual results may differ from those estimates. As applicable to the unaudited condensed consolidated financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation and measurement of revenue.

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 "finance (income) expenses."

Cash and Cash Equivalents; Marketable Securities

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

Cash and cash equivalents and marketable securities totaled $125.5 million as of September 30, 2020. The Company classifies its marketable securities as available-for-sale in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, "Investments — Debt and Equity Securities". Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported in other comprehensive income/loss within shareholders' equity. Realized gains and losses are recorded as a component of interest and other income (expense), net. The cost of securities sold is based on the specific-identification method.

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

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

Concentration of Credit Risk

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

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

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

Income Taxes

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

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. After concluding that a particular filing position can be recognized (i.e., has a more-likely-than-not chance of being sustained), ASC 740-10-30-7 requires that the amount of benefit recognized be measured using a methodology based on the concept of cumulative probability. Under this methodology, the amount of benefit recorded represents the largest amount of tax benefit that is greater than 50% likely to be realized upon settlement with a taxing authority that has full knowledge of all relevant information. As of September 30, 2020, and December 31, 2019, the Company had not accrued a provision for uncertain tax positions. See Note 14 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

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.

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.

The Company has lease agreements with lease and non-lease components. The Company applied the modified retrospective transition method and elected the transition option to use the effective date of January 1, 2019 as the date of initial application (“Transition Date”).

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.

Revenues

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 revenues recognized include management’s estimate of returns, consideration paid to the customer, chargebacks relating to differences between the wholesale acquisition cost and the contracted price offered to the end consumer, chargebacks relating to 340b drug pricing programs, Medicaid drug rebate programs, and the Company’s copay assistance program, which are estimated based on industry benchmarking studies as well as the Company’s historical experience.

The Company also derives revenues from its license and supply agreement (the “Allergan/AbbVie Agreement”) with Allergan Pharmaceuticals International Limited (“Allergan”), a wholly owned subsidiary of Allergan plc which is now a part of AbbVie Inc. Under the Allergan/AbbVie Agreement, the Company granted Allergan an exclusive license to develop, commercialize, and otherwise exploit products that contain reverse thermal hydrogel (“RTGel”) and agreed to supply Allergan with pre-clinical and clinical quantities of the RTGel product, also referred to as the RTGel vials. The Allergan/AbbVie Agreement contains up-front license fees, future supply fees, development, regulatory, and sales-based milestone payments, and sales-based royalty payments.

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 the 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, executives, finance, commercial, medical affairs, business development, investor relations and human resources functions). 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 Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments, or ASU 2016-13. ASU 2016-13 requires the Company to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the Company’s current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the prior other-than-temporary impairment model.

The Company applied the modified retrospective transition method as of the date of initial application, January 1, 2020, or the Transition Date. As of September 30, 2020, the Company believes the cost basis for its marketable securities were recoverable in all material aspects and no credit impairments were recognized in the period. Similarly, the Company estimates minimal current expected credit losses on trade receivables and has not recognized any allowance for doubtful accounts in the period.

NOTE 4-OTHER FINANCIAL INFORMATION

Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020	December 31, 2019
Accounts payable	$ 4,134	$ 4,694
Accrued clinical expenses	756	399
Accrued research and development costs	1,190	2,644
Accrued selling, general and administrative expenses	1,982	2,767
Accrued other expense	430	682
Total accounts payable and accrued expenses	$ 8,492	$ 11,186

Interest and Other Income (Expenses), Net

Interest and other income (expenses) consisted of the following as of September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,	
	2020	2019
Interest income	$ 1,719	$ 3,610
Other finance expenses	(192)	(144)
Total finance income	$ 1,527	$ 3,466

NOTE 5-INVENTORIES

Inventories consist of the following as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020	December 31, 2019
Raw materials	$ 927	—
Finished goods	419	—
	$ 1,346	$ —

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 other current assets, accounts payable and accrued liabilities are generally considered to be representative of their fair value because of the short-term nature of these instruments. No transfers between levels have occurred during the periods presented.

Assets and liabilities measured at fair value on a recurring basis based on Level 1 and Level 2 fair value measurement criteria as of September 30, 2020 are as follows (in thousands):

	Balance as of September 30, 2020	Fair Value Measurements Using	
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Marketable securities:			
US government	$ 42,551	$ 42,551	$ —
Corporate bonds	37,080	—	37,080
Commercial paper	19,696	—	19,696
Money market funds(1)	3,288	3,288	—
Certificates of deposit	1,631	—	1,631
	$ 104,246	$ 45,839	$ 58,407

(1) Included within cash and cash equivalents on the condensed consolidated balance sheets.

Assets and liabilities measured at fair value on a recurring basis based on Level 1 and Level 2 fair value measurement criteria as of December 31, 2019 are as follows (in thousands):

	Balance as of December 31, 2019	Fair Value Measurements Using	
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)
Marketable securities:			
US government	$ 66,094	$ 66,094	$ —
Corporate bonds	68,084	—	68,084
Commercial paper	7,658	—	7,658
Money market funds(1)	16,998	16,998	—
Certificates of deposit	4,108	—	4,108
	$ 162,942	$ 83,092	$ 79,850

(1) Included within cash and cash equivalents on the condensed consolidated balance sheets.

The Company’s marketable securities are valued based on publicly available quoted market prices for identical securities as of September 30, 2020 and December 31, 2019.

NOTE 7-MARKETABLE SECURITIES

The following table summarizes the Company’s marketable securities as of September 30, 2020 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities:				
US government	$ 42,204	$ 347	$ —	$ 42,551
Corporate bonds	36,939	141	—	37,080
Commercial paper	19,692	4	—	19,696
Money market funds(1)	3,288	—	—	3,288
Certificates of deposit	1,631	—	—	1,631
	$ 103,754	$ 492	$ —	$ 104,246

(1) Included within cash and cash equivalents on the condensed consolidated balance sheets.

The Company classifies its marketable securities as available-for-sale and they consist of all debt securities. The amortized cost basis as of September 30, 2020 includes $0.3 million of accrued interest receivable. As of September 30, 2020, marketable securities were in a net unrealized gain position of $0.5 million. Unrealized gains and losses on available-for-sale debt securities are included as a component of comprehensive loss.

As of September 30, 2020, the Company did not hold any marketable securities in an unrealized loss position. Per the Company's general investment strategy, the Company does not intend to sell the investments before maturity. As of September 30, 2020, the Company believes the cost basis for its marketable securities were recoverable in all material aspects and no credit impairments were recognized in the period.

The Company's marketable securities as of September 30, 2020 mature at various dates through February 2022. The fair values of marketable securities by contractual maturity consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Maturities within one year	$ 98,346	$ 114,386
Maturities after one year through three years	5,900	48,556
	$ 104,246	$ 162,942

NOTE 8-PROPERTY AND EQUIPMENT

Property and equipment, consists of the following as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020	December 31, 2019
Laboratory equipment	$ 331	$ 259
Computer equipment and software	1,256	416
Furniture	597	544
Leasehold improvements	606	530
Manufacturing equipment	226	226
	3,016	1,975
Less: accumulated depreciation and amortization	(1,291)	(998)
Property and equipment, net	$ 1,725	$ 977

Depreciation and amortization expenses were $0.1 million and $0.3 million and $0.1 million and $0.2 million, for the three and nine months ended September 30, 2020 and 2019, respectively.

NOTE 9-LEASES

Operating Leases

The Company has the following office and laboratory facility leases:

- In April 2016, UPL signed an addendum to its November 2014 lease agreement for the Company's executive offices located in Israel, in order to increase the office space rented and to extend the rent period until 2019. In March 2019, UPL utilized the agreement extension option and extended the rent period for additional three years until August 2022.
- In September 2017, UPI entered into a new lease agreement for its office space in New York, which the Company previously used as its headquarters. The lease agreement commenced in October 2017 and terminates in February 2021. The Company's remaining contractual obligation under this lease is approximately $0.3 million as of September 30, 2020.

- 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 $1.0 million as of September 30, 2020. 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 the end of November 2019. The remaining rental payments to be received over the lease term is approximately $0.8 million as of September 30, 2020. The Company accounts for the sublease as on operating lease in accordance with ASC 842-10-25-2 and ASC 842-10-25-3. The main lease was considered for impairment and the amount was determined to be immaterial.
- In November 2019, UPI entered into a new lease agreement for an office in Princeton, NJ, which the Company now uses as its headquarters. The lease commencement date was November 29, 2019 and the lease term is 38 months. The Company's remaining contractual obligation under this lease is approximately $1.3 million as of September 30, 2020.

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 2021 through 2023, with varying renewal and termination options.

The components of lease cost for the three and nine months ended September 30, 2020 were as follows (in thousands):

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Operating lease cost	$ 424	$ 1,282
Sublease income	$ (56)	$ (168)
Variable lease cost	28	114
	$ 396	$ 1,228

The amounts recognized as of September 30, 2020 were as follows (in thousands):

	September 30, 2020
Right of use asset	$ 2,652
Long-term lease liability	1,748
Other current liabilities	1,335

As of September 30, 2020, no impairment losses have been recognized to date.

Supplemental information related to leases for the periods reported is as follows (in thousands):

	Nine Months Ended September 30, 2020
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	1,306
Right-of-use assets obtained in exchange for new operating lease liabilities	135
Weighted-average remaining lease term of operating leases	2.40 years
Weighted-average discount rate of operating leases	5.42%

Subleases

As of September 30, 2020 undiscounted cash flows to be received under the Company's operating sublease on an annual basis was as follows (in thousands):

		Operating Leases
Years ending December 31,		
Remainder of 2020	$	57
2021		235
2022		243
2023		251
2024		49
2025 and thereafter		—
	$	835

Sublease income is recognized net within operating expenses. Sublease income for the three and nine months ended September 30, 2020 was as follows (in thousands):

		Three Months Ended September 30, 2020		Nine Months Ended September 30, 2020
Sublease income from fixed lease payments	$	56	$	168

NOTE 10-REVENUE FROM PRODUCT SALES

Net product sales consist of the following for the three and nine months ended September 30, 2020 (in thousands):

		Three Months Ended September 30, 2020		Nine Months Ended September 30, 2020
Jelmyto	$	3,461	$	3,833

NOTE 11-LICENSE AND COLLABORATION AGREEMENTS

Allergan/AbbVie Agreement

In October 2016, the Company entered into the Allergan/AbbVie Agreement and granted Allergan (now part of AbbVie) an exclusive worldwide license to research, develop, manufacture and commercialize pharmaceutical products that contain RTGel and clostridial toxins (including BOTOX®), alone or in combination with certain other active ingredients, referred to as the Licensed Products, which are approved for the treatment of adults with overactive bladder who cannot use or do not adequately respond to anticholinergics. Additionally, the Company granted Allergan a non-exclusive, worldwide license to use certain of the Company's trademarks as required for Allergan to practice its exclusive license with respect to the Licensed Products.

Under the Allergan/AbbVie Agreement, Allergan is solely responsible for costs and development of the Licensed Products and obtaining all regulatory approvals for Licensed Products worldwide, as well as worldwide commercialization of the Licensed Products after receiving the regulatory approval to do so. Allergan is required to use commercially reasonable efforts to develop and commercialize the Licensed Products for overactive bladder in certain major market countries.

The Company will supply Allergan with certain quantities of RTGel for development of Licensed Products through Phase 2 clinical trials using BOTOX together with RTGel in patients with overactive bladder, at Allergan's request and expense. Allergan has the right to reduce the next milestone payment if there is a material supply failure from the Company. Prior to completion of the first Phase 2 clinical trial, Allergan has the right to request that the Company transfers to Allergan the Company's manufacturing process for RTGel and Allergan will assume the responsibility to manufacture RTGel and Licensed Product for its own development and commercialization activities.

Further, the Company is eligible to receive additional material milestone payments of up to an aggregate of $200.0 million upon the successful completion of certain development, regulatory and commercial milestones. As of September 30, 2020, since inception of the Allergan/AbbVie Agreement the Company has received a total of $25.0 million in milestone payments from Allergan. Allergan will pay the Company a tiered royalty in the low single digits based on worldwide annual net sales of Licensed Products, subject to certain reductions for the market entry of competing products and/or loss of the Company's patent coverage of Licensed Products. The Company is responsible for payments to any third party for certain RTGel-related third-party intellectual properties.

Under the Allergan/AbbVie Agreement, Allergan granted the Company a non-exclusive, sublicensable, fully paid-up, perpetual, worldwide license under any improvements Allergan makes to the composition, formulation, or manufacture of RTGel for the research, development, manufacture and commercialization of any product containing RTGel and any active ingredient (other than a clostridial toxin) for all indications other than indications covered by the agreement and an exclusive, sublicensable, royalty-bearing (in low single digits), perpetual worldwide license under such improvements for use in the prevention or treatment of oncology indications.

In August 2020, the Company announced that the Phase 2 APOLLO trial did not meet the primary endpoint, believed to be the result of BOTOX not effectively permeating the urothelium. UroGen and AbbVie will continue to explore the use of RTGel with AbbVie's portfolio of toxin proteins.

Agenus Agreement

In November 2019, the Company entered into a license agreement with Agenus Inc, pursuant to which Agenus granted to the Company an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary antibody of Agenus known as AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. AGEN1884 is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients and in combination with Agenus' anti-PD-1 antibody in solid tumors. Initially, the Company plans to develop AGEN1884 in combination with UGN-201 for the treatment of high-grade non-muscle invasive bladder cancer.

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

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

As of September 30, 2020, since inception of the Agenus Agreement, the Company has paid a total of $10.0 million in milestone payments, which was recognized in acquired in-process research and development expenses during the three months ended December 31, 2019.

NOTE 12-SHAREHOLDERS' EQUITY

The Company had 100.0 million ordinary shares authorized for issuance as of September 30, 2020 and December 31, 2019, respectively. The Company had 22.1 million and 21.0 million ordinary shares issued and outstanding as of September 30, 2020 and December 31, 2019, 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.

In January 2019, the Company completed an underwritten public offering of 4,207,317 of its ordinary shares, including 548,780 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $41.00 per share. The net proceeds to the Company from the offering were approximately $161.4 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

In December 2019, the Company entered into a sales agreement (the “ATM Sales Agreement”) with Cowen and Company, LLC (“Cowen”), pursuant to which the Company may from time to time offer and sell the Company’s ordinary shares having an aggregate offering price of up to $100.0 million to or through Cowen, acting as sales agent or principal. During the second quarter of 2020, the Company sold 700,000 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $16.6 million. The net proceeds to the Company after deducting sales commissions to Cowen and other issuance expenses were approximately $15.8 million. The remaining capacity under the ATM Sales Agreement is approximately $83.4 million.

NOTE 13-SHARE-BASED COMPENSATION

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

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

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

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

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

In March 2017, the Board adopted the 2017 Equity Incentive Plan (the "2017 Plan"), which was approved by the shareholders in April 2017. The 2017 Plan provides for the grant of incentive stock options to the Company's employees and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, RSU awards, performance share awards, performance cash awards, and other forms of share awards to the Company's employees, directors and consultants.

The maximum number of ordinary shares that may initially be issued under the 2017 Plan is 1,400,000. In addition, the number of ordinary shares reserved for issuance under the 2017 Plan will automatically increase on January 1st of each calendar year, from January 1, 2018 through January 1, 2026, so that the number of such shares reserved for issuance will equal 12% of the total number of ordinary shares outstanding on the last day of the calendar month prior to the date of each automatic increase, or a lesser number of shares determined by the Board. The maximum number of ordinary shares that may be issued upon the exercise of stock options under the 2017 Plan is 5,600,000. On January 1, 2018, the share reserve increased by 250,167 to 1,650,167. On October 12, 2018, the Company increased the amount of registered ordinary shares of the Company’s 2017 Plan by 1,900,000 to 3,550,167. On June 8, 2020 the Company increased the amount of registered ordinary shares of the Company’s 2017 Plan by 400,000 to 3,950,167.

On January 3, 2019, the Company appointed Elizabeth Barrett as its President and Chief Executive Officer. In connection with Ms. Barrett's employment, she was granted 277,432 options to purchase the Company's ordinary shares, at an exercise price of $47.57, as well as 317,065 RSUs, with a combined grant-date fair value of $24.1 million.

In May 2019, the Company adopted the UroGen Pharma Ltd. 2019 Inducement Plan (the "Inducement Plan"). Under the Inducement Plan, the Company is authorized to issue up to 900,000 ordinary shares pursuant to awards issued under the Inducement Plan. The only persons eligible to receive grants of Awards (as defined below) under the Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Marketplace Rule 5635(c)(4) or 5635(c)(3) and the related guidance under Nasdaq IM 5635-1, including individuals who were not previously an employee or director of the Company or are following a bona fide period of non-employment, in each case as an inducement material to such individual's agreement to enter into employment with the Company. Under the Inducement Plan, an "Award" is a nonstatutory stock option, restricted stock unit or other right to receive ordinary shares pursuant to the Inducement Plan.

In June 2019, as part of the Company's Annual Meeting of Shareholders, the Board approved grants of 70,000 options to its non-employee directors. Each then current non-employee director, including the Chairman of the Board, received a grant of 10,000 options. Each option is exercisable into one ordinary share of the Company's stock at an exercise price of $34.83 per share. The options vest quarterly over one year and expire 10 years from grant date. The grant date fair value of these options was approximately $1.9 million.

In December 2019, the Board approved a modification of options and RSU's for a consultant. The Company recorded an expense of $0.9 million under general and administrative expenses with respect to options' modification. No compensation expense was taken in relation to the RSUs modification because the award vests upon a future performance condition that is not currently probable of occurring.

In June 2020, the Board granted an aggregate of 70,000 options to its non-employee directors. Each non-employee director, including the Chairman of the Board, received a grant of 10,000 options. Each option is exercisable into one ordinary share of the Company's stock at an exercise price of $28.24 per share. The options vest quarterly over one year and expire 10 years from the grant date. The grant date fair value of these options was approximately $1.5 million.

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

	For the Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development expenses	$ 1,519	$ 2,069	5,032	6,379
Selling, general and administrative expenses	5,244	5,174	16,467	15,523
	$ 6,763	$ 7,243	$ 21,499	$ 21,902

The total unrecognized compensation cost of options and RSUs at September 30, 2020 is $34.3 million with a weighted average recognition period of 1.67 years.

NOTE 14-INCOME TAXES

UroGen Pharma Ltd. is taxed under Israeli tax laws. As of September 30, 2020, 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 accounting losses for the years ended 2019, 2018 and 2017, and for the nine months ended September 30, 2020. 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.

NOTE 15-RELATED PARTIES

There were no related party transactions for the nine months ended September 30, 2020 or the nine months ended September 30, 2019.

NOTE 16-COMMITMENTS AND CONTINGENCIES

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of September 30, 2020 and December 31, 2019. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Grants from the Israeli Innovation Authority in Israel ("IIA")

The Company has received grants from the IIA for research and development funding. Up until 2007, the IIA participation in the funding of the Company's operations was as part of the Israeli Ministry of Industry and Commerce Director General Directive 8.2 by grants provided to Granot Ventures, a government supported technology incubator. Since 2008, the funding was provided directly to Company.

On January 12, 2020, the IIA Office of Chief Scientist approved the Company's request to unwind its obligation to the IIA regarding grants that were loaned to the Company between January 2004 and September 2016. The total payment under the IIA approval, net of the royalties already paid, $6.6 million, was fully paid during the first quarter of 2020 and recognized as research and development expense. Based on this payment, the Company will have full freedom to transfer IIA-funded technology or manufacture products developed with IIA-funded technology outside of the State of Israel. Other than the commitment to continue at least 75% of its based R&D jobs in Israel (at the time of settlement) for a period of at least three years, all other obligations with the IIA ceased to exist as per the agreement.

Separation Agreement

On September 7, 2020, the Company entered into a Separation Agreement with Peter Pfreundschuh, the Company's Chief Financial Officer, which sets forth the terms of Mr. Pfreundschuh's termination of employment with the Company, effective as of October 15, 2020. The arrangement includes cash severance, a pro rata portion of the target annual bonus for calendar year 2020 contingent on certain performance conditions, and partial acceleration of share-based compensation. The Company recognized $0.7 million during the quarter ended September 30, 2020 in relation to this arrangement.

Leases

See Note 9 for further discussion regarding lease commitments.

NOTE 17-SUBSEQUENT EVENTS

In October 2020, the Company appointed a new Chief Financial Officer and General Counsel. In connection with their employment, they were granted options to purchase the Company's ordinary shares as well as RSUs under the Inducement Plan with a combined grant-date fair value of $2.4 million.

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, 2019 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, 2019 (“Annual Report”), which was filed with the U.S. Securities and Exchange Commission (“SEC”) on March 2, 2020. The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended (“Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended, (“Exchange Act”), which are subject to the “safe harbor” created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, “Risk Factors” in this Quarterly Report. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Overview

We are a biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases. 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 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 (“LG-UTUC”) and low-grade non-muscle invasive bladder cancer (“LG-NMIBC”), respectively.

We estimate that the annual treatable population of LG-UTUC in the United States is approximately 6,000 to 7,000; the annual treatable population of LG-NMIBC is approximately 80,000.

We believe that RTGel-based drug formulations, which provide for the sustained release of an active drug, may improve the efficacy of treatment of various types of urothelial cancer with an acceptable safety profile that permits the natural flow of fluids from the kidney via the urinary tract to the bladder. Our formulations are designed to achieve this by increasing the dwell time in the kidney and bladder to prolong tissue exposure of the active drug. Consequently, we believe that RTGel-based drug formulations may enable us to overcome the anatomical and physiological challenges that have historically contributed to the lack of drug development for the treatment of urothelial cancer and other urological pathologies.

On April 15, 2020, the FDA approved our new drug application (“NDA”) for Jelmyto (mitomycin) for pyelocalyceal solution, formerly known as UGN-101, for the treatment of adult patients with LG-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. We have also obtained new product exclusivity through April 15, 2023 and Orphan Drug exclusivity through April 15, 2027 for Jelmyto.

LG-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 LG-UTUC patients annually. It is a challenging condition to treat due to the complex anatomy of the urinary tract system. The current standard of care includes multiple surgeries, and most require a radical nephroureterectomy, which includes the removal of the renal pelvis, kidney, ureter and bladder cuff. Treatment is further complicated by the fact that LG-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 major surgery.

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

- Complete response ("CR") (primary endpoint) of 58% 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, 19 patients remained in CR of a total of 41 patients, seven had experienced recurrence of disease and nine patients continued to be followed for the 12-month duration of response.
- The most commonly reported adverse events (≥ 20%) were ureteric obstruction, flank pain, urinary tract infection, hematuria, renal dysfunction, fatigue, nausea, abdominal pain, dysuria, and vomiting. Most adverse events were mild to moderate and manageable using well established treatments. No treatment-related deaths occurred.

The FDA evaluated Jelmyto under Priority Review, which is reserved for medicines that may represent significant improvements in safety or efficacy in treating serious conditions. Jelmyto was also granted Breakthrough Therapy designation by the FDA, which was created to expedite the development and review of drugs developed for serious or life-threatening conditions with high unmet need.

In June 2020, we initiated our commercial launch of Jelmyto in the United States. We have staffed, trained and prepared a commercial team comprising a field force of 48 representatives with deep experience in both urology and oncology. The sales representatives are led by seven regional business managers. Each region is supported by a Clinical Nurse Educator 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, we have a team of seven medical science liaisons who have appropriately engaged with physicians interested in learning more about UroGen and our technology, including through virtual meetings.

We are committed to helping patients access Jelmyto. Our market access teams have laid the foundation for coverage and reimbursement, meeting multiple times with payers. In addition to reimbursement and access, we have also been focused on ensuring seamless integration into physician practices. We have implemented processes to help make Jelmyto preparation and administration safe and seamless for practitioners and patients, including entering into an agreement with a major national pharmacy under which the pharmacy, following receipt of a patient prescription, will prepare and dispense the Jelmyto admixture on our behalf.

In addition, we are evaluating the safety and efficacy of UGN-102, our novel sustained-release high dose formulation of mitomycin, for the treatment of LG-NMIBC.

We have shared interim data from the Phase 2b OPTIMA II trial for UGN-102 in patients with low-grade, intermediate risk non-muscle invasive bladder cancer, defined as those with one or two of the following criteria: multifocal disease, large tumors and rapid rates of recurrence. The single-arm, open label study trial completed enrollment of 63 patients at clinical sites across the United States and Israel. Patients are treated with six weekly instillations of UGN-102 and undergo assessment of complete response, or CR (the primary endpoint) four to six weeks following the last instillation. These data were also published as a supplement to the April 2020 issue of The Journal of Urology.

In August 2020, we reported additional interim data consistent with our previous reports showing that 65%, or 41 out of 63 patients, treated with UGN-102 achieved a complete response three months after the start of therapy. In this subset of patients, the interim Kaplan-Meier ("KM") analysis shows a 72.4% estimated duration of response at 12 months after initiation of therapy. The most common adverse events, greater than 10%, were reported as mild to moderate and include dysuria, hematuria, urinary frequency, fatigue, urgency and urinary tract infection.

We believe that UGN-102 has the potential to be a new therapeutic option for the treatment of LG Intermediate Risk NMIBC patients. We have finalized the protocol for the Phase 3 pivotal study and expect to begin the study by the end of 2020.

We believe that urothelial cancer, which is comprised of bladder cancer and UTUC, affects a large and underserved patient population. Annual expenditures for Medicare alone in the United States for the treatment of urothelial cancer were estimated to have been at least $4.0 billion in 2010 and are projected to be at least $5.0 billion in 2020. The majority of the expenditures are spent on tumor resection surgeries such as transurethral resection of bladder tumor, or TURBT. In 2017, the estimated prevalence of urothelial cancer in the United States was 748,000 and in 2020 the annual incidence of urothelial cancer was approximately 85,000. The prevalence in 2017 of each of LG-NMIBC and LG-UTUC in the United States was approximately 340,000 and 14,000, respectively.

Our clinical stage pipeline also includes UGN-201 (imiquimod), our proprietary formulation of an immunotherapy product candidate. UGN-201 is a novel, liquid formulation of imiquimod, a generic toll-like receptor 7, or TLR 7, agonist, which has been evaluated for the treatment of high-grade NMIBC, which may include carcinoma in situ, or CIS. Toll-like receptor agonists play a key role in initiating the innate immune response system. We believe that the combination of UGN-201 with additional immunotherapy drugs, such as immune checkpoint inhibitors could represent a valid alternative to the current standard of care for the post-TURBT adjuvant treatment of high-grade NMIBC. In the fourth quarter of 2019, we entered into a worldwide license agreement with Agenus Inc. to develop and commercialize zalifrelimab (AGEN1884) via intravesical delivery in combination with UGN-201 (together UGN-302) for the treatment of urinary tract cancers, initially in high-grade non-muscle invasive bladder cancer (HG NMIBC). The combination treatment makes local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effects.

Our Research and Development and License Agreements

In October 2016, the Company entered into the Allergan/AbbVie Agreement and granted Allergan an exclusive worldwide license to research, develop, manufacture and commercialize pharmaceutical products that contain RTGel and clostridial toxins including BOTOX. The license grants the exclusivity for the RTGel and clostridial toxins including BOTOX alone or in combination with certain other active ingredients, referred to as the Licensed Products, which are approved for the treatment of adults with overactive bladder who cannot use or do not adequately respond to anticholinergics. Additionally, the Company granted Allergan a non-exclusive, worldwide license to use certain of the Company's trademarks as required for Allergan to practice its exclusive license with respect to the Licensed Products.

Under the Allergan/AbbVie Agreement, Allergan is solely responsible, at its expense, for developing, obtaining regulatory approvals for and commercializing, on a worldwide basis, pharmaceutical products that contain RTGel and clostridial toxins (including BOTOX), alone or in combination with certain other active ingredients (collectively, the "Licensed Products"). Allergan is obligated to pay us a tiered royalty in the low single digits based on worldwide annual net sales of Licensed Products, subject to certain reductions for the market entry of competing products and/or loss of our patent coverage of Licensed Products. We are responsible for payments to any third party for certain RTGel-related third-party intellectual properties.

In August 2017, we announced that Allergan had submitted an IND to the FDA in order to be able to commence clinical trials in the United States using an RTGel formulation in combination with BOTOX. In October 2017, Allergan commenced a Phase 2 clinical trial of BOTOX/RTGel for the treatment of OAB, with the potential to evolve from multiple injections of BOTOX into the bladder to a single instillation of the novel formulation. In August 2020, the Company announced that the Phase 2 APOLLO clinical trial of a RTGel hydrogel formulation in combination with BOTOX intravesical instillation did not meet the primary endpoint, believed to be the result of BOTOX not effectively permeating the urothelium. UroGen and AbbVie will continue to explore the use of RTGel with AbbVie's portfolio of toxin proteins.

In November 2019, we entered into a license agreement with the Agenus Inc. ("Agenus"). Pursuant to the agreement, Agenus granted us an exclusive, worldwide license (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary antibody of Agenus known as zalifrelimab for the treatment of cancers of the urinary tract via intravesical delivery. Zalifrelimab is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients, and in combination with Agenus' anti-PD-1 antibody (AGEN2034) in solid tumors. UGN-301 is a formulation of RTGel and zalifrelimab that is in early stage development for high grade non-muscle invasive bladder cancer ("HG NMIBC").

Based on nonclinical studies conducted by us, UGN-201 in combination with anti-CTLA-4 antagonists have shown encouraging results for the potential treatment of HG NMIBC. We intend to continue research and development work in HG NMIBC.

Under the terms of the agreement, we paid Agenus an upfront fee of $10.0 million and have agreed to pay Agenus up to $115.0 million upon achieving certain clinical development and regulatory milestones, up to $85.0 million upon achieving certain commercial milestones, and royalties on net sales of licensed products in the 14%-20% range. We are solely responsible for costs and development, obtaining all regulatory approvals, and commercialization of the licensed products after receiving the regulatory approval to do so.

For additional information regarding our research and development license and collaboration agreements, see Note 11 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

Impact of COVID-19 Pandemic

In the event of a prolonged disruption related to COVID-19, there could be detrimental impact to our ongoing and future clinical trials, our ongoing commercial launch and future commercialization activities for Jelmyto, and our ability to access capital markets. See Item 1A. Risk Factors below for further discussion.

Components of Operating Results

Revenues

During the three and nine months ended September 30, 2020 we recognized $3.5 million and $3.8 million, respectively, of revenues from sales of our product, Jelmyto. We did not recognize any revenues from RTGel sales under the Allergan/AbbVie Agreement during the three and nine months ended September 30, 2020. During the three and nine months ended September 30, 2019, the Company recognized $18,000 of revenue related to RTGel supplied to Allergan. In the future, we may generate revenue from a combination of product sales, reimbursements, up-front payments, milestone payments and royalties in connection with the Allergan/AbbVie Agreement and future collaborations. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, milestone and other payments, and the amount and timing of payments that we receive upon the sale of our products. If we fail to achieve clinical success and/or to obtain regulatory approval of future product candidates in a timely manner, our ability to generate future revenue will be limited.

Cost of Revenues

Cost of revenues consist primarily of inventory and related costs associated with the manufacturing, distribution, warehousing and preparation of Jelmyto. In periods prior to receiving FDA approval for Jelmyto, we recognized inventory and related costs associated with the manufacture of Jelmyto as research and development expenses.

Research and Development Expenses

Research and development expenses, net consist primarily of:

- salaries and related costs, including share-based compensation expense, for our personnel in research and development functions;
- expenses incurred under agreements with third parties, including clinical research organizations (“CROs”), subcontractors, suppliers and consultants, nonclinical studies and clinical trials;
- expenses incurred to acquire, develop and manufacture nonclinical study and clinical trial materials;
- expenses incurred to purchase active pharmaceutical ingredient (“API”) 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. Since our employees and internal resources may be engaged in projects for multiple programs at any time, our focus is on total research and development expenditures, and we do not allocate our internal research and development expenses by project.

We estimate nonclinical study and clinical trial expenses 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 expenses incurred by them.

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

We have received grants under the Israeli Law for the Encouragement of Industrial Research, Development and Technological Innovation, 5754-1984 (the “R&D Law”), from the Israel Innovation Authority in Israel (the “IIA”), formerly known as the Office of the Chief Scientist of the Ministry of Economy and Industry, an independent and impartial public entity, for some of our development programs. As of September 30, 2020, we had received grants in the aggregate amount of $2.1 million.

On January 12, 2020, the IIA Office of Chief Scientist approved the Company’s request to unwind its obligation to the IIA regarding grants that were loaned to the Company between January 2004 and September 2016. The total payment under the IIA approval, net of the royalties already paid, amounts to $6.6 million, which was fully paid during the first quarter of 2020. See Note 16 to the Consolidated Financial Statements included in this report for additional information.

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

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

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

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- delays or operational challenges resulting from the ongoing COVID-19 pandemic;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidates.

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

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

License fees and development milestone payments related to in-licensed products and technology are expensed as incurred if it is determined at that point that they have no established alternative future use. We recorded $10.0 million in research and development expenses for the year ended December 31, 2019, comprised of a milestone related to our license agreement with Agenus Inc.

The license agreement provides us with an exclusive worldwide, royalty bearing, and sub-licensable license under Agenus’s intellectual property rights to exploit licensed products incorporating zalifrelimab for the treatment of cancers of the urinary tract via intravesical delivery. It also provides us with preclinical and clinical supply of zalifrelimab. No inventory was purchased on the effective date of the License Agreement and subsequent purchases of preclinical and clinical supplies are at arm’s length and are priced at cost plus 30% mark-up. Our acquired right to Agenus’s intellectual property represents a single identifiable asset sourced from the agreement. Therefore, all the fair value associated with the agreement is concentrated in one identifiable asset and is not considered a business in accordance with ASC 805-10-55-5A. Therefore, we have accounted for the right to Agenus’s intellectual property acquired under the license agreement as an asset acquisition of in-process research and development. See Note 11 to the Consolidated Financial Statements for further information.

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 initial commercialization activities related to Jelmyto, formerly known as UGN-101. We anticipate that our selling and marketing expenses will increase during the remainder of 2020 as a result of the FDA's approval of Jelmyto in April 2020 and our commercial launch of Jelmyto in June 2020.

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.

We anticipate that our general and administrative expenses will increase in the future as we increase our administrative headcount and infrastructure to support the potential approval and commercialization of our product candidates and our continued research and development programs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses.

Interest and Other Income (Expenses), Net

Interest and other income (expenses), net, consisted primarily of interest income.

Income Taxes

We have yet to generate taxable income in Israel. We have historically incurred operating losses resulting in carry forward tax losses totaling approximately $151.9 million as of December 31, 2019. 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.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of our unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the revenues and expenses incurred during the reported periods. We base our estimates on historical experience and on various other factors that we believe are relevant under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity in *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 as filed with the SEC on March 2, 2020 ("Annual Report") as well as in the Note 3 to the Consolidated Financial Statements included in this report.

Results of Operations

Comparison of the three months ended September 30, 2020 and 2019

The following table sets forth our results of operations for the three months ended September 30, 2020 and 2019.

	Three Months Ended September 30,		
	2020	2019	Change
		(in thousands)	
Revenues	$ 3,461	$ —	$ 3,461
Cost of revenues	309	—	309
Gross profit	3,152	—	3,152
Operating expenses:			
Research and development	10,211	9,481	730
Selling and marketing	10,992	3,926	7,066
General and administrative	11,073	10,046	1,027
Total operating expenses	32,276	23,453	8,823
Operating loss	(29,124)	(23,453)	(5,671)
Interest and other income, net	308	1,201	(893)
Net loss	$ (28,816)	$ (22,252)	$ (6,564)

Revenues

Revenues were $3.5 million and $0 for the three months ended September 30, 2020 and 2019, respectively. The increase in revenues of $3.5 million reflects sales of our product Jelmyto following its approval by the FDA in April 2020.

Cost of Revenues

Cost of revenues were $0.3 million and $0 for the three months ended September 30, 2020 and 2019, 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. We expect this to continue to impact cost of revenues through the first quarter of 2022 as we produce Jelmyto at costs reflecting the full costs of manufacturing and as we deplete inventories that we had expensed prior to receiving FDA approval. Gross margin would have been approximately 86.7% versus 91.1% for the three months ended September 30, 2020 if we had not sold Jelmyto units that were expensed prior to regulatory approval.

Research and Development Expenses

Research and development (R&D) expenses were $10.2 million and $9.5 million for the three months ended September 30, 2020 and 2019, respectively. The increase of $0.7 million is primarily attributable to increased expenses related to the UGN-102 clinical trial and UGN-201 studies, partially offset by the completion of the Phase 3 clinical trial and regulatory activity for UGN-101 (now marketed as Jelmyto).

Selling and Marketing Expenses

Selling and marketing expenses were $11.0 million and $3.9 million for the three months ended September 30, 2020 and 2019, respectively. The increase in selling and marketing expenses of $7.1 million resulted from increased costs and activities related to the commercial launch of Jelmyto in June 2020 including headcount and related costs associated with our sales force.

General and Administrative Expenses

General and administrative expenses were $11.1 million and $10.0 million for the three months ended September 30, 2020 and 2019, respectively. The increase in general and administrative expenses of $1.1 million resulted primarily from an increase in costs as part of the buildout of the Company for the commercialization of our first product, in addition to consulting and other service provider fees.

Interest and Other Income (Expenses), Net

Interest and other income (expenses), net, was $0.3 million and $1.2 million for the three months ended September 30, 2020 and 2019, respectively. The decrease of $0.9 million in interest and other income was primarily due to a decrease in our cash and cash equivalents and marketable securities.

Comparison of the nine months ended September 30, 2020 and 2019

The following table sets forth our results of operations for the nine months ended September 30, 2020 and 2019.

	Nine Months Ended September 30,		
	2020	2019	Change
		(in thousands)	
Revenues	$ 3,833	$ 18	$ 3,815
Cost of revenues	357	—	357
Gross profit	3,476	18	3,458
Operating expenses:			
Research and development	34,905	29,203	5,702
Selling and marketing	34,398	9,701	24,697
General and administrative	33,658	30,753	2,905
Total operating expenses	102,961	69,657	33,304
Operating loss	(99,485)	(69,639)	(29,846)
Interest and other income, net	1,527	3,466	(1,939)
Net loss	$ (97,958)	$ (66,173)	$ (31,785)

Revenues

Revenues were $3.8 million and $18,000 for the nine months ended September 30, 2020 and 2019, respectively. The increase in revenues of $3.8 million reflects sales of Jelmyto following its approval by the FDA in April 2020.

Cost of Revenues

Cost of revenues were $0.4 million and $0 for the nine months ended September 30, 2020 and 2019, respectively, including certain one-time start-up costs. 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. We expect this to continue to impact cost of revenues through the first quarter of 2022 as we produce Jelmyto at costs reflecting the full costs of manufacturing and as we deplete inventories that we had expensed prior to receiving FDA approval. Gross margin would have been approximately 86.3% versus 90.7% for the nine months ended September 30, 2020 if we had not sold Jelmyto units that were expensed prior to regulatory approval.

Research and Development Expenses

Research and development expenses were $34.9 million and $29.2 million for the nine months ended September 30, 2020 and 2019, respectively. The increase of $5.7 million resulted primarily from a one-time payment of $6.6 million to unwind the Company's obligation to the Israeli Innovation Authority during the first quarter of 2020 and increased expenses related to the UGN-102 clinical trial and UGN-201 studies, partially offset by the completion of the Phase 3 clinical trial and regulatory activity for UGN-101.

Selling and Marketing Expenses

Selling and marketing expenses were $34.4 million and $9.7 million for the nine months ended September 30, 2020 and 2019, respectively. The increase of $24.7 million resulted primarily from increased costs and activities related to the commercial launch of Jelmyto in June 2020, including headcount and related costs associated with our sales force.

General and Administrative Expenses

General and administrative expenses were $33.7 million and $30.8 million for the nine months ended September 30, 2020 and 2019, respectively. The increase of $2.9 million resulted primarily from an increase in costs as part of the buildout of the Company for the commercialization of our first product and consulting and other service provider fees.

Interest and Other Income (Expenses), Net

Interest and other income (expenses), net, were $1.5 million and $3.5 million for the nine months ended September 30, 2020 and 2019, respectively. The decrease of $2.0 million in interest and other income was primarily due to a decrease in our cash and cash equivalents and marketable securities.

Liquidity and Capital Resources

As of September 30, 2020, we had $125.5 million in cash and cash equivalents and marketable securities. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation, and is held primarily in U.S. dollars. Based on our cash flow projections, we believe that our current cash and cash equivalents and marketable securities are sufficient to fund our planned operations for at least the next 12 months.

Through September 30, 2020, we funded our operations primarily through public equity offerings, private placements of equity securities and through the upfront payment received under the Allergan/AbbVie Agreement.

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

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

We have incurred losses since our inception and negative cash flows from our operations, and as of September 30, 2020 we had an accumulated deficit of $326.0 million. We anticipate that we will continue to incur losses for at least the next several years. Our primary uses of capital are, and we expect will continue to be, commercialization activities, research and development expenses, including third-party clinical research and development services, laboratory and related supplies, clinical costs, including manufacturing costs, legal and other regulatory expenses and general and administrative costs.

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

Cash Flows

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

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (84,644)	$ (45,017)
Investing activities	43,773	(154,889)
Financing activities	16,449	165,005
Net change in cash and cash equivalents	$ (24,422)	$ (34,901)

Operating Activities

Net cash used in operating activities was $84.6 million during the nine months ended September 30, 2020, compared to $45.0 million during the nine months ended September 30, 2019. The $39.6 million increase was attributable primarily to the increase of $31.8 million in the net loss, which is inclusive of the $6.6 million payment to the IIA. See Note 16 to the Condensed Consolidated Financial Statements included in this report for additional information.

Investing Activities

Net cash provided by investing activities was $43.8 million during the nine months ended September 30, 2020, compared to $154.9 million used in investing activities during the nine months ended September 30, 2019. The increase of $198.7 million is primarily related to maturities of our marketable securities, as well as a significant reduction in purchases of marketable securities.

Financing Activities

Net cash provided by financing activities was $16.4 million during the nine months ended September 30, 2020, compared to $165.0 million during the nine months ended September 30, 2019. The decrease of $148.6 million is primarily related to the net proceeds received from our January 2019 underwritten public offering of our ordinary shares as compared to proceeds from the issuance under the ATM Sales Agreement during the nine months ended September 30, 2020.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Fluctuation Risk

Some of the securities in which we invest have market risk in that a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents and marketable securities. As of September 30, 2020 we had $125.5 million of cash and cash equivalents and marketable securities. We invest our cash primarily in money market accounts, but also invest in commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. If a 10% change in interest rates were to have occurred on September 30, 2020, this change would not have had a material effect on the fair value of our cash and cash equivalents and marketable securities as of that date.

Inflation Risk

Inflation generally may affect us by increasing our cost of labor and clinical trial costs. Inflation has not had a material effect on our business, financial condition or results of operations during the three and nine months ended September 30, 2020 and 2019.

Foreign Currency Exchange Risk

The U.S. dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in NIS. As a result, we are exposed to the risk that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation, if any, of the NIS against the dollar. For example, although the dollar appreciated against the NIS in 2018 by 8.1%, the dollar depreciated against the NIS in 2019 by 7.8%. If the dollar cost of our operations in Israel increases, our dollar-measured results of operations will be adversely affected. Our operations also could be adversely affected if we are unable to effectively hedge against currency fluctuations in the future.

We do not currently engage in currency hedging activities in order to reduce this currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive and financial officers (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosures controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2020, 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

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes 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 September 30, 2020 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 principal factors that make an investment in our ordinary shares speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “Risk Factors” and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our ordinary shares.

- We are highly dependent on the successful commercialization of our only approved product, Jelmyto.
- We have limited experience as an organization in marketing and distributing products and are therefore subject to certain risks in relation to the commercialization of Jelmyto and any of our other product candidates that receives regulatory approval.
- The market opportunities for Jelmyto and our product candidates may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed and may be small.
- Jelmyto and any our product candidates that receives regulatory approval may fail to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success.
- Jelmyto and our product candidates, if approved, will face significant competition with competing technologies and our failure to compete effectively may prevent us from achieving significant market penetration.
- In addition to Jelmyto, we are dependent on the success of our lead product candidate, UGN-102, and our other product candidates, including obtaining regulatory approval to market our product candidates in the United States.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.
- We have entered into a licensing agreement and in the future may enter into collaborations with other third parties for the development or commercialization of our product candidates. If our collaborations 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 and UGN-201 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. There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers and with 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 or UGN-201 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 scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize any of the products we develop.
- Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic.

- We have a limited operating history and have incurred significant losses and negative cash flows since our inception, and we anticipate that we will continue to incur significant losses and negative cash flows for the foreseeable future, which makes it difficult to assess our future viability.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this capital when needed and on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, commercialization efforts or other operations.
- If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our product candidates and technologies are not adequate, we may not be able to compete effectively, and we otherwise may be harmed.
- If the FDA does not conclude that UGN-102 satisfies the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act, or Section 505(b)(2), or if the requirements for such product candidates are not as we expect, the approval pathway for these product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.
- Jelmyto and any of product candidates that receives 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 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 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, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risk factors set forth below that are marked with an asterisk (*) 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 Business and Strategy

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

Other than Jelmyto, which we commercially launched in the United States in June 2020, we have not commercialized any product candidates to date. 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 have only recently initiated our commercial launch of Jelmyto, and prior to that, we have 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 candidate in the future that receives 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 train physicians and nurses for 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 LG-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 LG-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 LG-UTUC is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to be treated with Jelmyto due to label warnings, adverse events associated with product administration or other reasons, the commercial potential of Jelmyto will be limited. At this time, we have only limited information regarding how physicians, patients and payors will respond to the pricing of Jelmyto. Physicians may not prescribe Jelmyto and patients may be unwilling to be treated with Jelmyto if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Jelmyto in our post-marketing commitments, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Jelmyto. Thus, significant uncertainty remains regarding the commercial potential of Jelmyto.

In addition, our ongoing commercial launch of Jelmyto and subsequent commercialization efforts could be hindered by the COVID-19 pandemic, although we are currently not able to predict or quantify any such potential impact with any degree of certainty.

If the launch or commercialization of Jelmyto is unsuccessful or perceived as disappointing, our stock 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 LG-UTUC. While the FDA granted approval of Jelmyto based on the data included in the NDA, including data from the OLYMPUS clinical trial, we do not know whether the results when a large number of patients and broader populations are exposed to Jelmyto, including results related to safety and efficacy, will be consistent with the results from earlier clinical studies of Jelmyto that served as the basis for the approval of Jelmyto. New data relating to Jelmyto, including from 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 other product candidates that receives regulatory approval.*

Our strategy is to build and maintain a fully integrated biopharmaceutical company to successfully execute the commercial launch 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 for prescription in the United States in June 2020. While we have established a commercial management team and have also established a field-based organization comprised of approximately 70 individuals, including a sales team, reimbursement support team, clinical nurse educators, national account managers and a medical liaisons, we only recently commenced the commercial launch of Jelmyto in the United States and currently have very limited experience commercializing pharmaceutical products as an organization. In order to successfully commercialize Jelmyto, we must continue to develop our sales, marketing, managerial, compliance and related capabilities or make arrangements with third parties to perform these services. This involves many challenges, such as recruiting and retaining talented personnel, training employees, setting the appropriate system of incentives, managing additional headcount and integrating new business units into an existing corporate infrastructure. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully further develop these capabilities. Additionally, we will need to maintain and further develop our sales force, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to effectively develop and maintain our commercial team, including our sales force, our ability to effectively commercialize Jelmyto would be limited, and we would not be able to generate product revenues successfully. If we fail to establish and maintain an effective sales and marketing infrastructure, we will be unable to successfully commercialize our product candidates, which in turn would have an adverse effect on our business, financial condition and results of operations.

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

Jelmyto is a newly-marketed drug and, therefore, none of the members of our sales force had ever promoted Jelmyto prior to its launch. In addition, Jelmyto is the first drug approved by the FDA for the treatment of LG-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 LG-UTUC to physicians and nurses. In addition, we must train our sales force to ensure that a consistent and appropriate message about Jelmyto is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of Jelmyto and its proper administration, our efforts to successfully commercialize Jelmyto could be put in jeopardy, which would negatively impact our ability to generate product revenues.

Additionally, our work-at-home policy due to COVID-19 includes our sales representatives, who would normally conduct in-person office visits with healthcare providers. Although we have developed digital materials and programs for our sales force to use in order to continue to engage virtually with their target physicians, there can be no assurance that these new tools and approaches will be effective at 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 LG-UTUC;
- if pharmacies are closed or suffering supply chain disruptions;
- if patients lose access to employer-sponsored health insurance due to period 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 and reimbursed.

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

Cancer therapies are sometimes characterized as first-line, second-line or third-line. When cancer is detected early enough, first-line therapy, often chemotherapy, hormone therapy, surgery, radiotherapy or a combination of these, is sometimes adequate to cure the cancer or prolong life. Second- and third-line therapies are administered to patients when prior therapy is not or is no longer effective. For urothelial cancers, the current first-line standard of care is surgery designed to remove one or more tumors. Chemotherapy is currently used in treating urothelial cancer only as an adjuvant, or supplemental therapy, after tumor resection. We are designing our lead product candidates with the goal of replacing surgery as the standard of care for certain urothelial cancers. However, there is no guarantee that our product candidates, if approved, would be approved for first-line or even later lines of therapy, and, that prior to any such approvals, we will not have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers who have previously failed prior treatments, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or third-party market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, our pivotal Phase 3 OLYMPUS clinical trial for Jelmyto was designed to evaluate the use of Jelmyto for the treatment of tumors in the renal pelvis (the funnel-like dilated part of the ureter in the kidney) and was not designed to evaluate the use of Jelmyto for the treatment of tumors in the ureter (the tube that connects the kidneys to the bladder). Even though Jelmyto is approved for the treatment of LG-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, LG-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 LG-UTUC. If our estimates of the incidence and prevalence of LG-UTUC are incorrect, Jelmyto's commercial viability may prove to be limited, which may negatively affect our financial results.

Jelmyto and any our product candidates that receives 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 candidate that receives 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 LG-

UTUC, and in the case of UGN-102, for the treatment of LG intermediate risk NMIBC, and for other therapeutic indications that we may seek to pursue with any of our product candidates. Physicians treating LG-UTUC and LG 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 risk/reward 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 LG-UTUC with Jelmyto and the treatment of LG 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 training 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 revenues and profitability that our products will offer physicians as compared to alternative therapies; and
- the effectiveness of our sales and marketing efforts, especially the success of any targeted marketing efforts directed toward physicians and clinics and any direct-to-consumer marketing efforts we may initiate.

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

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

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

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

We are aware of several pharmaceutical companies that are developing drugs in the fields of urology and uro-oncology, such as Roche, Vyriad, GSK, Celgene, Lipac Oncology, Samyang biopharma, Merck Sharp & Dohme Corp., Eleven biotherapeutics, Viralytics Limited, AADi, LLC, Biocancell Ltd., Altor BioScience Corporation, FKD Therapies Oy and Spectrum Pharmaceuticals, Inc. We do not know whether these potential competitors are already developing, or plan to develop, LG-UTUC or high-grade UTUC treatments or other indications that we are pursuing.

We are also aware that other companies, such as Taris and Lipac are conducting, or have recently conducted clinical trials for product candidates for the treatment of LG intermediate risk NMIBC, including carcinoma in situ, or CIS. 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 on an exclusive basis, 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, including transurethral resection of bladder tumor, or TURBT, surgery for bladder cancer. 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, which is first-line tumor surgical procedures. Generic mitomycin injectable drug products, while approved by FDA for gastric and pancreatic cancers, are neither approved for LG-UTUC nor reconstituted with hydrogel as Jelmyto is, although they may be used off-label by physicians for the treatment of LG-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 upper tract urothelial cancer. We are currently developing UGN-102 and UGN-201 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 other product candidate that receives 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 not 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 currently only three drugs that have been approved by the FDA for NMIBC, with the last approval having occurred over 15 years ago. 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, or 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 Investigational New Drug applications, or INDs, for our product candidates. Without such IND acceptances, we will be unable to commence clinical trials in the United States;
- the FDA's acceptance of the number, design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from nonclinical studies or clinical trials;
- the FDA's acceptance of the population studied in our clinical trials being sufficiently large, broad and representative to assess efficacy and safety in the patient population for which we seek approval;
- our ability to successfully complete the clinical trials of our product candidates, including timely patient enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of the product candidates undergoing such clinical trials;
- our ability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's need to schedule an advisory committee meeting, and to conduct such meeting, in a timely manner to evaluate and decide on the approval of our potential future NDA for UGN-102;
- if applicable, the recommendation of the FDA's advisory committee to approve our applications to market UGN-102 and our other product candidates in the United States, without limiting the approved labeling, specifications, distribution or use of the products, or imposing other restrictions;
- the FDA's determination of safety and efficacy of our product candidates;
- the FDA's determination that the 505(b)(2) regulatory pathway is available for our product candidates;
- the prevalence and severity of adverse events associated with our product candidates, including UGN-102, as there are no drugs and related drug administration procedures approved for low-grade non-muscle invasive bladder cancer, 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, administration and use of our product candidates, if approved, particularly in light of the fact that there are currently no drugs approved by the FDA for the treatment of upper tract urothelial carcinoma, or UTUC, and the FDA has not approved a drug for the treatment of non-muscle invasive bladder cancer, or NMIBC, in more than 15 years;
- 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 current good manufacturing practices, or cGMP;
- the FDA's acceptance of the manufacturing processes or facilities of third-party manufacturers with which we contract;
- our ability to secure supply of the raw materials from TAPI (Teva Active Pharmaceutical Ingredients) or other suppliers for our product candidates to support clinical trials and commercial use;
- our ability to obtain, protect and enforce our intellectual property rights with respect to our product candidates; and
- our ability to properly train physicians or nurses for the skillful preparation and administration of any of our product candidates that receive approval, including UGN-102, and our ability to develop a broad experiential knowledge base of aggregated clinician feedback from which we can refine appropriate procedures for product administration, without which there could be a risk of adverse events.

Many of these clinical, regulatory and commercial risks are beyond our control. Further, these risks and uncertainties impact all of our clinical programs that we pursue and have been amplified by the recent COVID-19 pandemic, as described below. Accordingly, we cannot assure you that we will be able to advance any of our product candidates through clinical development, or to obtain 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 successful commercialize any of them.

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

Positive results in nonclinical testing and early clinical trials do not ensure that later clinical trials will be successful. A number of pharmaceutical companies have suffered significant setbacks in clinical trials, including in Phase 3 clinical trials, after promising results in nonclinical testing and early clinical trials. These setbacks have included negative safety and efficacy observations in later clinical trials, including previously unreported adverse effects. To date, our clinical trials and other programs have involved small patient populations and because of the small sample size, the results of these clinical trials may be subject to substantial variability and may not be indicative of future results. We have finalized the protocol for our pivotal Phase 3 protocol for UGN-102, and expect to begin the study by the end of 2020. If our clinical trials do not ultimately indicate that our product candidates are safe and effective for their intended use, the FDA may not approve any NDA that we may submit to market such product candidates, and our business would not be able to generate revenue from the sale of any such product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

These risks and uncertainties impact all of our nonclinical programs that we pursue and have been amplified by the recent COVID-19 pandemic, as described below. If we are unsuccessful in advancing our nonclinical product candidates into clinical trials in a timely fashion, our business may be harmed. Even if we are successful in advancing our nonclinical product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this report and our other filings with the SEC. Accordingly, we cannot assure you that we will be able to develop, obtain regulatory approval for, commercialize or generate significant revenue from our product candidates.

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

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

- generate sufficient nonclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval or feedback on trial design, in order to commence a trial;
- identify, recruit and train suitable clinical investigators;

- reach agreement on acceptable terms with prospective 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, or IRB, approval at each clinical trial site;
- identify, recruit and 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, completed Compassionate Use Program for Jelmyto and clinical trials, we have observed several adverse events and serious adverse events, 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 as well as ureteral stricture and stenosis. 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 serious adverse events in the future or that the FDA will not determine them as such. Side effects such as toxicity or other safety issues associated with the use of Jelmyto or our product candidates could require us to perform additional studies or halt development or sale of Jelmyto or our product candidates or expose us to product liability lawsuits, which will harm our business.

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

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

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

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

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

We may continue to face future developmental and regulatory difficulties related to Jelmyto and any other 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 postmarketing 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 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 LG-UTUC, and we plan to devote a substantial portion of our resources to the continued clinical testing and potential approval UGN-102 for the treatment of LG 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 a licensing agreement and in the future may enter into collaborations with other third parties for the development or commercialization of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.*

In October 2016, we entered into the Allergan/AbbVie Agreement. Under the Allergan/AbbVie Agreement, we granted Allergan an exclusive worldwide license to research, develop, manufacture and commercialize pharmaceutical products that contain a proprietary RTGel formulation and clostridial toxins (including BOTOX), alone or in combination with certain other active ingredients, which we refer to collectively as the Licensed Products. Either party may terminate the Allergan/AbbVie Agreement for uncured material breach by the other party and for the insolvency of the other party. We may terminate the Allergan/AbbVie Agreement if Allergan or its affiliates challenges any of our patents licensed to Allergan and such patent challenge is not required under a court order or subpoena and is not a defense against a claim, action or proceeding asserted by us, our affiliates or licensees against Allergan, its affiliates or sublicensees. In addition, Allergan may unilaterally terminate the Allergan/AbbVie Agreement for any reason upon advance notice. If Allergan has the right to terminate the Allergan/AbbVie Agreement due to our uncured material breach, Allergan may elect to continue the agreement and reduce all future milestone and royalty payment obligations to us by a specified percentage. In the event of any termination of the Allergan/AbbVie Agreement, Allergan will assign or grant a right of reference to any regulatory documentation related to RTGel to us, all rights and licenses to Allergan will terminate, and the license Allergan granted to us under their improvements to RTGel will continue. If any of these events occurs, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for the Licensed Products and will not be able to, or may be delayed in our efforts to, successfully commercialize the Licensed Products, and our business will be harmed.

We may utilize a variety of types of 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. 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.

Our existing collaboration with AbbVie and any future collaborations that we enter into, may pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- product candidates developed by collaborators may not perform sufficiently in clinical trials to be determined to be safe and effective, thereby delaying or terminating the drug approval process and reducing or eliminating milestone payments to which we would otherwise be entitled if the product candidates had successfully met their endpoints and/or received FDA approval;
- clinical trials conducted by collaborators could give rise to new safety concerns;
- collaborators may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources, be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaborations may not lead to development or commercialization of product candidates in the most efficient manner, or at all, and may otherwise experience challenges. For example, in August 2020, we announced that the Phase 2 APOLLO trial did not meet the primary endpoint, believed to be the result of BOTOX not effectively permeating the urothelium. While we and AbbVie plan to continue to explore the use of RTGel with AbbVie's portfolio of toxin proteins, there can be no assurance that the collaboration will result in the successful development of a product candidate.

If the Allergan/AbbVie Agreement, and any future 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 and UGN-201 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. There are significant risks associated with the manufacture of pharmaceutical products and contracting with contract manufacturers and with 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 or UGN-201 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, UGN-102 and UGN-201 for our nonclinical studies, clinical trials and commercial use, should our drug candidates receive regulatory approval. We currently depend on Teva Pharmaceuticals Industries Ltd., or Teva, as our single-source supplier of mitomycin active pharmaceutical ingredient, or API, for Jelmyto and UGN-102. We rely on Cenexi-Laboratoires Thissen s.a., and Isotopia Molecular Imaging Ltd. as our sole suppliers for the gel contained in Jelmyto and UGN-102. We also currently depend on a single source supplier for imiquimod for UGN-201. Because there are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce Jelmyto for commercial sale and our product candidates for our clinical trials and their subsequent commercial sale, if approved. Even if we are able to engage alternate suppliers on reasonable terms, we may face delays or increased costs in our supply chain that could jeopardize the commercialization of Jelmyto. We do not have any control over the availability of raw materials. If we or our suppliers and manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development and commercialization of our product candidates or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of Jelmyto or any other approved products.

We expect to continue to rely on these or other subcontractors and suppliers to support our commercial requirements for Jelmyto, as well as UGN-102 or any of our other product candidates if approved for marketing by the FDA or foreign regulatory authorities. We also rely on a single third-party manufacturer to produce our proprietary drug product, or final mitomycin formulation, necessary for our clinical trial and commercial requirements. We plan to continue to rely on third parties for the production of mitomycin API, the gel contained in Jelmyto and UGN-102, and for imiquimod for UGN-201, 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, a drug product containing mitomycin, we have limited experience as a company in the commercial supply of drugs and may never be successful as a commercial supplier of drug products containing mitomycin. In addition, cost-overruns, unexpected delays, equipment failures, logistics breakdowns, labor shortages, natural disasters, power failures, production failures or product recalls, and numerous other factors could prevent us from realizing the intended benefits of our sales strategy and have a material adverse effect on our business. Further, although we commercially supply Jelmyto, further build-out is required and establishing such commercial-scale supply capabilities requires additional investment, is time-consuming and may be subject to delays, including because of shortage of labor, compliance with regulatory requirements or receipt of necessary regulatory approvals. In addition, building out our Jelmyto commercial supply capabilities may cost more than we currently anticipate, and delays or problems may adversely impact our ability to provide sufficient quantities of Jelmyto to support our ongoing commercial launch and commercialization of Jelmyto as well as our financial condition.

While we currently have over 12 months of mitomycin API and Jelmyto finished product on hand to continue our commercial and clinical operations as planned, depending on the duration of the COVID-19 pandemic and whether further disruptions occur, we may face such delays or costs in future years. Although we believe we have sufficient quantities of mitomycin API for planned manufacturing operations during 2020, a prolonged supply interruption of certain components could adversely affect our ability to conduct commercialization activities and planned clinical trials. If any third party in our supply or distribution chain for materials or finished product is adversely impacted by restrictions resulting from the ongoing COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture and distribute Jelmyto for commercial sales and our product candidates for our clinical trials and research and development operations.

In addition, before we can begin to commercially manufacture any product candidate that receives 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 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 is 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, also called 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 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 all key 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 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.

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

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

We and the third parties upon whom we rely are required to comply with Good Clinical Practice, or 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 or healthcare privacy and security 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 on commercially reasonable terms, or at all. Switching or adding CROs, clinical investigators or other third parties can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationship with our CROs, clinical investigators and other third parties, there can be no assurance that we will not encounter such challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, prospects, financial condition or results of operations.

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

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

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

As of September 30, 2020, we had 187 employees, of whom 44 are based in Israel and 143 are based in the United States. We will need to continue to expand our development, quality, managerial, operational, finance, marketing, sales and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

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

As we continue to grow as an organization, including by expanding our development efforts and building out and developing our commercial capabilities to support our ongoing commercial launch of Jelmyto, we will evaluate, and may implement, changes to our organization that may be appropriate in order to properly manage and direct our growth and transformation into a commercial-stage company. Due to our limited financial resources and our limited experience in managing a larger company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, the ongoing COVID-19 pandemic could make recruiting and training more difficult. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion or other significant changes to our organization could delay the execution of our development, commercialization and strategic objectives or disrupt our operations; and if we are not successful in commercializing our approved product or any of our product candidates that may receive regulatory approval, either on our own or through collaborations with one or more third parties, our revenues will suffer and we would incur significant additional losses.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk once we commercialize Jelmyto or any other product candidate that receives 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 our product candidates or products 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 intend to expand our insurance coverage to include the commercialization of Jelmyto; however, we may be unable to obtain this liability insurance on commercially reasonable terms. 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 nay 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 scientific 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 and scientific 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.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a disruption of our drug development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from cyber-security threats, including computer viruses, harmful code and unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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

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

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

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

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

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, or 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. 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, although the dollar appreciated against the NIS in 2018 by 8.1%, the dollar depreciated against the NIS in 2019 was 7.8%. If the dollar cost of our operations in Israel increase, our dollar-measured results of operations will be adversely affected.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the COVID-19 pandemic.*

The recent outbreak of the novel strain of coronavirus, SARS-CoV-2, causing COVID-19 disease, which has been declared by the World Health Organization to be a pandemic, has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, suppliers, potential customers, and other partners may be prevented from conducting certain business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the impact that COVID-19 could have on our business, the COVID-19 pandemic and mitigation measures have had and may continue to 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 continued spread of COVID-19 and the measures taken by various governments could disrupt the supply chain of material needed for our product candidates and our approved product, Jelmyto, interrupt healthcare services, delay coverage decisions from Medicare and third party payors, delay ongoing and planned clinical trials involving our product candidates and have a material adverse effect on our business, financial condition and results of operations. In addition, we and many of our potential customers and partners worldwide have in the past and may in the future be subject to stay-at-home orders as a result of the COVID-19 pandemic. In addition, our ongoing commercial launch of Jelmyto and subsequent commercialization activities could be hindered by the COVID-19 pandemic, although we are currently not able to predict or quantify any such potential impact with any degree of certainty. However, the worldwide spread of the COVID-19 virus has resulted and may continue to result in a global slowdown of economic activity which is likely to decrease demand for a broad variety of goods and services, including potentially for Jelmyto, while also disrupting sales channels and marketing activities for an unknown period of time until the disease is contained.

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

Additionally, during the COVID-19 pandemic, our sales force has had physical access to hospitals, clinics, healthcare providers and pharmacies curtailed, which may have affected our sales to date and may in the future have a material adverse effect on our future sales. While digital tools are available to our field employees to facilitate remote meetings with physicians and other healthcare providers, we cannot ensure that these methods will be effective. 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 prescription refills or new patient starts, affecting our revenues both in our currently approved indication and potentially impacting our anticipated launches in other indications, if approved.

Moreover, the global outbreak of the COVID-19 coronavirus continues to rapidly evolve, and the extent to which the COVID-19 coronavirus may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

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

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 biopharmaceutical 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 $104.9 million and $75.7 million for the years ended December 31, 2019 and 2018, respectively. For the nine months ended September 30, 2020 and 2019, we reported a net loss of $98.0 million and $66.2 million, respectively. As of September 30, 2020, we had an accumulated deficit of $326.0 million. We expect to continue to incur significant expenses and increasing 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;
- any product liability or other lawsuits related to our products;
- scientific breakthroughs in the field of urothelial cancer treatment and diagnosis that could significantly diminish the need for our product candidates or make them obsolete; and
- changes in reimbursement or other regulatory 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 biopharmaceutical industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have not obtained regulatory approval for any product except Jelmyto and we have not commercialized any of our products or generated any revenue from product sales.

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

Since our inception, almost all our resources have been dedicated to the nonclinical and clinical development of our first commercial product, Jelmyto, and our lead product candidate UGN-102. As of September 30, 2020, we had cash and cash equivalents and marketable securities of $125.5 million. In January 2019, we completed an underwritten public offering in which we received net proceeds of approximately $161.4 million, after deducting the underwriting discounts and commissions and payment of other offering expenses. During the second quarter of 2020, we sold 700,000 ordinary shares under the ATM Sales Agreement, for gross proceeds of approximately $16.6 million. The net proceeds to us after deducting sales commissions to Cowen and other issuance expenses were approximately $15.8 million. The remaining capacity under the ATM Sales Agreement is approximately $83.4 million.

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

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

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

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

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

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 other than funding under the existing exclusive license agreement we entered into with Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc, which is now a part of AbbVie Inc., in October 2016, or the Allergan/AbbVie Agreement. Under the Allergan/AbbVie Agreement, we may receive additional material milestone payments upon the successful completion of certain development, regulatory and commercial milestones and royalties with respect to future sales of collaboration products by Allergan. Allergan may unilaterally terminate our existing collaboration for any reason upon advance notice.

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 these securities may include liquidation or other preferences that adversely affect your rights as an ordinary shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring and distributing dividends, and may be secured by all or a portion of our assets.

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

Risks Related to Our Intellectual Property

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

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

We seek patent protection for our product candidates, and we have established several patent families comprised of issued patents and pending patent applications covering our proprietary RTGel technology, the pharmaceutical compositions, methods of use and manufacturing aspects of our product candidates. In the United States, we currently have 16 granted patents that are directed to protect our approved product, Jelmyto and our lead product candidate, UGN-102, a proprietary RTGel technology, various local compositions comprising different active ingredients, inter alia compositions comprising a Botulinium Toxin, UGN-201 and our future product candidates that are under company research. These patents claim methods, systems, combination products and novel compositions for treating different diseases, especially cancer in internal cavities, in particular urinary tract cancer. These issued patents are expected to expire between 2024 and 2037. In total, our IP portfolio includes 37 granted patents worldwide, and more than 40 pending patent applications filed worldwide 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 2037.

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 granted 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 to 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 United States Patent and Trademark Office, or 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 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, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business and financial condition.

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

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

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

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

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

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

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

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

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

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

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

We filed applications for trademarks (Jelmyto ®, RTGel™, Urogen ® and Cystoject ™) that identify our branding elements, such as Jelmyto and our unique technology in the United States, Europe and Japan. 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 or the patents of our licensors, which could be expensive and time consuming.

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

Drug manufacturers may develop, seek approval for, and launch generic versions of our products. If we file an infringement action against such a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors’ patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

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

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

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

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

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

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

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

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

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, for example, the intellectual property rights of competitors. Our research, development and 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 not be aware of patents that have already issued that a third party might assert are infringed by 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 Section 505(b)(2) of the Federal Food Drug and Cosmetic Act, or Section 505(b)(2), or if the requirements for such 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, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act. Section 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 new chemical entities, or NCEs, the submission of an NDA under the Section 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 Section 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 Section 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 Section 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 Section 505(b)(2) certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 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 Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 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 Section 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 Section 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 Section 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 and the Health Care and Education Reconciliation Act of 2010, or 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.

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report annually certain financial arrangements with physicians and teaching hospitals; as defined in the ACA and its implementing regulations, including reporting any payment or "transfer of value" provided to physicians, as defined by such law, and teaching hospitals and any ownership and investment interests held by such physicians and their immediate family members during the preceding calendar year, which will be expanded beginning in 2022 to include reporting obligations with respect to financial relationships with certain additional healthcare providers;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

There remain judicial, Congressional and executive branch challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. For example, since January 2017, President Trump has signed executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." For example, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program. On April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress's denial of $12 billion in "risk corridor" funding. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, which are expected to occur in the fall of 2020. It is unclear how such litigation and other efforts to repeal and replace the ACA 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, created the Joint Select Committee on Deficit Reduction, or a Joint Selection Committee, to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which started in 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will stay in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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.

Additionally, there have been several recent U.S. Congressional inquiries and proposed and enacted legislation at the federal and state levels designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump Administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump Administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump Administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On July 24, 2020, the Trump Administration announced four executive orders related to prescription drug pricing that attempt to implement several of the Administration's proposals, including a policy that would tie Medicare Part B drug prices to international drug prices, or the "most favored nation price," the details of which were released on September 13, 2020 and also expanded the policy to cover certain Part D drugs; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers, commonly known as the "rebate rule"; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of President Trump's importation executive order announced in July 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump Administration have both stated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. If healthcare policies or reforms intended to curb healthcare costs are adopted, or if we experience negative publicity with respect to the pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. In addition, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic. For example, the Trump Administration issued an executive order on August 3, 2020 directing CMS to propose a regulation extending Medicare coverage for certain telemedicine services provided to certain Medicare beneficiaries beyond the duration of the COVID-19 public health emergency. CMS is required to propose the regulation within 60 days of the issuance of the executive order. Further, on August 6, 2020, the President Trump issued an executive order that instructs the federal government to develop a list of "essential" medicines and then buy them and other medical supplies from U.S. manufacturers instead of from companies around the world, including China.

If we obtain regulatory approval and commercialization of UGN-102 or any of our other product candidates, 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 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, or 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 new product exclusivity to Jelmyto for the treatment of UTUC, we may not receive new product exclusivity for any of our other product candidates.

Although the FDA has granted Orphan Drug Designation to Jelmyto and UGN-201 for treatment of UTUC and CIS, 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 biopharmaceutical 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 product candidates that receives 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 receives regulatory approval will be subject to continual regulatory review by the FDA and/or foreign regulatory authorities. Additionally, Jelmyto and any 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 other product candidates that receives 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 penalties.*

We may currently be or may become 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, or 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 medical technology 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, or 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, or 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 will also be 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, as defined by such law, and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members to CMS, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year. We may also be subject to state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, drug pricing, and/or state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidelines promulgated by the federal government. Certain state and local laws also require the registration of pharmaceutical sales representatives.

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

Also, the U.S. Foreign Corrupt Practices Act 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.

U.S. state and federal data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.*

The European Union, or EU, has established its own data security and privacy legal framework, including but not limited to the European General Data Protection Regulation, or GDPR, which contains provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. 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 the EU countries in which we might operate, including the GDPR.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Effective January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. The CCPA could impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

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. As of October 2020, a Medicare C-Code has been issued for Jelmyto.

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.

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.

While we have obtained coverage under a miscellaneous code and received certain private and government payor reimbursement for Jelmyto, we cannot be sure that adequate coverage or reimbursement will be available for Jelmyto, UGN-102 or any of our other product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize Jelmyto, UGN-102 or our other product candidates, or achieve profitably at all, even if approved. Additionally, coverage policies and reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for any of our products or product candidates that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement for our products, the commercial success of our products may be greatly hindered and our financial condition and results of operations may be materially and adversely affected.

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

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of UGN-102 or any of our other product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- change in protocol design;
- additional treatment arm (control);
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could harm our business and our financial results.

Risks Related to Ownership of Our Ordinary Shares

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

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

- the success of our launch and commercialization of Jelmyto;
- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- physician and market acceptance of Jelmyto or any other approved product;
- the mix of products that we sell;
- any voluntary or mandatory recall of Jelmyto or any other approved product, or the imposition of any additional labeling, marketing or promotional restrictions;
- our success or failure to obtain approval for and commercialize our product candidates;
- changes in the structure of healthcare payment systems;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of nonclinical or clinical trials for Jelmyto, UGN-102 or our other product candidates;
- failure by us to achieve a publicly announced milestone;
- delays between our expenditures to develop and market new or enhanced product candidates and the generation of sales from those products;
- developments concerning intellectual property rights;
- the announcement of, or developments in, any litigation matters, including any product liability claims related to Jelmyto or any of our product candidates;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our products;
- our sale or proposed sale, or the sale by our significant shareholders, of our ordinary shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our ordinary shares; and
- general economic and market conditions and other factors, such as the COVID-19 pandemic, including factors unrelated to our operating performance.

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

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

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

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

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

In order to raise additional capital, we may in the future offer additional ordinary shares or other securities convertible into or exchangeable for our ordinary shares at prices that we determine from time to time, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders. We may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. On December 20, 2019, we entered into a sales agreement with Cowen and Company, LLC pursuant to which we may from time to time offer and sell our ordinary shares, having an aggregate offering price of up to $100.0 million, to or through Cowen, acting as sales agent or principal, in any manner deemed to be an "at-the market offering". The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 filed with the SEC on December 20, 2019, which was declared effective on January 2, 2020. Our prior open market sales agreement with Jefferies LLC, dated October 12, 2018, was terminated on December 20, 2019.

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, or PFIC, our U.S. shareholders may suffer adverse tax consequences.

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

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

We believe that we were classified as a PFIC for the taxable year ended December 31, 2019. We have not yet made a determination as to our expected PFIC status for the current taxable year. We cannot provide any assurances regarding our PFIC status for the current or future taxable years, and our U.S. tax counsel has not provided any opinion regarding our PFIC status.

If we are characterized as a PFIC, our U.S. Holders (as defined below) 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. Holders, 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. Holder may be able to elect out of such treatment if we are no longer characterized as a PFIC by making a "purging election." For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is or is treated as any of the following: (a) an individual who is a citizen or resident of the United States; (b) a corporation, or entity treated as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state thereof, or the District of Columbia; (c) an estate, the income of which is subject to U.S. federal income tax regardless of its source; or (d) a trust that (1) is subject to the supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

If we are a PFIC, we plan on providing to investors, by annually posting a "PFIC Annual Information Statement" on our website, the information required to allow investors to make a qualified electing fund election, or a QEF Election, for United States federal income tax purposes.

Future 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, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organisation for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS Project, the European Commission's state aid investigations and other initiatives.

Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or, in the specific context of withholding tax dividends paid. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act made many significant changes to the U.S. Internal Revenue Code of 1986, as amended, or the Code. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. 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 under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

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

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

If a U.S. Holder is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). 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, they may be treated as controlled foreign corporations of any U.S. Holder owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares. A United States shareholder of a controlled foreign corporation 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 controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation 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. We cannot provide any assurances that we will assist investors in determining whether any non-U.S. subsidiaries that we may form or acquire in the future would be treated as a controlled foreign corporation or whether such investor would be treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any U.S. shareholder information that may be necessary to comply with the reporting and tax paying obligations discussed above. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares.

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

Under U.S. federal income tax law, federal net operating losses, or NOLs, incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to utilize its pre-change NOL carryforwards and other pre-change tax attributes to offset future 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 an ownership change, our ability to utilize NOLs and other tax attributes could be limited by Sections 382 and 383 of the Code. Future changes in our share ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could negatively impact our future cash flows. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to our Operations in Israel

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

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

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

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

Further, our operations could be disrupted by the obligations of our employees to perform military service. As of September 30, 2020, we had 44 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 our assets and most of the assets of this director are located outside of the United States. Therefore, a judgment obtained against us, or this director, including a judgment based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It may also be difficult for you to effect service of process on this director in the United States or to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

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

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

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

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

Risks Related to Our Management and Employees

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

Our success depends upon the continued service and performance of our executive officers who are essential to our growth and development. The loss of one or more of our executive officers could delay or prevent the continued successful implementation of our growth strategy, could affect our ability to manage our company effectively and to carry out our business plan, or could otherwise be detrimental to us. As of September 30, 2020, we had 187 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 stockholder 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 stockholders. 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 stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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 Form 6-K filed on May 18, 2017).
10.1	Separation Agreement between the Company and Peter Pfreundschuh, dated September 8, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current report on Form 8-K, filed with the SEC on September 9, 2020).
10.2	Employment Agreement between the Company and Molly Henderson, dated September 3, 2020 (incorporated by reference to Exhibit 10.2 to the Company's Current report on Form 8-K, filed with the SEC on September 9, 2020).
10.3	Employment Agreement between the Company and Jason Smith, dated August 12, 2020.
10.4	Amendment No. 1 to Sales Agreement, dated as of December 20, 2019, by and between the Registrant and Cowen and Company, LLC.
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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	UroGen Pharma Ltd.
November 9, 2020	By: /s/ Elizabeth Barrett
	Elizabeth Barrett
	Chief Executive Officer
	(Principal Executive Officer)
November 9, 2020	By: /s/ Molly Henderson
	Molly Henderson
	Chief Financial Officer
	(Principal Financial and Accounting Officer)

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**"), is hereby made this 12th day of August, 2020, between UroGen Pharma, Inc., a wholly owned subsidiary (the "**Subsidiary**") of UroGen Pharma, Ltd. (the "**Parent**", and the Subsidiary and the Parent together, the "**Company**"), and Jason Smith (the "**Executive**") (collectively, the "**Parties**").

WHEREAS, the Company desires for Executive to provide services to the Company, and wishes to provide Executive with certain compensation and benefits in return for such employment services; and

WHEREAS, Executive wishes to be employed by the Company and to provide personal services to the Company in return for certain compensation and benefits;

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

1.

Employment by the Company.

1.1

Position.

Executive shall serve as the Company's General Counsel/Chief Compliance Officer/Corporate Secretary. Executive's employment with the Company shall commence on August 31, 2020 (the "**Start Date**"). During Executive's employment with the Company, Executive will devote Executive's best efforts and substantially all of Executive's business time and attention to the business of the Company, except for (i) approved outside activities (*e.g.*, charitable activities, conferences, events, etc.), and (ii) approved vacation periods, reasonable periods of illness or other incapacities permitted by the Company's general employment policies, and as otherwise permitted by this Agreement.

1.2

Duties and Location. Executive shall perform such duties as are typically required by a General Counsel/Chief Compliance Officer/Corporate Secretary, and will have day-to-day responsibility for all legal and compliance activities of the company.

Executive will report to the Company's Chief Executive Officer. Executive's primary work location will be the Company's Princeton, NJ office (or company's corporate headquarters location).

1.3

Policies and Procedures. The employment relationship between the Parties shall be governed by the general employment policies and practices of the Company, except that when the terms of this Agreement differ from, or are in conflict with, the Company's general employment policies or practices, this Agreement shall control.

2.

Compensation.

2.1 Salary.

For services to be rendered hereunder, Executive shall receive a base salary at the rate of $425,000.00 per year (the "**Base Salary**"), subject to

standard payroll deductions and withholdings and payable in accordance with the Company's regular payroll schedule.
2.2
Signing Bonus. The Company will pay Executive a one-time Signing
Bonus of $100,000.00, such payment is subject to standard payroll deductions and
withholdings. The Signing Bonus will be paid to Executive in advance of being earned, within thirty (30) days after your Start Date. You will earn the Signing Bonus if youremain continuously employed with the Company through the one-year anniversary of your Start Date. If your employment with the Company terminates for any reason prior to the one-year anniversary of your Start Date, you agree to repay the entire Start Bonus paid to you by the Company in advance of becoming earned.
2.3
Annual Bonus. Executive will be eligible for an annual discretionary
bonus, with an annual target of 50% of Executive's Base Salary (the "**Annual Bonus**"), pro-
rated in the case of a partial calendar year. Whether Executive receives an Annual Bonus for any given year, and the amount of any such Annual Bonus, will be determined by the Company, with input from the Company's Board of Directors, in its sole discretion based upon the Company's and Executive's achievement of goals and objectives to be determined on an annual basis by the Company in a manner consistent with other senior management. Except as outlined in Section 5.2, Executive must remain an active employee through the end of any given calendar year in order to earn an Annual Bonus for that year and any such bonus will be paid prior to March 15 of the following year.
3.
Standard Company Benefits. Executive shall be eligible to participate in
all employee benefit programs which are made available generally to the Company's U.S.- based senior executive group, on a basis comparable to such group. Employee shall be
eligible to receive two hundred hours (200) paid time off (PTO) hours annually, in accordance with the Company's paid time off policy. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time, provided that such cancellation or change is generally applicable to the Company's U.S.-based senior executive group participating in such plan or program.
4.
Equity.
4.1
Subject to approval by the Board of Directors of the Parent, Executive
shall be granted an option to purchase 60,000 of the Company's ordinary shares, par value NIS 0.01 (the "**Ordinary Shares**") in the Parent at the fair market value on the date of grant (the "**Option**") and 25,000 restricted stock units of the Parent (the "**RSU**"). The Option and RSU shall be governed in all respects by the terms of the governing plan documents and option and restricted stock agreements between Executive and the Parent. Employee equity
grants are made periodically at the discretion of the board of directors, typically on a quarterly basis. These equity grants are intended to be a material inducement to your acceptance of employment with the company. The Option and RSU will vest over 3 years - 1/3 will vest on the first anniversary of the Vesting Commencement Date, and 1/3 of the Option and RSU will vest annually thereafter for the remaining two (2) years. Executive will be eligible for consideration for annual grants of additional equity awards pursuant to the

process applicable to other members of the executive leadership team, with the terms of any such grants to be determined in the sole discretion of the Board. Target value of annual awards are at the discretion of the board but will target range equal to target bonus value.
i.e. 50% of annual salary.

5.
Termination of Employment; Severance.

5.1
At-Will Employment. Executive's employment relationship is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause or advance notice.

5.2
Termination By Company Without Cause; Termination by Executive With Good Reason; Death or Disability

(i) The Company may terminate Executive's employment with the Company at any time without Cause (as defined below). Executive may terminate his/her employment at any time for Good Reason, as defined below. Executive's employment with the Company may also be terminated due to Executive's death or Disability. For this purpose, "**Disability**" shall mean that Executive is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than 12 months, and shall be determined in the good faith and reasonable discretion of the Board.

(ii)
In the event Executive's employment with the Company is terminated by the Company without Cause, by the Executive for Good Reason, or by reason of Executive's death or Disability, then provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), and provided that Executive remains in compliance with the terms of this Agreement, the Company shall provide Executive with the following Severance Benefits:

(a)
The Company shall pay Executive, as severance, the equivalent of six (6) months of Executive's base salary in effect as of the date of Executive's employment termination (without taking into account any reduction in salary constituting Good Reason), subject to standard payroll deductions and withholdings (the "**Severance**"). The Severance will be paid as a continuation on the Company's regular payroll, beginning on the sixtieth (60th) day following Executive's Separation from Service, provided the Separation Agreement (as discussed in Paragraph 6) has become effective.

(b)
The Company shall pay Executive a pro-rata bonus through the date of termination, which bonus shall be paid only to the extent earned based on actual Company performance, not to exceed 100% of the target (with any individual performance component deemed achieved), on the date in the year following termination on which bonuses are paid to other senior executives of the Company (but in any event prior to

March 15 of such year), provided the Separation Agreement (as discussed in Paragraph 6) has become effective.

(c)

The Company shall pay Executive any annual bonus earned with respect to the year preceding the year of termination, if not already paid by the date of termination, which amount shall be paid on the sixtieth (60th) day following Executive's Separation from Service, provided the Separation Agreement (as discussed in Paragraph 6) has become effective.

(d)

The vesting of any of the Executive's unvested restricted shares and options, including the Option, shall be accelerated by one (1) quarter, such that 8.33% of the then-unvested restricted shares and options shall be deemed immediately vested and exercisable as of Executive's last day of employment.

(e)

The Company shall reimburse Executive the amount of any COBRA continuation premium payments made by Executive during the six (6) month period following the date of termination, or the period ending when Executive becomes eligible for comparable group medical benefits coverage from another source (whichever comes first).

5.3

Resignation by the Executive Without Good Reason; Termination by the Company for Cause

(i)

The Company may terminate Executive's employment with the Company at any time for Cause and Executive may resign at any time.

(ii)

If Executive resigns or the Company terminates Executive's employment for Cause, then (i) Executive will no longer vest in additional unvested portions in the Option and the RSU, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned), and (c) Executive will not be entitled to any Severance Benefits. In addition, Executive shall resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its affiliates, each effective on the date of termination.

6.

Conditions to Receipt of Severance Benefits. The receipt of the Severance Benefits will be subject to Executive signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Separation Agreement**").

No Severance Benefits will be paid or provided until the Separation Agreement becomes effective. Executive shall also resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its affiliates, each effective on the date of termination.

7.

Benefits in Connection with a Change of Control.

7.1

Termination of Employment in Connection with a Change of Control. If there is a Change of Control (as defined below) and (i) Executive's employment

is terminated Without Cause (as defined below), or (ii) Executive terminates his/her employment with Good Reason (as defined below), in either case within three months prior to, or 24 months following the effective date of the Change of Control, and provided a Separation Agreement (as discussed in Section 6) has become effective, then, in substitution for any benefits provided in Section 5.2, Executive shall be entitled to the following benefits:
(A) a lump sum payment equal to the sum of (y) 12 months of Executive's then-current annual Base Salary and (z) 100% of the current target bonus percentage of Executive's current annual Base Salary, to be made not later than 60 days following Executive's date of termination; and (B) the amount of any COBRA continuation premium payments made by Executive during the twelve (12) month period following the date of termination, or the period ending when Executive becomes eligible for comparable group medical benefits from another source (whichever comes first). For avoidance of doubt, under no circumstances shall Executive receive benefits under both this Section 7.1 and Section 5.2.

7.2 Acceleration of Options; Change of Control. In the event of a Change of Control (as defined below) that occurs prior to Executive's termination of employment, 100% of the Options and the RSU that have not yet become exercisable or vested shall become exercisable and vested immediately prior to the closing of the Change of Control.

8.
Section 409A. It is intended that all of the Severance Benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation", then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Paragraph shall be paid in a lump sum to Executive, and any remaining payments due shall

be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred.

9.

Definitions.

9.1

Change of Control. For purposes of this Agreement, "**Change of Control**" shall mean: the acquisition of the Company or the Parent by another entity by means of any transaction or series of related transactions approved by the Board of Directors of the Parent to which the Parent is party (including, without limitation, any stock acquisition, reorganization, merger or consolidation, but excluding any sale of stock for capital raising purposes) other than a transaction or series of transactions in which the holders of the voting securities of the Parent outstanding immediately prior to such transaction continue to retain (either by such voting securities remaining outstanding or by such voting securities being converted into voting securities of the surviving entity), as a result of Ordinary Shares in the Company held by such holders prior to such transaction, at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such transaction or series of transactions.

9.2

Cause. For purposes of this Agreement, "**Cause**" for termination will mean: (a) commission of any felony, or other crime involving dishonesty; (b) participation in any fraud against the Company; (c) material breach of Executive's duties to the Company; (d) intentional and material damage to any property of the Company; (e) misconduct or other violation of Company policy that causes material harm to the Company; (f) material breach of any material written agreement with the Company or any material written Company policy; and (g) conduct by Executive which in the good faith and reasonable determination by the Board of Directors demonstrates gross unfitness to serve. An event described in (c), (d), (f) and (g) shall not be treated as "Cause" until after Executive has been given written notice of such event, failure, conduct or breach and Executive fails to cure such event, failure, conduct or breach within 30 days from such written notice; provided, however, that such 30-day cure period shall not be required if the event, failure, conduct or breach is incapable of being cured.

9.3

Good Reason. For purposes of this Agreement, "**Good Reason**" for resignation will mean: (a) a material reduction in Executive's responsibilities, authorities, title or reporting relationship; (b) the requirement that Executive relocate to a location outside of the New York-Newark-Jersey City, NY-NJ-PA Metropolitan Statistical Area, as defined by the U.S. Office of Management and Budget; or (c) material breach by the Company of any material agreement between Executive and the Company, including this Agreement. In order for Executive to resign for Good Reason, Executive must provide written notice to the Company's Board or Chief Executive Officer within 90 days after the first occurrence of the event giving rise to Good Reason setting forth the basis for Executive's resignation. Executive must then allow the Company at least 45 days from receipt of such written notice to cure such event, and if such event is not reasonably cured by the Company within such 45 day period (the "**Cure Period**"), the Executive must then resign from all positions Executive then holds with the Company not later than 90 days after the expiration of the Cure Period.

10. Proprietary Information Obligations. As a condition of employment, Executive shall execute and abide by the Company's standard form of Employee Proprietary Information, Inventions, Non-Solicitation and Non-Competition Agreement (the "**Confidentiality Agreement**").

11. Outside Activities During Employment

11.1 Non-Company Business. Except with the prior written consent of the Company, which will not unreasonably be withheld, Executive will not during the term of Executive's employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which Executive is a passive investor. Executive may engage in civic and not-for-profit activities, so long as such activities do not materially interfere with the performance of Executive's duties hereunder.

12. Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise in connection with Executive's employment with the Company, Executive and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance, negotiation, execution, or interpretation of this Agreement, Confidential Information Agreement, or Executive's employment, or the termination of Executive's employment, including but not limited to all statutory claims, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration by a single arbitrator conducted in New York, New York by Judicial Arbitration and Mediation Services Inc. ("JAMS") under the then applicable JAMS rules (at the following web address: https://www.jamsadr.com/rules-employment-arbitration/); provided, however, this arbitration provision shall not apply to sexual harassment claims to the extent prohibited by applicable law. A hard copy of the rules will be provided to Executive upon request. A hard copy of the rules will be provided to Executive upon request. By agreeing to this arbitration procedure, both Executive and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. In addition, all claims, disputes, or causes of action under this section, whether by Executive or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The Arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. The Company acknowledges that Executive will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this Agreement) shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award; and (c) be authorized to award any or all remedies that Executive or the Company would be entitled to seek in a court of law. Executive and the Company shall equally share all JAMS' arbitration fees. Except as modified in the Confidential Information Agreement, each party is responsible for its own attorneys' fees. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction. To the extent applicable law prohibits mandatory arbitration of sexual harassment claims, in the event Executive intends to bring multiple claims, including a sexual harassment claim, the sexual harassment may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration.

13.
General Provisions.

13.1
Notices. Any notices provided must be in writing and will be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight carrier, to the Company at its primary office location and to Executive at the address as listed on the Company payroll.

13.2
Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties.

13.3
Waiver.
Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

13.4
Complete Agreement.
This Agreement, together with the Confidentiality Agreement, constitutes the entire agreement between Executive and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the Parties' agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. It is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in a writing signed by a duly authorized officer of the Company.

13.5
Counterparts.
This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

13.6
Headings. The headings of the paragraphs hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

13.7 Successors and Assigns. This Agreement is intended to bind and inure to the benefit of and be enforceable by Executive and the Company, and their respective successors, assigns, heirs, executors and administrators, except that Executive may not assign any of her duties hereunder and he may not assign any of her rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

13.8
Tax Withholding and Indemnification. All payments and awards contemplated or made pursuant to this Agreement will be subject to withholdings of applicable taxes in compliance with all relevant laws and regulations of all appropriate government authorities. Executive acknowledges and agrees that the Company has neither made any assurances nor any guarantees concerning the tax treatment of any payments or awards contemplated by or made pursuant to this Agreement. Executive has had the opportunity to retain a tax and financial advisor and fully understands the tax and economic consequences of all payments and awards made pursuant to the Agreement.

13.9
Insurance and Indemnification. The Company agrees to indemnify Executive in accordance with Company policy and applicable laws with respect to any acts or omissions Executive may have committed in her capacity as an office holder of the Company, and to include her in the Company's existing D&O insurance policy in accordance with Company policy and applicable laws.

13.10 **Choice of Law.** All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of New Jersey.

/s/ Jason Smith

IN WITNESS WHEREOF, the Parties have executed this Agreement on the day and year first written above.

UROGEN PHARMA, INC.

By:

Liz Barrett
Chief Executive Officer

EXECUTIVE

Jason Smith

/s/ Liz Barrett

Exhibit 10.4

UROGEN PHARMA LTD.
AMENDMENT NO. 1 TO
SALES AGREEMENT

August 12, 2020

Cowen and Company, LLC
599 Lexington Avenue
New York, New York 10022

Ladies and Gentlemen:

Reference is made to the Sales Agreement, dated as of December 20, 2019 (the "**Sales Agreement**"), between Cowen and Company, LLC ("**Cowen**") and UroGen Pharma Ltd., a company organized under the laws of the State of Israel (the "**Company**"). All capitalized terms used in this Amendment No. 1 to the Sales Agreement between the Company and Cowen (this "**Amendment**") and not otherwise defined herein shall have the respective meanings assigned to such terms in the Sales Agreement. Cowen and the Company hereby agree as follows:

A. <u>Amendments to Sales Agreement</u>. The Sales Agreement is amended as follows:

1. Section 2(k) of the Sales Agreement shall be replaced as follows:

<u>Independent Accountants</u>. Each of Kesselman & Kesselman, Certified Public Accountants (Israel), an independent registered public accounting firm and a member firm of PricewaterhouseCoopers International Limited, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement and the Prospectus, and PricewaterhouseCoopers LLP is (i) an independent registered public accounting firm as required by the Securities Act and the rules of the Public Company Accounting Oversight Board ("**PCAOB**"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

2. Section 4(q) of the Sales Agreement shall be replaced as follows:

<u>Comfort Letter</u>. On or prior to the Settlement Date for the event in Section 4(o)(D) hereof, and within five (5) Trading Days of each Triggering Event Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 4(o) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause each of Kesselman & Kesselman, Certified Public Accountants (Israel), an independent registered public accounting firm and a member firm of PricewaterhouseCoopers International Limited, and PricewaterhouseCoopers LLP, to furnish the Agent a comfort letter, dated the date of delivery, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel; provided, however, that any such comfort letters will only be required on the Triggering Event Date specified to the extent that it contains financial

statements filed with the Commission under the Exchange Act and incorporated or deemed to be incorporated by reference into a Prospectus. If requested by the Agent, the Company shall also cause comfort letters to be furnished to the Agent within ten (10) Trading Days of the date of occurrence of any material transaction or event requiring the filing of a current report on Form 8-K containing material amended financial information of the Company, including the restatement of the Company's financial statements. The Company shall be required to furnish no more than one comfort letter per accounting firm hereunder per calendar quarter, unless requested by the Agent pursuant to Section 4(o)(D) hereof.

B. No Other Amendments. Except as set forth in Part A above, all of the terms and provisions of the Sales Agreement shall continue in full force and effect.

C. Counterparts. This Amendment may be executed in two or more counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument, and may be delivered by facsimile transmission or by electronic delivery of a portable document format (PDF) file.

D. Governing Law. This Amendment shall be governed by, and construed in accordance with, the internal laws of the State of New York applicable to agreements made and to be performed in such state.

[*Signature Page Immediately Follows*]

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms

Very truly yours,

UROGEN PHARMA LTD.

By: /s/ Peter Pfreundschuh

Name: Peter Pfreundschuh

Title: Chief Financial Officer

The foregoing Amendment is hereby confirmed and accepted by the Agent in New York, New York as of the date first above written.

COWEN AND COMPANY, LLC

By: /s/ Michael Murphy
Name: Michael Murphy
Title: Managing Director

[*Signature Page to Amendment No. 1 to Sales Agreement*]

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Elizabeth Barrett, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date:	November 9, 2020	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, Molly Henderson, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2020

By: /s/ Molly Henderson
Molly Henderson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of UroGen Pharma, Ltd. (the “Company”) on Form 10-Q for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Elizabeth Barrett, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 9, 2020

By: /s/ Elizabeth Barrett

Elizabeth Barrett
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of UroGen Pharma, Ltd. (the "Company") on Form 10-Q for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter Pfreundschuh, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 9, 2020	By: /s/ Molly Henderson
	Molly Henderson
	Chief Financial Officer
	(Principal Financial and Accounting Officer)