UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

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	**Not applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
499 Park Avenue, New York, New York	**10014**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code:
(646) 768-9780

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Ordinary Shares, par value NIS0.01 per share	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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. (Check one):

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 Act). Yes ☐ No ☑

The aggregate market value of the ordinary shares held by non-affiliates of the registrant as of June 30, 2018 totaled approximately $719.5 million based on the closing price for the registrant's ordinary shares on that day as reported by the Nasdaq Global Market. Such value excludes ordinary shares held by executive officers, and directors as of June 29, 2018.

As of February 22, 2019, there were 20,476,443 of the registrant's ordinary shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	**10-K Part**
Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after registrant's fiscal year end of December 31, 2018 are incorporated by reference into Part III of this report	III

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PART I

INTRODUCTION

Unless otherwise indicated, "UroGen Pharma," "the Company," "our Company," "we," "us" and "our" refer to UroGen Pharma Ltd. and its subsidiary, Urogen Pharma, Inc.

UroGen and RTGel are trademarks of ours that we use in this Annual Report. This Annual Report also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, our trademarks and tradenames referred to in this Annual Report appear without the ® or ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to our trademark and tradenames. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We maintain our books and records in U.S. dollars, and prepare our financial statements in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, as issued by the Financial Accounting Standards Board, or FASB.

The terms "shekel," "Israeli shekel" and "NIS" refer to New Israeli Shekels, the lawful currency of the State of Israel, and the terms "dollar," "U.S. dollar" or "$" refer to United States dollars, the lawful currency of the United States. All references to "shares" in this Annual Report refer to ordinary shares of UroGen Pharma Ltd., par value NIS 0.01 per share.

We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or this Annual Report, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part I, Item 1A, "Risk Factors" in this Annual Report.

We may, in some cases, use words such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements and are based upon our current expectations, beliefs, estimates and projections, and various assumptions, many of which, by their nature, are inherently uncertain and beyond our control. Forward-looking statements in this Annual Report include, but are not limited to, statements about:

- the timing and conduct of our clinical trials of UGN-101, UGN-102 and our other product candidates, including statements regarding the timing, progress and results of current and future preclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of UGN-101, UGN-102 and our other product candidates;
- our plans regarding utilization of regulatory pathways that would allow for accelerated marketing approval in the United States;
- our expectations regarding timing for application for and receipt of regulatory approval for any of our product candidates;
- our ongoing and planned discovery and development of product candidates;
- our expectations regarding future growth, including our ability to develop, and obtain regulatory approval for, new product candidates;
- our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
- our ability to maintain our collaboration with Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc, enter into and successfully complete other collaborations, licensing arrangements or in-license or acquire rights to other products, product candidates or technologies;
- our plans to develop and commercialize our product candidates;
- our estimates regarding the market opportunity for our product candidates;

- our estimates regarding expenses, future revenues, capital requirements and the need for additional financing; our planned level of capital expenditures and our belief that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months;
- the impact of our research and development expenses as we continue developing product candidates;
- our expected use of the remaining net proceeds from our initial public offering; and
- the impact of government laws and regulations.

We caution you that the risks, uncertainties and other factors referenced above may not contain all of the risks, uncertainties and other factors that are important to you. In addition, we cannot guarantee future results, level of activity, performance or achievements. You should refer to the section of this Annual Report under Part I, Item 1A, “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

If our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. Any forward-looking statement made by us in this Annual Report speaks only as of the date of this Annual Report or as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed as exhibits to this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This Annual Report may contain market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this Annual Report is generally reliable, such information is inherently imprecise.

Item 1. Business

Overview

We are a clinical stage biopharmaceutical company focused on developing novel therapies designed to change the standard of care for urological pathologies. We have an innovative and broad pipeline of product candidates that we believe can overcome the deficiencies of current treatment options for a variety of urological conditions with a focus on uro-oncology. Our lead product candidates, UGN-101 and UGN-102, are proprietary formulations of the chemotherapy drug mitomycin a generic drug, which is currently used off-label for urothelial cancer treatment only in a water-based formulation as an adjuvant, or supplemental post-surgery, therapy. We are developing our product candidates as primary intervention without surgical removal or resection ("chemoablation" or "chemoablate") agents, which means they are designed to ablate tumors by minimally invasive means, to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma, or LG UTUC, and low-grade non-muscle invasive bladder cancer or LG NMIBC. We believe that UGN-101 and UGN-102, which are both local drug therapies, have the potential to significantly improve patients' quality of life by replacing costly, sub-optimal and burdensome tumor resection and kidney removal surgeries as the first-line standard of care. Additionally, we believe that our product candidates, which are based on novel formulations of previously approved drugs, may qualify for streamlined regulatory pathways to market approval.

Our lead product candidates, UGN-101 and UGN-102, are formulated using our proprietary reverse thermal hydrogel, or RTGel, technology. 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 without compromising the safety of the patient or interfering with the natural flow of urine from the upper urinary tract to the bladder. Our formulations are designed to achieve this by increasing the dwell time as well as the tissue coverage 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. No drugs have been approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of LG NMIBC, in more than 15 years and for the treatment of LG UTUC, there are no drugs approved.

We are currently evaluating the safety and efficacy of UGN-101, our novel sustained-release formulation of mitomycin, in patients with LG UTUC in a Phase 3 pivotal, single-arm, open label clinical trial, which follows a recently completed "Compassionate Use" program for UGN-101 for the treatment of the same indication. The Compassionate Use Program was conducted in the U.S., Europe and Israel. "Compassionate Use" is the use outside of a clinical trial of an investigational, or not approved, medical product when patient enrollment in a clinical trial is not possible, typically due to patient ineligibility or a lack of ongoing clinical trials. In the Compassionate Use Program, 22 patients were enrolled, 18 of whom had confirmed LG UTUC. Of the 18 patients, 13 patients had completed the six-weekly treatment regimen and were evaluated for tumor response. These 13 patients were evaluated for tumor response at the primary evaluation time either endoscopically or through the use of a nonsurgical viewing instrument. Complete response was also confirmed by a cytology (urine) confirmation. Eight, or approximately 44%, achieved a complete response, with a median durability of response without recurrence of 12 months to date, based on investigator reports.

Five out of the 13 evaluated patients achieved a partial response at the primary evaluation time. One patient who achieved a partial response received three additional monthly courses of UGN-101, and thereafter achieved a complete response. In this Compassionate Use program, UGN-101 had been observed to be well-tolerated. We have obtained Orphan Drug, Fast Track and Breakthrough Therapy Designations for UGN-101 for the treatment of patients with LG UTUC. We have initiated a rolling review of the UGN-101 New Drug Application, or NDA, using the 505(b)(2) pathway through submission of nonclinical data to the FDA in December 2018, and expect to complete the NDA submission process in 2019.

In addition, we evaluated the safety and dosing schedule of UGN-102, our novel sustained-release high dose formulation of mitomycin, for the treatment of LG NMIBC in a Phase 2a study that was conducted in Europe and Israel. The 80mg mitomycin dose was associated with acceptable treatment emergent adverse events and was observed to produce tumor ablation in the majority of subjects treated with this dose. Treatment with UGN-102 was also observed to produce durable complete response at 12 months. We submitted an IND for UGN-102 in June 2018 and have commenced a U.S.-based Phase 2b clinical trial for UGN-102 evaluating the safety and efficacy of UGN-102 in the U.S. We also intend to pursue a 505(b)(2) regulatory pathway for UGN-102. We believe that UGN-102 has the potential to be a new therapeutic option for the treatment of intermediate risk LG NMIBC patients.

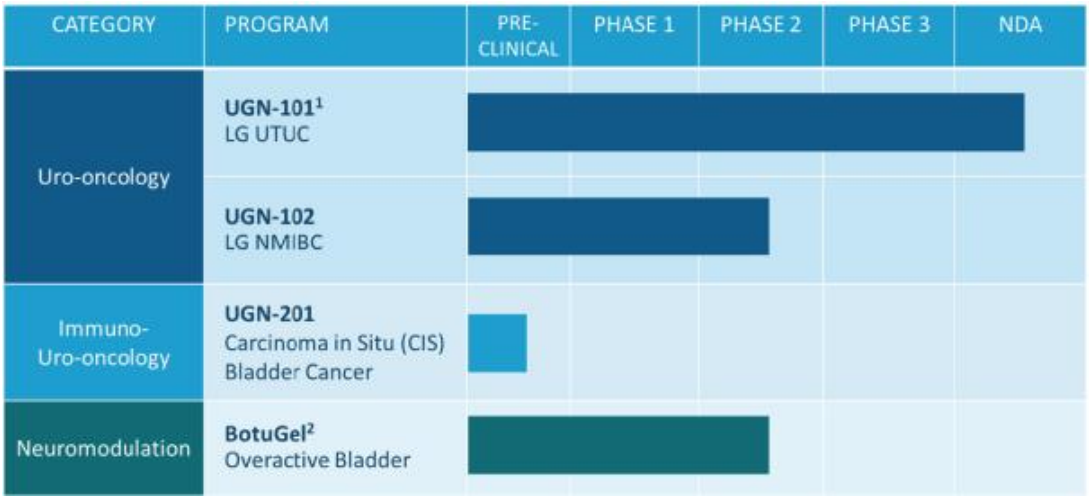
We believe that urothelial cancer, which is comprised of bladder cancer and UTUC, affects a large and underserved patient population. Annual expenditures for Medicare alone in the United States for the treatment of urothelial cancer were estimated to have been at least $4.0 billion in 2010 and are projected to be at least $5.0 billion in 2020. The majority of the expenditures is spent on tumor resection surgeries such as transurethral resection of bladder tumor, or TURBT, and upper urinary tract removals. In 2015, the estimated prevalence of urothelial cancer in the United States was 700,000 with an annual incidence of approximately 80,000. The prevalence of each of LG NMIBC and LG UTUC in the United States was approximately 343,000 and 14,500, respectively.

Our clinical stage pipeline also includes UGN-201, our proprietary immunotherapy product candidate for the treatment of high-grade NMIBC, which may include Carcinoma in Situ, or CIS. UGN-201 is a novel, liquid formulation of imiquimod, a generic toll-like receptor 7, or TLR7, agonist. 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 or sustained release chemotherapy drugs like UGN-102, could represent a valid alternative to the current standard of care for the post-TURBT adjuvant treatment of high-grade NMIBC.

BotuGel is a proprietary novel RTGel-based formulation of BOTOX®, a branded drug, that we believe can potentially serve as an effective treatment option for patients suffering from overactive bladder. In October 2016, we announced the licensing of the worldwide rights to RTGel in combination with neurotoxins, including BOTOX®, to Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc (the "Allergan Agreement"). 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 the RTGel in combination with BOTOX®. In October 2017, Allergan commenced a Phase 2 clinical trial of BotuGel for the treatment of overactive bladder.

Our Product Candidate Pipeline

The following chart summarizes the current status of our product candidate pipeline:



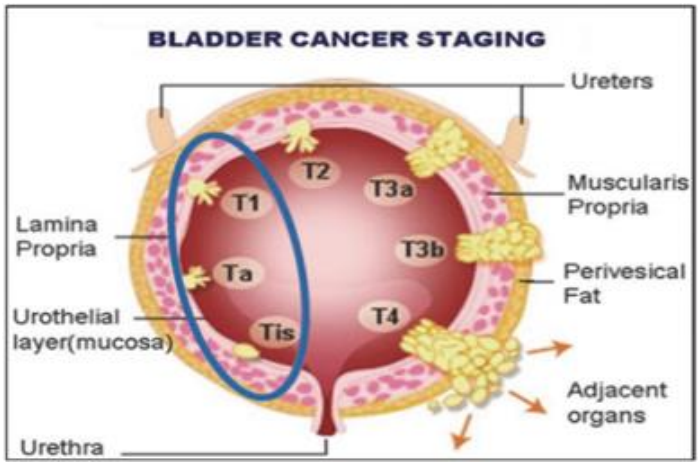
1 Rolling NDA submission initiated in December 2018
2 Licensed to Allergan

Uro-Oncological Indications Targeted by Our Product Candidates

Our product candidates are administered locally using the standard practice of intravesical instillation directly into the bladder or upper urinary tract via a catheter. The instillation into the bladder is expected to take place in a physician's office as a same-day treatment, in comparison with TURBT or similar tumor surgical procedures, which are operations conducted under general anesthesia in a hospital setting and may require at least an overnight stay. Surgical tumor removal often has limited success due to the inability to properly identify, reach and resect all tumors. We believe that an effective chemoablation agent can potentially provide better eradication of tumors irrespective of the detectability and location of the tumors. In addition, by removing the need for surgery, patients may avoid potential complications associated with surgery and hospital-acquired infections.

Bladder Cancer

The bladder is a hollow organ in the pelvis with flexible muscular walls. Its main function is to store urine before it leaves the body. Urine is produced by the kidneys and is then carried to the bladder through the upper urinary tract tubes, called ureters. The bladder wall has four main layers. The innermost lining is comprised of cells called urothelial or transitional cells, and this inner layer is called the urothelium or transitional epithelium. Beneath the urothelium, there is a layer called the lamina propria. Next is a thick layer of muscle called the muscularis propria followed by a layer of perivesical fat.

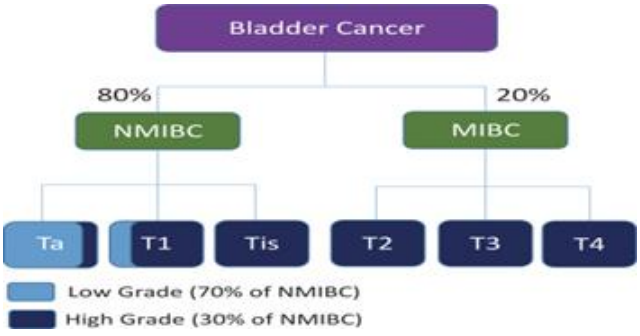


NMIBC tumor types are circled

Bladder cancer accounts for approximately 90% to 95% of all new cases of urothelial cancer in the United States. Bladder cancer is nearly three to four times more common in men than women, and, with an average age at diagnosis of 72, mostly affects the elderly. Bladder cancers are described as non-muscle invasive or muscle-invasive based on how far into the wall of the bladder they have invaded. The magnitude and rate of the spreading of the cancer is called “staging,” which ranges from Ta to T1 for NMIBC, and T2 to T4 for muscle-invasive bladder cancers, as defined by the American Joint Committee on Cancer TNM System. In addition, Carcinoma in Situ, or CIS, a form of NMIBC, has a staging designation of Tis. Muscle-invasive bladder cancer, or MIBC, has an average five-year survival rate of 15% to 63%, depending on severity. MIBC represents a worse prognosis than NMIBC, which has a five-year survival rate of approximately 90%. NMIBC accounts for approximately 80% of all new cases of bladder cancer diagnosed in the United States each year, which corresponds to an estimated annual incidence and prevalence of approximately 60,000 and 500,000 cases, respectively.

Non-muscle invasive bladder cancers are divided into two grades, low and high, with high-grade tumors more likely to recur and progress into muscle-invasive tumors. CIS tumors are all high-grade. Overall, approximately 70% of patients with NMIBC present with low-grade disease at diagnosis.

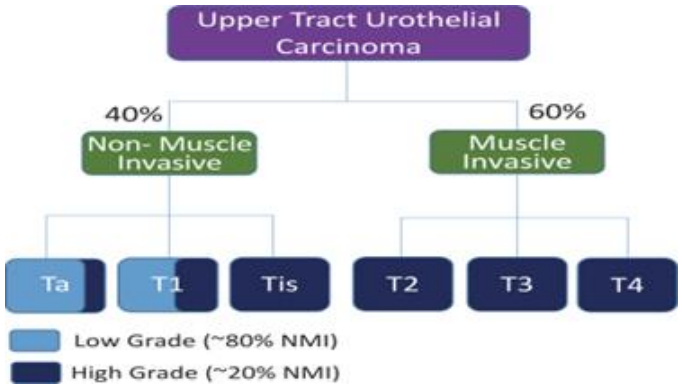
The chart below indicates the prevalence of stage and grade of bladder cancer in the United States.



Upper Tract Urothelial Carcinoma

UTUC refers to malignant changes of the transitional urothelial cells lining the upper urinary tract of the renal pelvis and ureter. UTUC typically exhibits high local recurrence and in cases of high-grade disease, development of metastases. Similar to NMIBC, the prognosis of patients with UTUC correlates with the stage and grade of disease at the time of initial diagnosis. The key prognostic factor at the time of diagnosis of UTUC is whether the tumor is in the muscle-invasive or non-muscle invasive stage. The number, size and location of tumors presented also represent important prognostic factors for UTUC. Approximately 40% of the patients diagnosed annually with UTUC in the United States present with non-muscle invasive UTUC. Non-muscle invasive UTUC is also divided into two grades, low and high.

The chart below indicates the prevalence of stage and grade of UTUC in the United States.



UTUC accounts for approximately 5% to 10% of all new cases of urothelial cancer, which corresponds to an estimated annual incidence in the United States of up to 7,500 cases. In 2015, the estimated prevalence of LG UTUC in the United States was approximately 14,500. UTUC is nearly three times more common in men than women and affects mostly the elderly.

There are currently no drugs approved by the FDA for the treatment of LG UTUC, representing a significant unmet medical need. Moreover, the anatomical complexity of the upper urinary tract, particularly the renal pelvis, presents significant challenges to the proper identification and ability to reach and resect all tumors in tumor resection surgical procedures (i.e. endoscopic laser ablation). Consequently, patients with high-grade disease or patients with low-grade disease that present with a large number of tumors typically undergo radical nephroureterectomy, which is kidney and upper urinary tract removal. In addition, the stage and grade of UTUC are often misdiagnosed. Due to these factors, the current standard of care for the treatment of UTUC is radical nephroureterectomy.

Endoscopic tumor resection, which aims to be a kidney sparing surgical procedure, is conducted only in patients with low-grade disease that present with a limited number of tumors. However, the upper urinary tract's anatomical constraints limit the effectiveness of surgical procedures and adjuvant chemotherapy treatments, leading to high rates of recurrence and risk for progression in this patient population. In a study published in 2009 in the Journal of Endourology evaluating 57 patients with LG UTUC who underwent tumor resections, 89.5% of patients recurred with a mean of 5.5 recurrences per patient over a four-year period. Moreover, approximately 20% of the patients in this study progressed and ultimately underwent kidney and upper urinary tract removal.

Non-Muscle Invasive Bladder Cancer

Patients treated with the current standard of care have up to an approximately 60% rate of recurrence of NMIBC within one year, and the rate of progression of NMIBC to MIBC is between 20% and 30%. As a consequence, NMIBC patients often undergo multiple repeat TURBT procedures.

The standard of care for treating LG NMIBC patients is TURBT. TURBT is a surgical operation for tumor removal conducted under general anesthesia in a hospital setting and may require an overnight stay. Moreover, TURBT's success is tied to the physician's ability to overcome challenges in properly identifying, reaching and resecting all tumors. No drugs have been approved by the FDA as first-line treatment for NMIBC and only three drugs have been approved by the FDA for NMIBC, all used as adjuvant treatment, following TURBT. Efficacy of drug treatments has historically been limited due to challenges presented by bladder physiology, specifically the fact that urine is produced and voided frequently, thus diluting the concentration of the drug almost immediately and causing the excretion of the drug from the bladder at first urine voiding.

Recent Developments

Appointment of New Chief Executive Officer

On January 3, 2019, we appointed Elizabeth Barrett as our President and Chief Executive Officer, replacing Ron Bentsur in those capacities. Concurrently, Ms. Barrett was appointed as a member of our board of directors and Mr. Bentsur resigned from our board of directors.

Phase 3 OLYMPUS Clinical Trial of UGN-101: Interim Data

On January 8, 2019, we announced interim results from our ongoing pivotal Phase 3 OLYMPUS clinical trial of UGN-101 (mitomycin gel) for instillation, an investigational mitomycin formulation for the non-surgical treatment of LG UTUC. This analysis showed that on an intent-to-treat basis, 57% of patients achieved a complete response, or CR, rate at their primary disease evaluation (PDE, or the primary endpoint) which was conducted four to six weeks after completion of UGN-101 treatment. All evaluated patients in CR for whom six-month follow-up data was available remained disease free at six months. Durability is a secondary endpoint for the trial.

The Phase 3 OLYMPUS clinical trial is an international, multi-center trial, which completed enrollment with 71 patients in December 2018. At the time of the interim data analysis, of the 71 patients enrolled in the trial, 61 patients had been evaluated for the primary endpoint which was a CR as defined as a negative ureteroscopic evaluation and a negative wash cytology. The remaining 10 patients were awaiting PDE evaluation.

Approximately 45% of tumors treated were categorized as unresectable by surgery at baseline. Of the patients who achieved CR, we now have six-month durability on half of these patients.

With regard to the safety profile of UGN-101, most treatment-emergent adverse events were characterized as mild or moderate and were transient and in line with ureteral procedures. These included ureteral stricture/stenosis, urinary tract infection/urosepsis, nausea and vomiting, flank pain and renal failure.

We intend to seek regulatory approval of UGN-101 in LG UTUC based on primary endpoint data from substantially all 71 patients. We initiated a rolling submission of an NDA to the FDA in December 2018. The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of UTUC. If approved, UGN-101 would be the first drug approved by the FDA for the treatment of LG UTUC.

January 2019 Underwritten Public Offering

On January 28, 2019, we completed an underwritten public offering of 4,207,317 of our 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 us from the offering were approximately $161.8 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

Our Competitive Strengths

We believe our lead product candidates for uro-oncology, which are being developed by leveraging our expertise in drug development and our proprietary formulation technology, have the ability to replace the costly, sub-optimal and burdensome tumor resection procedures that represent the current first-line standard of care. Furthermore, we believe our proprietary formulation technology has broad applications and may allow us to develop additional product candidates for indications within and beyond the urinary tract.

Potential ability to develop minimally invasive, first-line drug therapies for uro-oncology. Leveraging our innovative formulation technology, we are developing two lead product candidates, UGN-101 and UGN-102, as potential replacements to first-line treatment for LG UTUC and NMIBC, respectively. Both UGN-101 and UGN-102 are chemoablation agents designed to overcome the challenges posed by the anatomy of the urinary tract by increasing the dwell time and enhancing the tissue coverage of mitomycin. Clinical data generated to date supports our belief that our lead product candidates may provide new therapeutic options to the current first-line tumor surgical procedures, providing a chemoablation treatment that has the potential to better eradicate tumors irrespective of their detectability and location within the urinary tract. Of the 13 LG UTUC patients treated with UGN-101 in a recently-completed Compassionate Use program and evaluated endoscopically or through the use of a nonsurgical viewing instrument for efficacy, eight achieved a complete response and the remaining five achieved a partial response at the primary evaluation time. In the case of UGN-102, 19 of 22, or approximately 86%, of the patients treated with the high dose of UGN-102 in a recently-completed Phase 2a trial conducted in Europe and Israel, evaluating the efficacy and safety of UGN-102's chemoablation properties, achieved a complete response at the primary evaluation time.

Expertise in developing proprietary formulations of drugs for clinical benefit. We focus on developing proprietary RTGel formulations of previously approved drugs whose efficacy for a particular indication is limited by current formulations or routes of administration. While we have not yet brought a drug to market, our expertise has enabled us to develop proprietary RTGel-based formulations for several previously approved drugs to date, including clinical stage proprietary formulations of mitomycin and botulinum toxin. Our formulations are designed to significantly increase the dwell time and exposure of the drugs to the target sites and limit the need for urine retention, potentially providing enhanced clinical activity, reduced patient burden and increased patient compliance over existing formulations and modes of administration. We have a strong research and development team to advance our product candidates.

Lower development risks and costs for our pipeline product candidates. We expect the approval process for each of our current uro-oncology product candidates to be conducted according to the FDA's 505(b)(2) regulatory pathway, a streamlined, lower-cost pathway to drug approval when compared to traditional drug development. Furthermore, two of our product candidates, UGN-101 and UGN-201, have received Orphan Drug Designation from the FDA for the treatment of LG UTUC and CIS, respectively, which we expect will provide seven years of regulatory exclusivity following FDA approval, if received. UGN-101 was also granted Fast Track and Breakthrough Therapy designations by the FDA. We submitted an IND for UGN-101 in November 2016, which was accepted by the FDA in December 2016. We commenced a single pivotal, open-label, single-arm Phase 3 clinical trial for the treatment of LG UTUC in the first quarter of 2017. The clinical trial was conducted in the United States and Israel with enrollment of 71 patients. We submitted an IND for UGN-102 in June 2018 which was accepted by the FDA. We have commenced an open-label, single-arm Phase 2b clinical trial for the treatment of LG NMIBC. Additionally, we expect that our lead candidates are more likely to show an acceptable safety profile because they are novel formulations of previously approved drugs.

Leverageable proprietary formulation technology. We believe that RTGel has multiple potential applications beyond urology. Our formulation know-how may enable us to develop different drug formulations to facilitate the delivery, retention and sustained release of active drugs to a variety of targeted body cavities. We believe that our proprietary formulation technology can improve the efficacy of locally administered drugs in body cavities such as the stomach, uterus and rectum that present anatomical and physiological challenges related to frequent wash out, rapid excretion and bodily secretions. In October 2016, we announced that we licensed worldwide rights to a proprietary RTGel formulation with BOTOX® to Allergan for the treatment of overactive bladder and related indications pursuant to the Allergan Agreement.

Strong intellectual property position. We have a robust intellectual property portfolio that includes 32 issued patents worldwide and more than 45 pending patent applications filed worldwide. In the United States, we have 15 granted patents that are directed to protect our lead product candidates UGN-101, UGN-102, UGN-201 and Botugel as well as our RTGel technology and our other potential product candidates that are under preclinical review. These patents claim methods, systems, and novel compositions and combinations for treating cancer in internal cavities, in particular treating a urinary tract cancer. These issued patents are expected to expire between 2024 and 2035. Additionally, the FDA has granted Orphan Drug Designation to UGN-101 for the treatment of LG UTUC and UGN-201 for the treatment of CIS bladder cancer, which potentially entitles us to regulatory exclusivity for UGN-101 and UGN-201 for seven years following approval, if granted, by the FDA.

Experienced and accomplished leadership team with proven track record. We have an experienced management team, with each member possessing deep experience in the biopharmaceutical and related industries. Our Chief Executive Officer, Liz Barrett was CEO of Novartis Oncology and a member of the Executive Committee of Novartis. She previously served as Global President of Oncology at Pfizer Inc. At Pfizer, she held numerous leadership positions, including President of Global Innovative Pharma for Europe, President of the Specialty Care Business Unit for North America, and President of United States Oncology. Prior to Pfizer, she was Vice President and General Manager of the Oncology Business Unit at Cephalon Inc. Ms. Barrett also worked at Johnson & Johnson. In addition, our Chairman, Arie Belldegrun, M.D., is a seasoned biotech executive and was the founder, Chairman, Chief Executive Officer and President of Kite Pharma, Inc., which was recently sold to Gilead Sciences, Inc. Dr. Belldegrun is also a urologist by training. We believe that our leadership team is well-positioned to lead us through clinical development, regulatory approval and commercialization for our product candidates.

Our Growth Strategy

We intend to become the leading biopharmaceutical company focused on the development of novel therapies for local treatment of urological pathologies. The key elements of our strategy are as follows:

Establish each of our lead product candidates, UGN-101 and UGN-102, as the first-line treatment in its target indication. We believe that data from treatments in our Compassionate Use program conducted in the United States, Europe and Israel provide preliminary evidence of the potential safety and efficacy of UGN-101 for the treatment of LG UTUC. We submitted an IND for UGN-101 with the FDA in November 2016, which was accepted by the FDA in December 2016, and we commenced a single pivotal Phase 3 clinical trial in the first quarter of 2017 pursuant to the FDA's 505(b)(2) regulatory pathway. We completed enrollment in that trial in December 2018, and commenced a rolling NDA submission to the FDA.

We completed a Phase 2a randomized, open-label, single-arm, active-controlled clinical trial of UGN-102 for the treatment of LG NMIBC, conducted in Europe and Israel. We submitted an IND for UGN-102 in June 2018, and, have commenced a Phase 2b clinical trial in NMIBC. We also expect to pursue a 505(b)(2) regulatory pathway for UGN-102. We believe that these local drug treatments have the potential to offer an alternative to costly, sub-optimal and burdensome tumor resection and kidney removal surgeries to become the first-line standard of care.

Expand our uro-oncology product pipeline. A Phase 2 clinical trial of UGN-201 was completed under an IND in 12 patients with CIS, an aggressive form of high-grade urinary bladder cancer. In the trial, 10 patients were evaluated for response, of which 20% achieved a complete response rate with UGN-201 as a single-agent treatment. We believe that combining UGN-201 with immune checkpoint inhibitors or chemotherapy has the potential to serve as a treatment option for high-grade urothelial tumors. We are also pursuing preclinical oncology programs that take advantage of our RTGel technology. We are conducting preclinical programs for high-grade bladder cancer. We may also evaluate in-licensing or acquiring additional product candidates for the treatment of urological cancers.

Utilize our proprietary technology to expand our pipeline to other body cavities and indications. We believe that RTGel may be suitable for multiple additional applications. Our know-how may enable us to develop different drug formulations to facilitate the delivery, retention, increased dwell time and sustained release of active drugs to a variety of targeted body cavities. Beyond the urinary tract, we may target the gastrointestinal tract and the female reproductive system. In the future, we may also choose to develop our RTGel technology in combination with other drugs to treat cancer and other indications endemic to such body cavities.

Evaluate and selectively pursue potential collaborations to develop improved formulations and product life-cycle management strategies. We entered into the Allergan Agreement as part of our strategy to research, develop, manufacture and commercialize pharmaceutical products that contain RTGel alone or in combination with certain other active ingredients. This collaboration provides us with funding for our research and development efforts and may accelerate the development and commercialization of our approved products, if any. In addition, we may in-license or acquire additional product candidates for urological indications. Such collaborations would allow us to obtain financial support and to capitalize on the expertise and resources of our potential partners, which could allow for new and improved versions of approved or clinical stage drugs and could accelerate the development and commercialization of additional product candidates.

RTGel: Our Reverse Thermal Hydrogel Platform Technology

We have developed RTGel, a novel proprietary polymeric biocompatible, reverse thermal gelation hydrogel, which, unlike the general characteristics of most forms of matter, is liquid at lower temperatures and converts into gel form when heated. We believe that these characteristics promote ease of delivery into and retention of drugs in body cavities, including the bladder and the upper urinary tract, by conforming to the anatomy of the target organ while preventing rapid excretion of the drug. The following images show the progression of five stages of RTGel at different temperatures.

RTGel's components are polymer-based and are inactive ingredients that have been approved by the FDA for use in other products such as Oraqix, a periodontal gel, Namenda, an oral solution for Alzheimer's disease, and Xeloda, an oral chemotherapy. We formulate RTGel with an active drug: mitomycin in the case of UGN-101 and UGN-102, and botulinum toxin in the case of BotuGel. The resulting formulations are instilled intravesically in liquid form directly into the bladder or upper urinary tract using standard instillation methodologies via catheters and thereafter convert into gel form at body temperature. Subsequently, upon contact with urine, RTGel gradually dissolves and releases the active drug over a period of several hours and is less affected by urine creation and voiding cycles as compared to water formulations.

We believe that RTGel, when formulated with an active drug, may allow for the improved efficacy of treatment of various types of urothelial cancer without compromising the safety of the patient or interfering with the natural flow of fluids from the urinary tract to the bladder. RTGel achieves this by:

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

- administering higher doses of an active drug than would otherwise be possible using standard water-based formulations. For instance, it is only possible to dissolve 0.5 mg of mitomycin in 1 ml of water while it is possible to formulate up to 8 mg of mitomycin with 1 ml of RTGel; and
- maintaining the active drug's molecular structure and mode of action.

These characteristics of RTGel enable sustained release of mitomycin in the urinary tract for both UGN-101 and UGN-102, and of botulinum toxin in the case of BotuGel. Further, RTGel may be particularly effective in the bladder and upper urinary tract where tumor visibility and access are challenging, and where there exists a significant amount of urine flow and voiding. We believe that these characteristics of RTGel may prove useful for the local delivery of active drugs to other bodily cavities in addition to the bladder and upper urinary tract.

Mitomycin—Our Target Active Drug for the Treatment of UTUC and NMIBC

Mitomycin is a generic drug currently utilized off-label as the standard adjuvant chemotherapy for the treatment of LG UTUC and NMIBC after tumor resection, such as TURBT. Mitomycin, a chemotherapy agent, is typically administered using a water-based formulation, which has a relatively short dwell time in the bladder limited to first voiding. Mitomycin often causes temporary irritation of the bladder, including the need to urinate frequently and urgently. This often results in first voiding occurring shortly after instillation. In the upper urinary tract, the dwell time is limited to approximately five minutes as urine flows continuously and no active retention by the patient is feasible. Numerous in vitro models, in vivo studies and computer simulations have shown that increased dwell time of mitomycin in the bladder results in more efficacious treatment of bladder cancer. In one such study, it was shown that mitomycin activity increased with exposure time. Specifically, the MIC90, or mean inhibitory concentration that causes 90% inhibition in cell growth, was 11-fold lower when exposure time was increased from 30 minutes to eight hours.

Mitomycin's main effect is on the cancer cell's DNA and has been demonstrated to be most effective when the cancer cell is in its S-phase, or synthesis phase, during which the DNA is replicated. Each cancer cell goes through various phases during the cell cycle. However, the cell cycle is not synchronized in all cancer cells, which means that at any given point in time only a portion of the cancer cells are at their S-phase, or susceptible to the instilled mitomycin in the bladder. Thus, because our RTGel-based mitomycin sustained-release formulations, UGN-101 and UGN-102, provide for a significantly longer dwell time of mitomycin in the upper urinary tract and in the bladder as compared to standard mitomycin water formulations, there is a greater chance that tumor cells will go through their S-phase while the instilled mitomycin is still present using UGN-101 or UGN-102, potentially resulting in a higher percentage of tumor cells being affected by the instilled mitomycin.

Limitations of Current Therapies for Upper Tract Urothelial Carcinoma

There are currently no drugs approved by the FDA for the treatment of UTUC, representing a significant unmet medical need. The current standard-of-care for the treatment of UTUC is radical nephroureterectomy, which is complete kidney and upper urinary tract removal. Recent advances in resection instrument technology have allowed physicians in some cases to treat patients with LG UTUC using endoscopic tumor resection, a kidney-sparing treatment, rather than nephroureterectomy followed by adjuvant chemotherapy, typically mitomycin, treatment. However, the specific anatomy and physiology of the upper urinary tract make the performance of organ-sparing endoscopic tumor resection and instillation of adjuvant chemotherapy challenging, leading to high recurrence rates. Patients often undergo multiple endoscopic resection procedures, which increases the probability of potential complications of resection, including perforation and ureteral stricture, or a narrowing of the ureter. A recent study published in 2009 in the Journal of Endourology, evaluating 57 patients with LG UTUC who underwent tumor resections showed that recurrence occurred in 89.5% of patients, with a mean of 5.5 recurrences per patient, over a four-year period. Moreover, approximately 20% of the patients in this study progressed and ultimately underwent kidney and upper tract removal.

Mitomycin is currently administered using a water-based formulation, which limits the dwell time in the bladder until first voiding. In the upper urinary tract, the dwell time of mitomycin is approximately five minutes as urine flows continuously and no active retention by the patient is feasible.

Our Solution: UGN-101

UGN-101 is our novel sustained-release RTGel-based formulation of mitomycin that we are developing for the treatment of LG UTUC. RTGel is liquid at lower temperatures and converts into gel form at body temperature. This temperature-dependent viscosity characteristic allows for simple and convenient instillation of the cooled UGN-101 in its liquid form to the upper urinary tract via standard catheters. Once instilled, UGN-101 converts into gel form at body temperature. Subsequently, upon contact with urine, UGN-101 gradually dissolves and releases the active drug, mitomycin, over a period of several hours versus several minutes for mitomycin in its water-based formulation. We believe that this substantial increase in dwell time of mitomycin positions UGN-101 as a potential first-line chemoablation treatment for LG UTUC, potentially sparing patients from repeated tumor resection surgeries and potentially reducing the need for bladder and upper urinary tract surgeries, including upper urinary tract removal.

The Orphan Drug Designation granted to UGN-101 for the treatment of UTUC potentially entitles us to regulatory exclusivity for UGN-101 for seven years following approval by the FDA, if granted. We believe Breakthrough Designation may allow us to obtain priority review of our NDA submission. We have initiated a rolling review of the NDA through submission of nonclinical data to the FDA in December 2018, we expect to complete the NDA submission process in 2019.

Initial Clinical Results for UGN-101

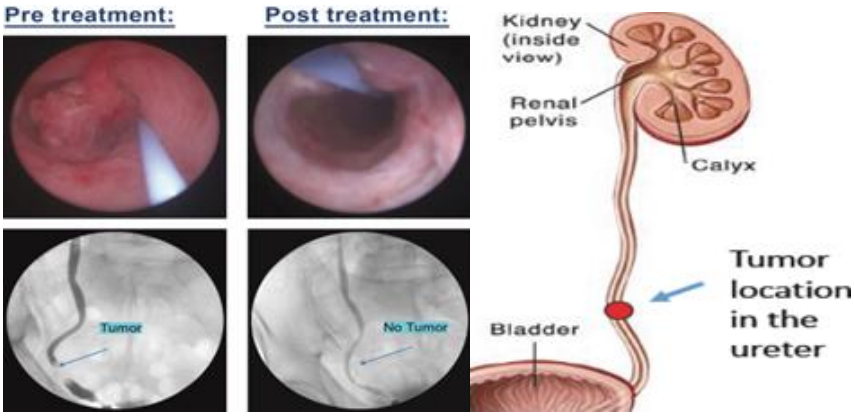
UGN-101 was evaluated in an investigator-initiated Compassionate Use program for the treatment of severe, non-resectable UTUC, which commenced in September 2014. The Compassionate Use program, which was conducted in the United States, Europe and Israel, included patients diagnosed with unilateral and bilateral low- and high-grade UTUC, as well as patients with a solitary kidney. Patients in the Compassionate Use program received six weekly instillations of UGN-101 administered directly to the upper urinary tract. Consistent with the nature of Compassionate Use programs, which are investigator-initiated programs, a statistical plan or primary endpoint was not used as in a regular clinical trial. Approximately four weeks following the completion of treatment, the patients were evaluated for response. Patients were visually evaluated endoscopically or through the use of a nonsurgical viewing instrument, with additional confirmation through urine cytology, or examination of cells collected from a urine specimen. At the evaluation time, which was approximately four weeks following the completion of the treatment course, patients were deemed to have achieved a complete response if, in the judgment of the physician, no tumors initially diagnosed by the physician were detected and a partial response if, in the judgment of the physician, the size or number of tumors had decreased or if, following an initial complete response, there is tumor recurrence within three months after the evaluation time. Safety and feasibility of treatment with UGN-101 were also evaluated. Twenty-two patients were treated in the study, with more than 130 instillations of UGN-101 performed. Of the 22 patients treated, 18 were assessed as having LG UTUC. Of the 18 patients assessed as having low-grade disease, 14 completed six instillations of UGN-101. Of these 14 patients, 13 were evaluated for response and one could not be evaluated to confirm response. Of the 13 patients who were evaluated for response, eight achieved a complete response and five, achieved a partial response at the primary evaluation time. One of the patients who received a partial response subsequently received an additional three courses of UGN-101 and thereafter achieved a complete response.

Of the eight patients who have achieved a complete response at the primary evaluation time, we are aware of three patients who have subsequently experienced recurrences to date. Recurrences were generally of small tumors, a few millimeters in diameter, and were manageable by endoscopic tumor resection. To our knowledge, five of the eight patients have not recurred to date, with three of the five patients having achieved durability of 12 months or greater to date. The median durability for these eight patients is still ongoing and is now greater than twelve months, based on investigator reports. The follow-up evaluation plan for patients in our Compassionate Use program is determined by each individual investigator and varies from patient to patient, and some patients have not undergone follow-up evaluation or have been lost to follow-up. As part of the ongoing single pivotal Phase 3 clinical trial, in order to potentially further extend durability, patients who achieve a complete response at the primary disease evaluation visit will be followed for durability of response and may receive monthly maintenance UGN-101 instillations for up to 12 months.

UGN-101 was observed to be well-tolerated in the Compassionate Use Program. The main observed adverse events, or AEs, related to UGN-101 have been fatigue, allergic reaction, nausea, fever, and dysuria, which is pain or difficulty while urinating. All of the AEs that have been observed to date are known side effects associated with the use of mitomycin and appear on the mitomycin label as potential side effects. Various serious adverse events, or SAEs, were also reported most of which were determined to be unrelated to treatment with UGN-101. These SAEs include acute pyelonephritis, a kidney infection caused by bacteria; hydronephrosis, which is the swelling of the upper urinary tract due to a build-up of urine caused by some degree of obstruction; severe arrhythmia, which is a severe abnormal heart rhythm; cardiac asthma, which is a medical diagnosis of wheezing, coughing or shortness of breath due to congestive heart failure; aggravation of renal function; hyperkalemia, which is a condition of elevated levels of potassium in the blood; pancytopenia, which is a deficiency of red cells, white cells and platelets in the blood; scarring and narrowing of the calyceal infundibulum, which was most probably present at baseline; asymptomatic extravasation from the upper tract, which is leakage of fluids from the upper tract to the surrounding tissue; and death.

This Compassionate Use program was allowed by the FDA to accumulate safety and efficacy data. In the first quarter of 2017, we commenced a pivotal, open-label, single-arm Phase 3 clinical trial of UGN-101 for the treatment of LG UTUC.

The following images show pre-treatment and post- UGN-101 treatment results from one LG UTUC patient in the Compassionate Use program.



(Courtesy of Dr. J. Gregory Wirth, Geneva Hospital, Switzerland)

The top left image is a pre-treatment ureteroscopic view of a tumor located in the ureter. The bottom left image is a pre-treatment x-ray revealing an obstruction within the ureter in which no contrast (black) can be visualized in the distal ureter (denoted by arrow). The top right image is a post-treatment ureteroscopic view of the same location following UGN-101 chemoablation treatment. The bottom right image is a post-treatment x-ray of the ureter which reveals no obstruction within the ureter.

FDA Pathway for UGN-101

As part of our IND-enabling work for UGN-101, we completed a large-scale good laboratory practices, or GLP, toxicity study in an upper urinary tract swine model in which more than 250 instillations of UGN-101 were performed. This study evaluated the safety of the procedure and UGN-101 administration, also utilizing higher dosage levels than those used in the clinical settings. In this GLP toxicology study, the instillation of UGN-101 was found to be safe. We are also conducting chemistry, manufacturing and controls, or CMC, studies as part of our development process.

Next Steps in the Clinical Development of UGN-101

Based on discussions with the FDA, we intend to develop UGN-101 through the FDA's 505(b)(2) regulatory pathway. We submitted an IND for UGN-101 in November 2016, which was accepted by the FDA in December 2016. We commenced a pivotal, open-label, single-arm Phase 3 clinical trial of UGN-101 for the treatment of LG UTUC in the first quarter of 2017. The company completed recruitment in the fourth quarter of 2018, and is currently in a rolling NDA submission process which is expected to be completed in the second half of 2019. Based on UGN-101's Breakthrough Therapy Designation, the company expects a six-month priority review process from the completion and FDA's acceptance for filing of the NDA submission.

This Phase 3 clinical trial is being conducted in the United States and Israel with enrollment of 71 patients. We expect this clinical trial, if successfully completed, to support an NDA for LG UTUC for UGN-101. The patients will initially receive six weekly instillations of UGN-101. The primary efficacy endpoint is the complete response rate, defined as the percentage of patients with a complete response (CR) at the primary disease evaluation (PDE) visit, which occurs approximately four to five weeks following the sixth weekly instillation. In addition, patients who achieve a CR at the PDE visit will be followed for durability of response. Such patients may also receive monthly UGN-101 maintenance instillations for up to 12 months. We anticipate submitting the clinical data to the NDA for UGN-101 in the second half of 2019. In the Phase 3 trial, to date, UGN-101 therapy has been well tolerated. Adverse events encountered in treated subjects include the expected effects of mitomycin administration to the upper urinary tract (ureteral inflammation and stenosis, pain and urinary tract irritation). In addition, perturbation of laboratory measures of renal and hematopoietic function has been observed.

UGN-102: Our Product Candidate for the Treatment of Low-Grade Non-Muscle Invasive Bladder Cancer

UGN-102 is our novel sustained-release formulation of high dose mitomycin that we are developing for the treatment of LG NMIBC as a first-line non-surgical chemoablation alternative to TURBT. We recently completed a Phase 2a randomized, open-label, three arm, active-controlled clinical trial in Europe and Israel that evaluated the safety and efficacy of UGN-102 (40mg and 80mg mitomycin) compared to 40mg mitomycin in water in patients with LG NMIBC. We commenced the trial in September 2013 and the last patient was enrolled in March 2016. For the primary endpoint, 19 of 22, or approximately 86%, of the patients with confirmed LG NMIBC in the 80mg mitomycin dose group of UGN-102 achieved a complete response.

We have submitted an IND for UGN-102 in June 2018, as well as commenced a Phase 2b clinical trial in patients with LG NMIBC at intermediate risk of recurrence in the US and in Israel.

Limitations of Current Therapies for Non-Muscle Invasive Bladder Cancer

Tumor grade and stage are the most important variables for determining the likelihood of progression from NMIBC to MIBC. The three stages of NMIBC are: Ta (70%), T1 (20%) and CIS or Tis (10%). Approximately 70% of NMIBC patients have a tumor that is classified as low-grade upon diagnosis. Ta and CIS are limited to the urothelial layer, and T1 is limited to the layer below, which is the lamina propria.

Recurrence, which occurs in approximately 80% of patients, is the primary threat for NMIBC patients. Multiplicity, or number of tumors, tumor size and prior recurrence rate are the most important variables in determining the likelihood and potential severity of recurrence. In T1 and CIS NMIBC patients, progression, which occurs in approximately 45% of patients, is the main threat. Treatment ranges from one or more TURBT procedures followed by adjuvant chemotherapy or immunotherapy instillation(s) in NMIBC patients with a low risk of recurrence to cystectomy for the treatment of NMIBC patients with a high risk of recurrence.

TURBT is conducted in a hospital setting under general anesthesia and can often have side effects and complications. The most common complications, risks and limitations of TURBT include:

- bleeding at the time of surgery that requires clot irrigation and mild burning;
- infection of the bladder;
- injury to the urethra and bladder perforation with potential intra-abdominal leakage;
- reimplantation and cell migration;
- repeat TURBT procedures, which are necessary for approximately 10% of patients within three months;
- complete removal of tumor tissue often not being feasible;
- potential recurrence of up to 25% of the tumors at the original treatment site; and
- some tumors not being detectable.

Post-operative adjuvant treatments for NMIBC, which are given to prevent reimplantation of the cancerous cells, consist primarily of chemotherapy in the case of low-grade tumors and immunotherapy in the case of high-grade tumors, and are administered intravesically via catheter. Adjuvant intravesical chemotherapy is used primarily in low-grade tumors following TURBT in order to try to delay tumor recurrence but is not used as a chemoablation agent. The rationale is to expose tumors to high local drug concentrations while minimizing the systemic exposure, thereby enhancing the treatment effect and reducing the drug toxicity. However, these traditional adjuvant treatments to treating bladder cancer have been limited because, after instillation, the drug concentration is reduced, and the drug is washed out due to urine voiding. As a result, the cancerous tissue is not exposed to the chemotherapy drug for the optimal length of time.

No drugs have been approved by the FDA as first-line treatment for NMIBC and only three drugs have been approved for NMIBC, all used as adjuvant treatment: Thiotepa, which was approved in 1959; bacille Calmette-Guerin, or BCG, which was approved in 1989; and Valstar, which was approved in 1998. Mitomycin is the drug used most often for intravesical chemotherapy. It is used off-label as an adjuvant treatment in the post-operative setting for low-grade tumors with high risk of recurrence. Other drugs that can be used include docetaxel and gemcitabine. BCG, an immunotherapy-based drug, is used as an adjuvant treatment for patients with high-grade NMIBC. Upon recurrence, which occurs in approximately 35% of patients, the patients undergo another round of BCG therapy with a response rate of 30% to 50%. Radical cystectomy, or surgical removal of the bladder, is also a common treatment option for patients who fail multiple intravesical BCG therapies. However, treatment with BCG is associated with severe side effects, as evidenced by a boxed warning on the label, which is a warning placed on a prescription drug's label by the FDA and is designed to call attention to serious or life-threatening risks.

We are not aware of any drugs currently in development for the treatment of NMIBC that take into consideration bladder physiology, specifically the fact that urine is produced and voided frequently, thus diluting the concentration of the active drug almost immediately.

Our Solution: UGN-102

UGN-102, an RTGel-based formulation of high dose mitomycin, is our product candidate for the treatment of LG NMIBC. UGN-102 is administered locally using standard catheters and is designed to conform to the bladder's anatomy and persist in the bladder despite urine flow and bladder movement. Once instilled, UGN-102 converts into gel form at body temperature. Subsequently, upon contact with urine, UGN-102 gradually dissolves and releases the active drug, mitomycin, over a period of several hours versus the time until first voiding,

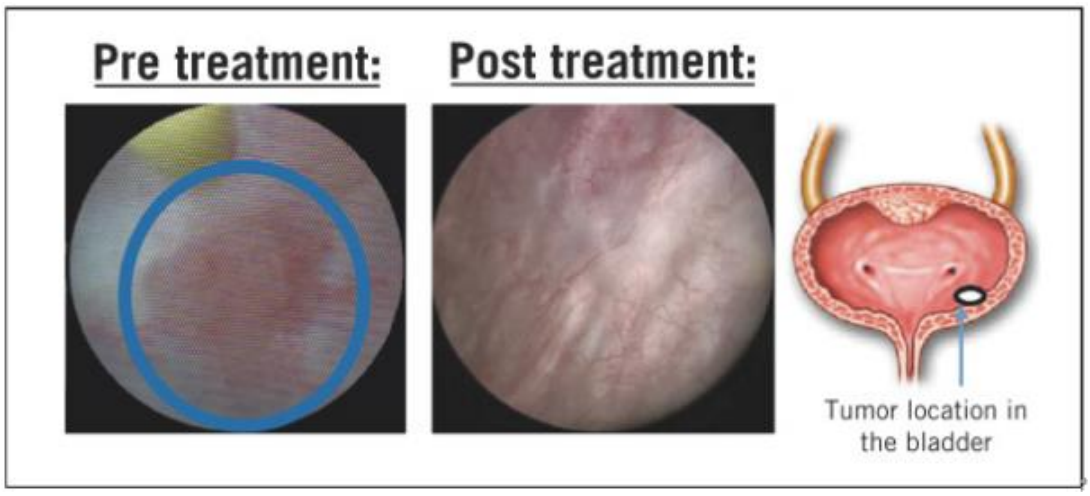
often less than an hour, for mitomycin in its current water-based formulation, without compromising the safety of the patient or interfering with the natural flow of urine out of the bladder. We believe that the resulting significantly increased dwell time of mitomycin in the bladder prolongs exposure of mitomycin to the tissue and therefore has the potential to chemoablate visible and unseen tumors. As a result of these properties, our goal is to develop UGN-102 as a first-line chemoablation non-surgical alternative to TURBT for the treatment of LG NMIBC.

Phase 2a Clinical Trial

We completed a Phase 2a randomized, open-label, single-arm, active-controlled clinical trial in Europe and Israel that evaluated the safety and efficacy of UGN-102 0.06% (40 mg mitomycin in 64 ml gel) and UGN-102 0.12% (80 mg mitomycin in 64 ml gel) in LG NMIBC compared to the intravesical instillation of 40 mg of mitomycin in water (mitomycin 0.1%). We commenced the trial in September 2013 and the last patient was enrolled in March 2016. In this trial, patients underwent six weekly instillations according to their assigned treatment arm. The primary endpoint of the trial used for observational purposes only is the complete response rate at the primary disease endpoint, which is evaluated approximately four weeks after the sixth weekly installation. Safety, feasibility of local treatment with UGN-102 and durability of response were also evaluated. 81 patients were enrolled, 65 of whom have been evaluated for response. Of the 65 evaluable patients in the study, 20, 22 and 23 patients were in the UGN-102 40mg mitomycin, UGN-102 80mg MCC and the water-based 40mg mitomycin control arm, respectively. The results indicate complete response rates at the primary evaluation time of 45%, 86% and 70% for UGN-102 40mg mitomycin, UGN-102 80mg mitomycin and water-based 40mg mitomycin control arm, respectively. Durability at 12 months in patients who were CR demonstrated numerical differences across the treatment arms and was higher in the 80mg UGN-102 arm than in the 40mg UGN-102 arm or the 40 mg MMC + water (control) arm (30.8% vs. 12.5% and 14.3%, respectively). This can be explained at least in part by imbalances in the baseline tumor characteristics in patients across treatment arms, whereby more patients in the 80 mg UGN-102 arm were at increased risk of recurrence compared to the other treatment arms.

In treating LG NMIBC, resection of small tumors is primarily conducted in the outpatient setting, typically without anesthesia using fulguration, a procedure that destroys the diseased area in the lining of the bladder by burning using electric current. The effectiveness of tumor resection in these cases is high and the one-year recurrence rate is estimated to be only 10%. However, in patients with larger tumors and multiple tumors, standard management includes surgical removal using TURBT, a procedure conducted in the operating room in a hospital setting under general anesthesia, which may require at least an overnight stay. TURBT is associated with increased risks and costs and higher recurrence rates that can reach up to 60%.

The following images show cytoscopic views of complete responses in a LG NMIBC patient treated with UGN-102.



The image to the left is a pre-treatment cystoscopic view of a tumor located in the bladder. The image to the right is a post-treatment cystoscopic view of the same location following UGN-102 chemoablation treatment.

Next Steps in the Clinical Development of UGN-102

We completed the Phase 2a clinical trial in the first half of 2017. We have met with the FDA to discuss next steps in the clinical development program for UGN-102. We submitted an IND for UGN-102 in June 2018 and commenced a U.S. based Phase 2b clinical trial for UGN-102 In NMIBC.

UGN-201: Our Product Candidate for the Treatment of High-Grade NMIBC

We are developing UGN-201, our immune-modulation product candidate, for the treatment of high-grade NMIBC. A Phase 1 dose escalation study was conducted in 23 NMIBC patients and UGN-201 appeared to be well-tolerated in the study. This was followed by a Phase 2 pilot study under an IND in 12 patients with CIS bladder cancer in the United States. 20% of the 10 patients evaluated for efficacy achieved a complete response, and UGN-201 was observed to be well-tolerated in the trial. We intend to further investigate the use of UGN-201 for the treatment of high-grade NMIBC, as a single agent or possibly combining it with UGN-102, UGN-101 or with immune checkpoint inhibitors.

Limitations of Current Therapies for High-Grade NMIBC

High-grade NMIBC is a highly aggressive form of bladder cancer. TURBT is the initial treatment of choice for high-grade NMIBC; however, the high rates of recurrence and significant risk of progression to muscle-invasive tumors are particularly dangerous. Bladder removal can be the first treatment of choice for young, otherwise healthy patients with high-grade disease or for patients who cannot tolerate BCG. BCG, an immunotherapy-based drug, is the current standard of care as an adjuvant therapy post-resection in high-grade tumors. However, treatment with BCG is associated with severe side effects, as evidenced by a boxed warning on the label.

Our Solution: UGN-201

We believe that UGN-201 our immune-modulation product candidate, could represent a valid alternative to the current standard of care for the BCG adjuvant, post-TURBT treatment of high-grade NMIBC. UGN-201's active ingredient is imiquimod, an imidazoquinoline, synthetic immune modulator, which specifically targets TLR7, which is expressed in bladder cancer cells. Toll-like receptors are pattern recognition receptors whose importance in stimulating innate and adaptive immunity has been established by recent studies. Toll-like receptors are able to sense microbial components as well as host-derived endogenous molecules released by injured tissues and play a critical role in defending against invading pathogens.

Imiquimod, in its topical formulation, is FDA approved for several indications, including superficial basal cell carcinoma. UGN-201 is a liquid formulation of imiquimod for intravesical administration that has been optimized for delivery in the urinary tract. UGN-201 does not use our RTGel technology. We believe that UGN-201 may elicit an adaptive immune response in the presence of released bladder cancer antigens, which may translate into a long lasting acquired immune response. We also believe the combination of UGN-201 with immune checkpoint inhibitors could further increase the adaptive immune response and potentially represent a viable alternative to BCG for the adjuvant treatment of high-grade NMIBC or UTUC.

We have obtained Orphan Drug Designation for UGN-201 for the treatment of CIS in the bladder. We have an active IND for UGN-201, which has been effective since 2013.

We acquired UGN-201 from Telormedix SA, a private Swiss-based biotechnology company, in the fourth quarter of 2015. Telormedix conducted all of the previous studies related to UGN-201, including the Phase 1 and Phase 1b studies.

UGN-201 Clinical Results

UGN-201 was evaluated in a Phase 1 dose escalation study that enrolled 23 patients diagnosed with NMIBC. UGN-201 was well-tolerated at the doses used. Subsequently, a Phase 2 study of UGN-201 was conducted under an IND in patients with CIS bladder cancer in the United States. The Phase 2 study was commenced in April 2013 and completed in February 2014. Patients were dosed with UGN-201 0.4% weekly for six weeks. The study was designed to evaluate the safety and preliminary efficacy of UGN-201 in CIS patients. The primary efficacy endpoint for observational purposes only was the rate of complete response at five to seven weeks after the sixth weekly instillation. Twelve patients were enrolled into the pilot study, of whom 10 patients were evaluable for response. As per the publication, two of the 10 patients, or 20%, achieved a complete response. UGN-201 was observed to be well tolerated in this trial. The most common AEs related to UGN-201 were urination urgency, dysuria, fatigue, urinary tract infections and hematuria. One SAE, a urinary tract infection, was observed and was resolved.

Next Steps in the Clinical Development of UGN-201

We intend to further investigate the use of UGN-201 for the treatment of high-grade NMIBC, as a single agent or possibly combined with UGN-101, UGN-102 or other immunotherapy agents. Such a combination study would evaluate whether this multimodality approach, harnessing the power of the immune system together with the chemoablation properties of UGN-102 or UGN-101, can provide a safe and effective approach for the treatment of high-grade urothelial tumors.

Preclinical Programs

Using our proprietary RTGel formulation technology, we are pursuing additional preclinical programs to expand and enhance our uro-oncology product portfolio. In particular, we are pursuing preclinical programs for high-grade bladder cancer and high-grade UTUC using checkpoint inhibitors such as an anti PD-L1 or an anti CTLA-4.

License Agreement with Allergan

In October 2016, we entered into the Allergan Agreement with Allergan and granted Allergan 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, to which we refer 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, we granted Allergan a non-exclusive, worldwide license to use certain of our trademarks as required for Allergan to practice its exclusive license with respect to the Licensed Products.

Under the Allergan Agreement, Allergan is solely responsible, at its expense, for developing the Licensed Products and obtaining all regulatory approvals for Licensed Products worldwide. Allergan is also solely responsible, at its expense, for commercializing the Licensed Products worldwide 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.

We 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 to us if there is a material supply failure from us. Prior to completion of the first Phase 2 clinical trial, Allergan has the right to request that we transfer to Allergan our manufacturing process for RTGel and Allergan will assume the responsibility to manufacture RTGel and Licensed Product for its own development and commercialization activities.

Allergan paid us a nonrefundable upfront license fee of $17.5 million upon signing the agreement, and, in the third quarter of 2017, we received an additional $7.5 million milestone payment upon the submission by Allergan of an IND to the FDA for a Licensed Product. In October 2017, we announced that Allergan had begun a Phase 2 study of RTGel in combination with BOTOX® for the treatment of overactive bladder.

Further, we are 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, including $20.0 million upon initiation of a Phase 3 clinical trial for a Licensed Product for overactive bladder; $15.0 million upon initiation of a Phase 3 clinical trial for a Licensed Product for a specified second indication; $50.0 million and $25.0 million upon the first commercial sale of a Licensed Product for overactive bladder in the United States and the European Union, respectively; $25.0 million and $15.0 million upon the first commercial sale of a Licensed Product for a specified second indication in the United States and the European Union, respectively; and $50.0 million upon net sales of all Licensed Products of $500.0 million. Allergan will 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.

Under the Allergan Agreement, Allergan granted us 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.

We plan to continue to research, develop and commercialize other products combining RTGel with other active ingredients, except that there are certain restrictions with respect to the overactive bladder and neurogenic detrusor overactivity indications. Neurogenic detrusor overactivity is when a known neurologic abnormality impairs the signaling systems between the bladder and the central nervous system, and the brain is unable to inhibit the detrusor muscles controlling urination.

Either party may terminate the Allergan Agreement for uncured material breach by the other party and for the insolvency of the other party. We may terminate the Allergan 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 Agreement for any reason upon advance notice. If Allergan has the right to terminate the Allergan 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 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.

Intellectual Property

Our patent estate includes patents and applications with claims directed to our UGN-101, UGN-102, RTGel, BotuGel and UGN-201 product candidates, as well as broader claims for potential future product candidates. On a worldwide basis, our patent estate includes more than 70 patent filings and pending patent applications for our product candidates claiming new treatment methods, manufacturing process, novel intravesical devices and future combination products that are mainly designed to treat internal cavity cancers. In the United States, we currently have 15 issued patents and more than 45 patent applications filed worldwide that are directed to methods, systems and compositions for treating internal cavity cancers, and in particular, urinary tract cancer and bladder cancer. These U.S.-issued patents are expected to remain in effect until between 2024 and 2035.

Our worldwide intellectual property portfolio includes patents and patent applications filed in many jurisdiction such as the United States, European Union, Canada, Israel, Australia, China, Japan, Mexico of which are expected to remain in effect until 2035:

- hydrogel-based pharmaceutical compositions for optimal delivery of various therapeutic agents to the internal cavity such as a bladder and/or urinary tract
- The method for treating bladder cancer, upper urinary tract cancer, and urothelial cancer using hydrogel-based composition
- The method for treating overactive bladder and IC topically without a need for injections
- Special catheters and in-dwelling ureter-catheter systems for optimal delivery of a drug into the renal cavity
- Pharmaceutical compositions comprising an imidazoquinolin-amine (specifically imiquimod) and lactic acid for treating bladder cancer diseases
- Novel phospholipid drug analogs (new chemical entities) for treating cancer or infections.

In addition to patents, we have filed applications for trademark registration with the United States Patent and Trademark Office, or the USPTO, for “Jelmyto,” “VesiGel,” “RTGel,” “BotuGel” and for certain other tradenames and logos. Furthermore, we rely upon trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. Preparing and filing patent applications is a joint endeavor of our research and development team and our in-house and external patent attorneys. Our patent attorneys conduct patent prior-art searches and then analyze the data in order to provide our research and development team with recommendations on a routine basis. This results in:

- protecting our product candidates that are under development;
- encouraging pharmaceutical companies to negotiate development agreements with us; and
- preventing competitors from attempting to design-around our inventions.

Competition

The standard of care for treating NMIBC patients is the TURBT procedure for tumor resection, followed by post-operative adjuvant chemotherapy or immunotherapy instillations, administered to prevent reimplantation of the cancerous cells. The adjuvant agents used are predominately generic treatments and regimens. Only three drugs have been approved for the treatment of non-muscle invasive bladder cancer (NMIBC: Thiotepa, which was approved by the FDA in 1959; BCG, which was approved by the FDA in 1989; Valstar, which was approved by the FDA in 1998. Despite the approval of these drugs, there remain high unmet needs in the bladder cancer market. BCG has been used to treat patients with CIS and high-grade T1 since 1990. Valstar is indicated for patients with CIS (High Grade NMIBC) that do not respond to BCG treatment and Thiotepa is an over 50-year-old drug, rarely used, indicated for superficial papillary carcinoma of the bladder. Mitomycin is used off-label as the standard adjuvant treatment in the post-TURBT setting for LG NMIBC patients. Off-label means that while the FDA has not approved mitomycin as adjuvant treatment in the post-TURBT setting for LG NMIBC patients, physicians are permitted to utilize it as standard of care for this indication as part of medical practice. However, off-label usage as a standard of care does not change the FDA’s approval criteria and does not suggest that FDA approval is more likely than for other investigational drugs. In the UTUC space, there are no approved drugs used to treat the disease. Tumor resection surgeries are conducted in some cases of LG UTUC; however, complete kidney and upper urinary tract removal is the standard of care for frequently recurring UTUC.

There are several products in the development pipeline, most of which are second- or third line-treatments mainly targeted for high-grade NMIBC patients who have failed BCG treatment. All are targeted to reduce recurrence, but none are developed to reduce the need for TURBT and other tumor resection therapies.

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 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 TURBT, which is 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 to replace the existing standard of care, which is a first-line tumor surgical procedure for both bladder cancer and UTUC.

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.

These potential competitors may therefore introduce competing products without our prior knowledge and without our ability to take preemptive measures in anticipation of their commercial launch. 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 exclusively licensing products that are more effective, easier to administer or less costly than our product candidates.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of our products.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests that must be conducted in accordance with good laboratory practices, or GLPs;
- submission of an IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board, or IRB, for each clinical site or centrally before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended use, performed in accordance with good clinical practices, or GCPs;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMP and GCPs; and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

Prior to the commencement of marketing of controlled substances, the U.S. Drug Enforcement Agency, or DEA, must also determine the controlled substance schedule, taking into account the recommendation of the FDA.

The testing and approval process requires substantial time, effort and financial resources. Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a product candidate, we must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to

commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each study site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans. Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, if the drug has been associated with unexpected serious harm to subjects, or based on evolving business objectives or competitive climate. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise us to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

In general, for purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—Studies are initially conducted to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.
- Phase 2—Controlled studies are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—These clinical trials are undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. Evidence is considered to be statistically significant when the probability of the result occurring by random chance, rather than from the efficacy of the treatment, is sufficiently low. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These trials may be done globally to support global registrations so long as the global sites are also representative of the U.S. population and the conduct of the study at global sites comports with FDA regulations and guidance, such as compliance with GCPs.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 studies may be made a condition to be satisfied after approval. The results of Phase 4 studies can confirm the effectiveness of a product candidate and can provide important safety information.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which includes the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial, and the review and approval of the study by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical analysis plan. Information about some clinical trials, including a description of the trial and trial results, must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their ClinicalTrials.gov website.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the Federal Food, Drug and Cosmetic Act, or the FDCA. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if SAEs occur.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

505(b)(2) Regulatory Approval Process

Section 505(b)(2) of the FDCA, or 505(b)(2), provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The applicant may rely upon the

FDA's prior findings of safety and efficacy for an approved product that acts as the reference listed drug for purposes of a 505(b)(2) NDA. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support any changes from the reference listed drug. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

Section 505 of the FFDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy, but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical and clinical data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Any applicant who submits an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a Paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the competitor has provided a Paragraph IV certification to the FDA, the competitor must also send notice of the Paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a Paragraph IV certification, the NDA holder or patent owner regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. The applicant may also elect to submit a statement certifying that its proposed label does not contain, or carves out, any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

Exclusivity

The FDA provides periods of regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to NCEs. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound), or clathrate (i.e., a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

If a product is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA, including a 505(b)(2) NDA, for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, was essential to the approval of the application and was conducted or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

The Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan Drug Designation must be requested before submitting an NDA. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA Orphan Drug Designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and a waiver of the NDA application user fee.

Fast Track and Breakthrough Therapy Designations

The FDA is required to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment, and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the submission of the IND for the product candidate. The FDA must determine if the product candidate qualifies for Fast Track and Breakthrough Therapy designations within 60 days after receipt of the sponsor's request.

For Fast Track and Breakthrough Therapy products, the sponsor may have more frequent interactions with the FDA and the FDA may initiate review of sections of a Fast Track or Breakthrough Therapy product's NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a Fast Track or Breakthrough Therapy application does not begin until the last section of the NDA is submitted. In addition, the Fast Track and Breakthrough Therapy designations may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process. A Fast Track and Breakthrough Therapy designated product candidate would ordinarily meet the FDA's criteria for priority review.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. These user fees must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances. One basis for a waiver of the application user fee is if the applicant employs fewer than 500 employees, including employees of affiliates, the applicant does not have an approved marketing application for a product that has been introduced or delivered for introduction into interstate commerce, and the applicant, including its affiliates, is submitting its first marketing application.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

The FDA may refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients, that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary of the reasons for not referring it to an advisory committee. The FDA may also refer drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. The FDA's NDA review times may differ based on whether the application is a standard review or priority review application. The FDA may give a priority review designation to drugs that are intended to treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has set the review goal of 10 months from the 60-day filing date to complete its initial review of a standard NDA for an NME and make a decision on the application. For non-NME standard applications, the FDA has set the review goal of 10 months from the submission date to complete its initial review and to make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date and non-NME applications within six months of the submission date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding the submission.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter, or CRL, or approval letter. A CRL indicates that the review cycle of the application is complete, and the application is not ready for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing, or other information or analyses in order for the FDA to reconsider the application. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product, or impose additional post-marketing requirements, based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, which has resulted in a boxed warning. The FDA also may not approve the inclusion of labeling claims necessary for successful marketing. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies.

Post-approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including manufacturing, periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for any approved products, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements upon us and our third-party manufacturers. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented, or FDA notification. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA. Physicians, in their independent professional medical judgement, may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. We, however, are prohibited from marketing or promoting drugs for uses outside of the approved labeling but may share truthful and not misleading information that is otherwise consistent with the product's approved labeling.

In addition, the distribution of prescription pharmaceutical products, including samples, is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act also imposes obligations on manufacturers of pharmaceutical products related to product and tracking and tracing.

Failure to comply with any of the FDA's requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. Any of these sanctions could result in adverse publicity, among other adverse consequences.

Other Healthcare Regulations

Our business activities, including but not limited to, research, sales, promotion, distribution, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services, or HHS, and its various divisions, including the Centers for Medicare & Medicaid Services, or CMS, and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense and state and local governments. Our business activities must comply with numerous healthcare laws and regulations, including those described below.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable, in whole or in part, by Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value, including unlawful financial inducements paid to prescribers and beneficiaries, as well as impermissible promotional practices. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, amended the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute, or the specific intent to violate it, to have violated the statute. The ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or for approval by, the federal government, including the Medicare and Medicaid programs, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

As a condition of receiving Medicaid coverage for prescription drugs, the Medicaid Drug Rebate Program requires manufacturers to calculate and report to CMS their Average Manufacturer Price, or AMP, which is used to determine rebate payments shared between the states and the federal government and, for some multiple source drugs, Medicaid payment rates for the drug, and for drugs paid under Medicare Part B, to also calculate and report their average sales price, which is used to determine the Medicare Part B payment rate for the drug. In January 2016, CMS issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the AMP is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the ACA. Drugs that are approved under a biologics license application, or BLA, or an NDA, including a 505(b)(2) NDA, are subject to an additional requirement to calculate and report the manufacturer's best price for the drug and inflation penalties which can substantially increase rebate payments. For BLA and NDA drugs, the Veterans Health Care Act requires manufacturers to calculate and report to the Department of Veterans Affairs a different price called the Non-Federal AMP, offer the drugs for sale on the Federal Supply Schedule, and charge the government no more than a statutory price referred to as the Federal Ceiling Price, which includes an inflation penalty. A separate law requires manufacturers to pay rebates on these drugs when paid by the Department of Defense under its TRICARE Retail Pharmacy Program. Knowingly submitting false pricing information to the government creates potential federal civil False Claims Act liability.

The Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including public and private payors, or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. The ACA amended the federal health care fraud criminal statute implemented under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have violated the statute.

Additionally, the federal Open Payments program pursuant to the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information on HIPAA covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates, including mandatory contractual terms and the 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 the federal HIPAA laws 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.

In addition, 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. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA will likely 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.[1]

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. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to marketing expenditures or payments and other transfers of value to physicians and other healthcare providers, and drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives.

Enforcement actions can be brought by federal or state governments or, in some cases, as "qui tam" actions brought by individual whistleblowers in the name of the government. Depending on the circumstances, failure to comply with these laws can result in significant penalties, including criminal, civil and administrative penalties, damages, fines, disgorgement, debarment from government contracts, 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, exclusion from government programs, refusal to allow us to enter into supply contracts, including government contracts, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our business.

Coverage and Reimbursement

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for our products, once approved, and related treatments will be available from third-party payors, such as government health administration authorities, private health insurers and managed care organizations. Third-party payors determine which medications they will cover and separately establish reimbursement levels. Even if we obtain coverage for a given product by a third-party payor, the third-party payor's reimbursement rates may not be adequate to make the product affordable to patients or profitable to us, or the third-party payors 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. 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.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for medical products. Further, no uniform policy for determining 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 is often a time-consuming and costly process that will 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 cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available, or if reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Healthcare Reform Measures

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals designed 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 and/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, the ACA was passed, which has changed health care financing by both governmental and private insurers and significantly affected the U.S. pharmaceutical industry. The ACA, among other things, subjected manufacturers to new annual fees and taxes for specified branded prescription drugs, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, expanded health care fraud and abuse laws, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, imposed an additional rebate similar to an inflation penalty on new formulations of drugs, extended the Medicaid Drug Rebate Program to Medicaid managed care organizations, expanded the 340B program, which caps the price at which manufacturers can sell covered outpatient pharmaceuticals to specified hospitals, clinics and community health centers, and provided incentives to programs that increase the federal government's comparative effectiveness research.

However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump Administration to repeal or replace certain aspects of the ACA. For example, since January 2017, President Trump has signed two 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, two bills affecting the implementation of certain taxes under the ACA has been signed into law. Legislation enacted in 2017 (H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018"), informally titled the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision which 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." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." 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. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional U.S. Congressional action is taken. In addition, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, 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 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug 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. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump Administration have both stated that it 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. Additional health reform measures may continue and affect our business in unknown ways.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Manufacturing, Supply and Production

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturers for all of our required raw materials, active ingredients and finished products for our preclinical research and clinical trials. The company is in the process of negotiating commercial supply agreements with its primary third-party vendors. We anticipate that these agreements will be executed in advance of commercial approval for UGN-101. The company also intends on negotiating back-up supply agreements with other third-party manufacturers for the commercial production of those products.

Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors. The relevant manufacturers of our drug products for our current preclinical and clinical trials have advised us that they are compliant with both current good laboratory practice, or cGLP, and cGMP.

Our product candidates, if approved, may not be producible in sufficient commercial quantities, in compliance with regulatory requirements or at an acceptable cost. We and our contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. We and our contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP and cGLP for drugs on an ongoing basis, as mandated by the FDA and foreign regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers.

Marketing, Sales and Distribution

Given our stage of development, we do not have any internal sales, marketing or distribution infrastructure or capabilities, and our marketing department currently consists only of a marketing director, whose main responsibility is to produce marketing and communication materials, exhibitions, website content and to identify unmet needs in the urology market, assess their commercial potential and advise on the prioritization of the development of our future product candidates accordingly. The Company’s U.S. subsidiary, Urogen Pharma, Inc., was formed to support our U.S. development and potential commercialization efforts.

In the event that we receive regulatory approvals for our products in markets outside of the United States, we intend, where appropriate, to pursue commercialization relationships, including strategic alliances and licensing, with pharmaceutical companies and other strategic partners, which are equipped to market or sell our products through their well-developed sales, marketing and distribution organizations in such countries.

In addition, we may out-license some or all of our worldwide patent rights to more than one party to achieve the fullest development, marketing and distribution of any products we develop.

Employees

As of February 22, 2019, we had 78 employees worldwide, 19 of whom hold PhD, PharmD, or M.D. degrees. None of our employees is subject to a collective bargaining agreement. We have never experienced any employment-related work stoppages and consider our relationships with our employees are good.

Israeli labor laws govern the length of the workday and workweek, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination, payments to the National Insurance Institute, and other conditions of employment and include equal opportunity and anti-discrimination laws. While none of our employees is party to any collective bargaining agreements, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees in Israel by order of the Israeli Ministry of Economy and Industry. These provisions primarily concern pension fund benefits for all employees, insurance for work-related accidents, recuperation pay and travel expenses. We generally provide our employees with benefits and working conditions beyond the required minimums.

Corporate Information

Our legal and commercial name is UroGen Pharma Ltd, with registered offices at 9 Ha'Ta'asiya St., Ra'anana 4365007, Israel. We are a company organized under the laws of State of Israel. We were formed in 2004 with an indefinite duration. We are registered with the Israeli Registrar of Companies. Our principal executive offices are located at 499 Park Ave 12th Floor, New York, New York 10022. Our telephone number is (646) 768-9780. Investors should contact us for any inquiries through the address and telephone number of our principal executive office. We maintain a web site at http://www.urogen.com. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our website is not incorporated into this Annual Report.

For all documents filed after January 1, 2019, we file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other information with the SEC. Our filings with the SEC are available free of charge on the SEC's website at *www.sec.gov* and on our website under the "Investors" tab as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Unless the context requires otherwise, references in this Annual Report to "we," "us", "our" and "UroGen" refer to UroGen Pharma, Ltd. and its subsidiaries.

Item 1A. Risk Factors

An investment in shares of our ordinary shares involves a high degree of risk. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the United States Securities and Exchange Commission, or the SEC, including the following risk factors which we face, and which are faced by our industry. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this Annual Report. See "Special Note Regarding Forward-Looking Statements" above.

Risks Related to Our 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 clinical stage 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 $75.7 million and $20.0 million for the years ended December 31, 2018 and 2017, respectively. 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 preclinical 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 preclinical 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 if our products are approved for sale, including marketing, sales and distribution costs;
- the cost of third-party manufacturing of our 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 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 any regulatory approvals for any of our product candidates, commercialized any of our product candidates or generated any material 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 preclinical and clinical development of our lead product candidates, UGN-101 and UGN-102. As of December 31, 2018, we had cash and cash equivalents of $101.3 million. In January 2019, we completed an underwritten public offering in which we received net proceeds of approximately $161.8 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

We believe we have sufficient cash and cash equivalents to fund our operating expenses and capital expenditure requirements 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, 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 preclinical 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 preclinical 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 UGN-101, UGN-102 or any of our other product candidates.

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, in October 2016, or the Allergan Agreement. Under the Allergan 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 Business and Strategy

We are dependent on the success of our lead product candidates, including obtaining regulatory approval to market our product candidates in the United States.

We have invested almost all our efforts and financial resources in the research and development of our lead product candidates, UGN-101 and UGN-102. Our future success depends on our ability to market and sell these product candidates. However, these drugs are in various stages of clinical development and each of these drugs has yet to receive marketing approval from the U.S. Food and Drug Administration, or the FDA, or any other regulatory agency. Our product candidates' marketability is subject to significant risks associated with successfully completing current and future clinical trials, including:

- the FDA's timely acceptance of our investigational new drug, or IND, filings 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 our parameters for regulatory approval relating to UGN-101, UGN-102 and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways;
- 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 preclinical studies or clinical trials;

- 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;
- the FDA's timely acceptance for filing of our New Drug Application, or NDA, for UGN-101, upon completion of our rolling submission expected in the second half of 2019, and eligibility for priority review of our NDA by the FDA;
- our ability to complete in a timely fashion the single pivotal Phase 3 clinical trial for UGN-101 for the treatment of low-grade upper tract urothelial carcinoma, or LG UTUC, and that the single pivotal Phase 3 clinical trial, even if successfully completed, will be sufficient to support NDA submission and subsequently, FDA approval;
- our ability to successfully complete the FDA requirements related to chemistry, manufacturing and control, or CMC, for UGN-101, UGN-102 and our other product candidates, and if completed, their sufficiency to support an NDA;
- 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 NDAs for UGN-101 and UGN-102;
- if applicable, the recommendation of the FDA's advisory committee to approve our applications to market UGN-101, 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 prevalence and severity of adverse events associated with our product candidates as there are no drugs and related drug administration procedures approved for LG UTUC or low-grade non-muscle invasive bladder cancer,
- or LG NMIBC, that are based on RTGel technology;
- the timely and satisfactory performance by third-party contractors of their obligations in relation to our clinical trials;
- our success in educating physicians and patients about the benefits, 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;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our ability to secure supply of the raw materials from TAPI (Teva Active Pharmaceutical Ingredients) or other suppliers for our product candidates to support the clinical trial 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 administration of our products, including UGN-101 and 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. 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 or commercialize any of our product candidates. If we fail to achieve these objectives or overcome the challenges presented above, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we may not be able to generate sufficient revenues through the sale of our product candidates to enable us to continue our business.

We may be unable to obtain regulatory approval for our product candidates.

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. We have not yet obtained regulatory approval to market any of our product candidates in the United States or any other country. Our business depends upon obtaining these regulatory approvals. There are currently no drugs approved by the FDA for the treatment of UTUC and only three drugs 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, including:

- our inability to satisfactorily demonstrate that the product candidates are safe and effective for the target indication;
- the FDA's disagreement with our trial protocol, the interpretation of data from preclinical studies or clinical trials or conduct and control of clinical trials;
- the patient population studied in the clinical trial may not be sufficiently large, broad or representative to assess efficacy and safety in the patient population for which we seek approval;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's determination that the 505(b)(2) regulatory pathway is not available for our product candidates;
- the FDA's determination that additional preclinical studies or clinical trials are required;
- the FDA's determination that the Fast Track Designation, or FTD, for UGN-101 is no longer warranted or our trial results do not meet the criteria for FTD;
- the FDA's determination that the Orphan Drug Designation, or ODD, for UGN-101, for the treatment of UTUC is not valid;
- the FDA's determination that UGN-101 for the treatment of LG UTUC no longer meets the conditions for breakthrough therapy designation;
- the FDA's determination that the quality of our drug substance or drug product, formulation, labeling or the specifications of our product candidates is insufficient for approval;
- the FDA's failure to accept the manufacturing processes or facilities of third-party manufacturers with which we contract;
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval; or
- resistance to approval from the FDA's advisory committee for any reason including safety or efficacy concerns.

Although we have initiated a rolling NDA submission for UGN-101 for LG UTUC, our NDA may receive a refuse to file communication from FDA during the filing review period or a complete response letter at the conclusion of a substantive FDA review period. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly and potentially time-consuming additional post-approval clinical trials or subject to restrictive risk evaluation and mitigation strategies. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization 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.

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

Positive results in preclinical 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 preclinical 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. For instance, we enrolled only 22 patients in the UGN-101 Compassionate Use program and enrolled only 71 patients in our ongoing pivotal Phase 3 OLYMPUS clinical trial for UGN-101. To date, in our preclinical testing, completed Compassionate Use program for UGN-101 and clinical trials, we have observed several adverse events and serious adverse events, including ureteral edema, transient inhibition of urine flow, rash, flank pain, kidney swelling, kidney 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 renal 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 adverse events related to UGN-101 and UGN-102 that are not directly attributable to mitomycin specifically will not occur. In addition, our clinical trials may not be successful. If our clinical trials do not ultimately indicate that our product candidates are safe and efficacious for their intended application, the FDA may not approve any NDA that we may file 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. For instance, at the time when we announced topline results from our ongoing pivotal Phase 3 OLYMPUS clinical trial for UGN-101 in January 2019, only 61 of the 71 patients enrolled in the trial had reached the primary disease evaluation, or PDE, at that time, and the remaining 10 patients were awaiting PDE evaluation. Moreover, while we announced that all evaluated patients who had achieved a complete response, or CR, at PDE remained disease free at six months, we only had six-month durability data on approximately half of the patients who had achieved a CR at PDE. Durability is a key secondary endpoint for our ongoing pivotal Phase 3 OLYMPUS clinical trial. In addition, it is possible that when we obtain and report six-, nine- and twelve-month durability data for the patients who achieved a CR at PDE, durability data for certain patients may not be available due to patients being lost to follow-up, which may result in a smaller sample of durability data than we anticipated. Moreover, while we announced that the safety profile for UGN-101 was observed to be acceptable, with most treatment-emergent adverse events characterized as mild or moderate and transient and in line with ureteral procedures, we continue to accrue safety and adverse event data in our ongoing pivotal Phase 3 OLYMPUS clinical trial and additional adverse events may occur. 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. For instance, both our ongoing pivotal Phase 3 OLYMPUS clinical trial for UGN-101 and our ongoing Phase 2b clinical trial for UGN-102 are conducted on an open-label basis. Because these clinical trials are not blinded, we regularly receive interim updates on the data accumulated in such trials but may only provide periodic public updates on such trials. 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-101, UGN-102 or any other 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 have never obtained approval for any product candidates and may be unable to do so successfully.

As a company, we have limited experience in conducting clinical trials and have never progressed a 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. In addition, due to the significant lack of drug development for non-muscle invasive urothelial cancers over the past 15 years, neither we nor any third-party clinical investigators, clinical research organizations, or

CROs, and/or consultants are likely to have extensive experience conducting clinical trials for the indications we are targeting. 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 applied for regulatory approvals to market any of our product candidates, 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 preclinical 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. Our pivotal clinical trial for UGN-101 is intended to evaluate 71 patients, and we initiated a rolling submission to the FDA of an NDA for UGN-101 in December 2018. We cannot assure you that we will be able to complete the submission of the NDA for UGN-101 in a timely fashion. 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, during the trial or before approving our rolling NDA submission for UGN-101.

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, preclinical, 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, including beginning on December 22, 2018, 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 preclinical product candidates into clinical development and through regulatory approval and commercialization.

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

- generating adequate and sufficient preclinical 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.

If we are unsuccessful in advancing our preclinical product candidates into clinical trials in a timely fashion, our business may be harmed. Even if we are successful in advancing our preclinical product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this Annual 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 preclinical, 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 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.

The market opportunities for 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 first-line standard of care for certain urothelial cancers. We intend to seek approval of UGN-101 for the first-line treatment of LG UTUC and of UGN-102 for the first-line treatment of LG NMIBC in both cases as a chemoablation agent to replace tumor resection surgeries. 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 ongoing pivotal Phase 3 OLYMPUS clinical trial for UGN-101 is designed to evaluate the use of UGN-101 for the treatment of tumors in the renal pelvis (the funnel-like dilated part of the ureter in the kidney) and is not designed to evaluate the use of UGN-101 for the treatment of tumors in the ureter (the tube that connects the kidneys to the bladder). Even if UGN-101 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 UGN-101. Even if we receive regulatory approval for our product candidates and 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, UGN-101's commercial viability may prove to be limited, which may negatively affect our financial results.

UGN-101, UGN-102 or any of our other product candidates may produce undesirable side effects that we may not have detected in our previous preclinical 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, use of UGN-101, UGN-102 or our other product candidates may be associated with side effects or adverse events that can vary in severity and frequency. Our proprietary reverse thermal gelation hydrogel, or RTGel, which is used in the formulation of UGN-101 and UGN-102, has not undergone extensive testing in humans. Side effects or adverse events associated with the use of UGN-101 and 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 preclinical testing, completed Compassionate Use program for UGN-101 and clinical trials, we have observed several adverse events and serious adverse events, including ureteral edema, transient inhibition of urine flow, rash, flank pain,

kidney swelling, kidney 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 renal 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 our product candidates could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits, which will harm our business.

Furthermore, our single pivotal Phase 3 clinical trial for UGN-101 and our Phase 2b clinical trial for UGN-102 involve larger patient bases than in our prior studies of these candidates, and the commercial marketing of UGN-101 and UGN-102, if approved, 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 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 preclinical 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 approval or market acceptance of the affected product candidate and could substantially increase commercialization costs 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.

Even if our product candidates receive marketing approval, we may continue to face future developmental and regulatory difficulties. In addition, we are subject to government regulations and we may experience delays in obtaining required regulatory approvals to market our proposed product 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.

Even if our product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and use and market acceptance necessary for commercial success.

Even if we obtain FDA or foreign regulatory approvals for our product candidates, the commercial success of such products will depend significantly on their broad adoption and use by physicians, for approved indications, including, in the case of UGN-101, for the first-line treatment of LG UTUC, and in the case of UGN-102, for the first-line treatment of LG NMIBC, and for other therapeutic indications that we may seek to pursue with any of our product candidates. Physicians treating LG UTUC and LG NMIBC have never had to consider first-line treatments other than surgery. The degree and rate of physician and patient adoption of our product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved;
- 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 product 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 our lead product candidates as locally-administered drug replacements to current surgical standards of care;
- the cost of treatment, safety and efficacy of our product candidates in relation to alternative treatments, including the recurrence rate of our treatments;
- the extent to which the costs of our product candidates 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 product candidates, including the treatment of LG UTUC with UGN-101 and the treatment of LG NMIBC with UGN-102, 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 products, including UGN-101 and UGN-102, 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 UGN-101, 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.

If we are not successful in developing, receiving regulatory approval for and commercializing our preclinical and clinical product candidates other than UGN-101 or UGN-102, our ability to expand our business and achieve our strategic objectives could be impaired.

Although we will devote a substantial portion of our resources to the continued clinical testing and potential approval of UGN-101 for the treatment of LG UTUC and UGN-102 for the treatment of LG NMIBC, another key element of our strategy is to discover, develop and commercialize a portfolio of products based on our proprietary RTGel platforms 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-101, 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. While we have commenced a single pivotal Phase 3 clinical trial for UGN-101 and a Phase 2b clinical trial for UGN-102, all of our other potential product candidates remain in the preclinical and/or early clinical stages of development. 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.

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 (durbalumab) 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 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.

We have no experience in marketing or distributing products and no internal capability to do so and are therefore subject to certain risks in relation to the commercialization of our product candidates once approved.

We have not yet established a commercial organization for the marketing, sale and distribution of our product candidates. Therefore, even if we receive approval to market our product candidates in the United States or other markets, in order to successfully commercialize our product candidates, we will need to either build marketing, sales, distribution, managerial and other non-technical capabilities or contract with third parties to obtain these capabilities. 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. The development of our own sales infrastructure or contracting with third parties will involve substantial expense, much of which we will incur well in advance of any marketing or sales. Moreover, we do not have experience as a company in establishing a significant sales infrastructure, and we cannot be certain that we will successfully develop this capability or contract successfully with third parties for the necessary services. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain personnel for medical affairs, marketing and sales. If we fail to establish an effective sales and marketing infrastructure or contract with third parties to do so, 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.

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 Agreement. Under the Allergan Agreement, we granted Allergan 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, which we refer to collectively as the Licensed Products. Either party may terminate the Allergan Agreement for uncured material breach by the other party and for the insolvency of the other party. We may terminate the Allergan 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 Agreement for any reason upon advance notice. If Allergan has the right to terminate the Allergan 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 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 Allergan 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;
- clinical trials, such as the ongoing Phase 2 trial being conducted by Allergan for overactive bladder with BotuGel, could fail to meet its efficacy objectives;
- 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.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If the Allergan 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 Annual 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 our perception in the business and financial communities could be harmed.

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 preclinical 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 manufacture economically 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 currently contract with third-party subcontractors and single-source suppliers for certain raw materials, compounds and components necessary to produce UGN-101, UGN-102 and UGN-201 for preclinical studies and clinical trials, and expect to continue to do so to support commercial scale production of UGN-101, 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 potential commercialization efforts. This increases the risk that we will not have sufficient quantities of UGN-101, 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 UGN-101, UGN-102 and UGN-201 for our preclinical 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 UGN-101 and UGN-102. Teva is in the midst of a corporate restructuring. Although we are not aware of any impact of the restructuring as currently in effect on Teva's ability or willingness to supply us with mitomycin API in the quantities and on the timeline required, it is possible that the restructuring could adversely affect our ability to obtain mitomycin in any given period and could require us to expend funds and effort to identify and engage one or more alternate suppliers of mitomycin. We also currently depend on single sources for the gel contained in UGN-101 and UGN-102, and 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 our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the availability of raw materials. If we or our 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 any approved products.

We expect to continue to rely on these or other subcontractors and suppliers to support our commercial requirements if UGN-101, UGN-102 or any of our other product candidates is approved for marketing by the FDA or foreign regulatory authorities. We also rely on a single third-party manufacturer to produce the mitomycin drug product, or final mitomycin formulation, necessary for our clinical trial and commercial requirements. We have yet to complete the mitomycin drug product validation process, and scale-up work at this manufacturer that would be required for approval and commercial purposes, and there is a risk that we will not be able to do so in a timely or satisfactory manner. Even if we establish ourselves as an approved commercial supplier of mitomycin through this drug product manufacturer, we plan to continue to rely on third parties for such production of mitomycin API, as well as for the raw materials, compounds and components necessary to produce our product candidates and for preclinical studies and clinical trials. We would expect that if we become a commercial supplier of mitomycin, through a third-party manufacturer of mitomycin, it would provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long-term margins. However, we have no experience as a company in the commercial supply of drugs and may never be successful as a commercial supplier of mitomycin.

Even if we are successful in being approved as a commercial supplier of mitomycin, cost-overruns, unexpected delays, equipment failures, 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, establishing ourselves as a commercial supplier of mitomycin, if we choose to pursue this, will require additional investment, will be 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 mitomycin commercial supply capabilities may cost more than we currently anticipate, and delays or problems may adversely impact our ability to provide supply for the development and commercialization of our product candidates as well as our financial condition.

Moreover, before we can begin to commercially manufacture our product candidates, 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 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 UGN-101, 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 UGN-101, UGN-102 or any other product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

Failure to obtain marketing approval in international jurisdictions would prevent 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 approved for sale 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 intend to rely on third parties and consultants to assist us in conducting our single pivotal Phase 3 clinical trial for UGN-101, our Phase 2b clinical trial for UGN-102 and certain clinical trials for our other 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-101, UGN-102 or any of our other product candidates.

We do not have the ability to independently conduct many of our preclinical 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 cGMP 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.

Our ability to market our product candidates, if approved, 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.

We are currently developing UGN-101 for the treatment of LG UTUC, and 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 our product candidates are approved for marketing, and we are found to have improperly promoted off-label uses, 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. For example, if we receive marketing approval for UGN-101 for the treatment of LG UTUC, the first indication we are pursuing, we cannot promote the use of our product 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 UGN-101 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. 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.

If we fail to manage our growth effectively, our business could be disrupted.

As of December 31, 2018, we had 70 employees, of whom 38 are based in Israel and 32 are based in the United States. We will need to continue to expand our development, quality, sales, managerial, operational, finance, marketing 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.

Due to our limited financial resources and our limited experience in managing a larger company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion could delay the execution of our development and strategic objectives or disrupt our operations; and if we are not successful in commercializing our product candidates, 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 if we commercialize any products. 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. If and when we obtain approval for marketing UGN-101, UGN-102 or any other product candidate, we intend to expand our insurance coverage to include the commercialization of UGN-101, UGN-102 or any other approved product that we may have; however, we may be unable to obtain this 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; 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, 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 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.

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 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, the level of devaluation of the NIS against the dollar in 2018 was 8.1%, and if the dollar cost of our operations in Israel continues to increase, our dollar-measured results of operations will be adversely affected.

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.

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 formulation technology and the formulations, methods of use and manufacturing aspects of our product candidates. In the United States, we currently have 15 granted patents that are directed to protect our lead product candidates, UGN-101, UGN-102, BotuGel, UGN-201 and RTGel as well as to our future product candidates that are under company research. These patents claim methods, systems, and novel compositions for treating cancer in internal cavities, in particular urinary tract cancer. These issued patents are expected to expire between 2024 and 2035. Moreover, our IP portfolio includes more than 45 patent applications filed worldwide that are directed to various methods, systems and compositions for treating cancer locally, by intravesical means. We have four pending patent applications relating to the product candidate BotuGel in the European Union, China and Israel as well as one granted patent in Russia. In addition, we have two granted patents related to UGN-201 in the United States as well as two granted patents in the European Union, two granted patents in Japan and one granted patent in each of Australia, Mexico, China, Russia, and Hong Kong, each of which is expected to remain in effect until approximately 2035. In addition to the issued patents mentioned above, our portfolio includes pending patent applications relating to UGN-201 in the European Union, Hong Kong, Canada, Brazil and Israel. Moreover, we hold five granted patents in the United States as well as patent applications filed worldwide that relate to novel formulations of phospholipid drug analogs (saturated lipid conjugate compositions) for the treatment of urinary tract cancer.

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 existing compounds and our granted patents and pending patent applications are directed to, among other things, novel formulations of these existing compounds with our RTGel. 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.

However, the patent applications that we own 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 patents granted from them are complex, lengthy and highly technical documents that are often prepared under very 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.

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 UGN-101, UGN-102 and any of our product candidates.

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

If we encounter delays in our clinical trials or regulatory approval of our product candidates, the period of time during which we could market any of our product candidates under patent protection could be reduced. 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 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 or any of our product candidates or (ii) conceive and invent any of the inventions claimed in our patents or patent applications.

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 own trademarks that identify UGN-101, UGN-102 and UGN-201 and have registered these trademarks in the United States and Israel. 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.

Generic 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-101, UGN-102, or our other product candidates satisfy 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.

We are conducting a single pivotal Phase 3 clinical trial for UGN-101 and a Phase 2b clinical trial of UGN-102 under the FDA's Section 505(b)(2) regulatory pathway. 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-101, UGN-102 and our other product candidates by potentially decreasing the amount of preclinical 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 or biologics and, therefore, will not be treated as new chemical entities, or NCEs, the submission of an NDA under the Section 505(b)(2) or similar regulatory 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) or similar regulatory pathway as anticipated, we may need to conduct additional preclinical 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) or similar regulatory 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) or similar regulatory 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) over the last few years, 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.

Fast track designation for one or more of our product candidates may not actually lead to a faster development or regulatory review or approval process.

In August 2017, we received fast track designation for UGN-101 for the treatment of UTUC. If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA fast track designation. Even though we have received fast track designation for UGN-101 for the treatment of UTUC, fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with fast track designation compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

A breakthrough therapy designation by the FDA for UGN-101 for LG UTUC may not lead to a faster development or regulatory review or approval process, and it will not increase the likelihood that the product candidate will receive marketing approval.

We received breakthrough therapy designation for UGN-101 for LG UTUC. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA.

Designation as a breakthrough therapy is within the discretion of the FDA. The receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

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 agree to offer 50% (70% commencing on January 1, 2019) 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 and teaching hospitals and any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year;
- expansion of healthcare fraud and abuse laws, including the federal civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

There have been judicial and Congressional 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 two 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, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and the 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." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. 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 July 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 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 in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, 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 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump Administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional 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. HHS has already started the process of soliciting feedback on some of these measures and is concurrently implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other proposed measures may require authorization through additional legislation 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.

If we obtain regulatory approval and commercialization of UGN-101, 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 the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of UGN-101, UGN-102 or our other product candidates may be.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients under the Right to Try Act.

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 Orphan Drug Designation to UGN-101 for the treatment of UTUC and to UGN-201 for treatment of 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.

UGN-101 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. 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.

Even if we receive regulatory approval for our product candidates, we 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.

If and when regulatory approval has been granted, our product candidates or any approved product will be subject to continual regulatory review by the FDA and/or foreign regulatory authorities. Additionally, any product candidates, if approved, 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.

Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indications for which the product may be marketed or to the conditions of approval, or 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, if the applicable regulatory agency approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product 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 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 and state health care laws, including those intended to prevent health care fraud and abuse.

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 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 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.

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. When it goes into effect on January 1, 2020, the CCPA will require covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA will likely 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.

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 and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members to CMS. We may also be subject to state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, drug pricing, and/or state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidelines promulgated by the federal government. Certain state and local laws also require the registration of pharmaceutical sales representatives.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any payor, including commercial insurers. 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.

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 UGN-101, 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.

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. We cannot be sure that coverage will be available for UGN-101, 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. 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. 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 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. We cannot be sure that coverage or adequate reimbursement will be available for UGN-101, 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 commercialize UGN-101, UGN-102 or our other product candidates, or achieve profitably at all, even if approved.

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-101, UGN-102 or any of our other 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 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-101, 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:

- actual or anticipated variations in our and our competitors' results of operations and financial condition;
- physician and market acceptance of our products;
- the mix of products that we sell;
- 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 preclinical or clinical trials for UGN-101, 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, including our involvement in litigation brought by or against us;
- regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products;
- changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses;
- changes in our expenditures to promote our products;
- our sale or proposed sale, or the sale by our significant shareholders, of our ordinary shares or other securities in the future;
- changes in key personnel;
- success or failure of our research and development projects or those of our competitors;
- the trading volume of our ordinary shares; and
- general economic and market conditions and other factors, including factors unrelated to our operating performance.

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

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.

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 Annual 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. In October 2018, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, which allows us to sell our ordinary shares through Jefferies LLC as our sales agent. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

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 or control, directly or indirectly, approximately 14.3% of our outstanding ordinary shares, as of December 31, 2018. 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.

We expect to be classified as a passive foreign investment company for the taxable year ended December 31, 2018 and taxable year ending December 31, 2019, and, as such, 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 passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in offerings of our shares) and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. We believe that we were classified as a PFIC for the taxable year ended December 31, 2018 and, based upon the expected nature and composition of our income and assets, we anticipate that we will be classified as a PFIC for the taxable year ending December 31, 2019. 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.

Our status as a PFIC depends on the nature and composition of our income and the nature, composition and value of our assets (which may be determined based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our ordinary shares, which may be volatile) from time to time. 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.

Because we believe that we are a PFIC, we plan on providing to investors, by annually posting a "PFIC Annual Information Statement" on our website, with 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.

In addition, on December 22, 2017, the Tax Act was signed into law and significantly revised the U.S. Internal Revenue Code of 1986, as amended, or the Code. The Tax Act, among other things, contains significant changes to U.S. corporate income taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for business interest expense to 30% of adjusted earnings (except with respect to certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repealing of many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of this tax reform on holders of our ordinary shares is also uncertain and could be adverse. We urge you to consult with your legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our ordinary shares.

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 net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards, or NOLs, to offset future taxable income. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code has occurred after each of our previous issuances of ordinary shares. In addition, if we undergo an ownership change, our ability to utilize NOLs could be limited by Section 382 of the Code. As of December 31, 2018, our NOLs were immaterial to the overall company. 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. Furthermore, our ability to utilize our NOLs may be subject to limitations. 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.

Unlike in prior years, as of January 1, 2019, we are required to comply with the domestic reporting regime under the Exchange Act and will incur significant legal, accounting and other expenses, and our management will be required to devote substantial additional time to new compliance initiatives and corporate governance matters.

We determined that, as of December 31, 2018, we no longer qualified as a "foreign private issuer" under the rules and regulations of the SEC. While we were a foreign private issuer, we were exempt from compliance with certain laws and regulations of the SEC, including the proxy rules, the short-swing profits recapture rules and certain governance requirements, such as independent director oversight of the nomination of directors and executive compensation. In addition, we were not required to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies registered under the Exchange Act. As a result of this determination, beginning January 1, 2019, we were no longer entitled to "foreign private issuer" exemptions and must report as a domestic U.S. filer, including filing quarterly reports on Form 10-Q, current reports on Form 8-K and proxy statements under Section 14 of the Exchange Act. In addition, our "insiders" are now subject to the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act and we are no longer exempt from the requirements of Regulation FD promulgated by the SEC under the Exchange Act. Moreover, as a domestic filer, we are required to comply with the corporate governance obligations imposed by the Nasdaq Global Market and no longer have the option to follow our home country rules in lieu of such obligations.

The regulatory and compliance costs associated with the reporting and governance requirements applicable to U.S. domestic issuers may be significantly higher than the costs we previously incurred as a foreign private issuer. As a result, we expect that the loss of foreign private issuer status will increase our legal and financial compliance costs and will make some activities highly time-consuming and costly. In addition, we need to develop our reporting and compliance infrastructure and may face challenges in complying with the new requirements applicable to us.

Furthermore, we also determined that, as of December 31, 2018, we no longer qualified as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. Because we no longer qualify as an emerging growth company, and as certain extended transition periods available to emerging growth companies expire, we will become subject to additional reporting requirements and standards and accelerated filing deadlines for our periodic reports. For example, we have incurred significant expenses and devoted substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. If we are unable to implement these changes effectively or efficiently, it could harm our operations, financial reporting or financial results and could result in an adverse opinion on internal control from our independent registered public accounting firm. If we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. We will also be subject to enhanced disclosures obligations regarding executive compensation in our periodic reports and proxy statements and requirements to hold a nonbinding advisory vote on executive compensation. While we are taking steps to implement the systems and processes required to comply with these additional requirements, we cannot assure you that the measures we have taken to date, and are continuing to implement, will enable us to comply fully and in a timely manner.

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. In addition, the majority of our key employees are residents of 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, 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 December 31, 2018, we had 38 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.

The Israeli government grants we have received for research and development activities restrict our ability to manufacture products and transfer technologies outside of Israel and require us, in addition to the payment of royalties, to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received and incur financial penalties.

We have received grants under the Israeli Law for the Encouragement of Industrial Research, Development and Technological Innovation, 5754-1984, or the R&D Law, from the Israel Innovation Authority in Israel, or 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. Through December 31, 2018, we had received grants in the aggregate amount of $2.1 million. We may in the future apply to receive additional grants from the IIA. However, we cannot predict whether we will be entitled to any future grants, or the amounts of any such grants.

The IIA may also impose certain conditions on any arrangement under which it permits us to transfer IIA-funded technology outside of the State of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of the State of Israel of IIA-funded technology (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to IIA. The restrictions under the R&D Law will continue to apply even after we have repaid the full amount of royalties due to the IIA. If we fail to satisfy the conditions of the R&D Law, we may be required to refund the amounts of the grants previously received, together with interest and penalties.

A recipient of a grant from the IIA is obligated to pay royalties generally at a rate of 3% to 5% on revenues from sales of products developed with IIA-funded technology, up to the amount of the grant related to any such products plus accrued interest. As of December 31, 2018, we have accrued $0.8 million in royalties due to the IIA, which has been recorded in cost of revenues in our results of operations for the year ended December 31, 2018. Under the R&D Law, a company that received grants from the IIA may not transfer IIA-funded technology or manufacture products developed with IIA-funded technology outside of the State of Israel without first obtaining the approval of the IIA. We may be required to pay increased royalties of up to 300% of the amount of the original grant and other amounts; if we do not receive such approvals, we may be required to pay significant penalties.

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 and technical 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 December 31, 2018, we had 70 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 and technical 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease an approximately 11,495 square foot facility in Israel, which is used primarily as research and development laboratories as well as for administrative purposes. We lease approximately 9,336 square feet of space in New York, which serves as our principal executive offices and is used for marketing as well as general and administrative purposes. We lease approximately 4,906 square feet of space in Los Angeles, which is used for general and administrative purposes. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms.

Item 3. 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 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities

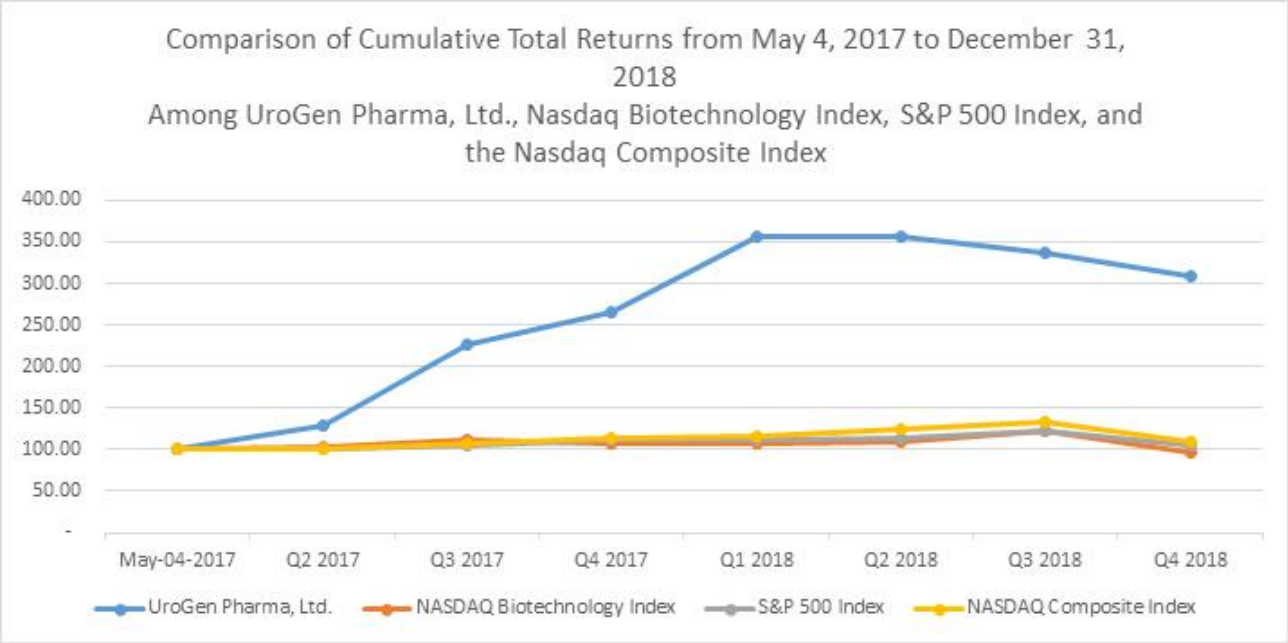
Recent Sales of Unregistered Securities

None.

Stock Performance Graph

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Our ordinary shares has been traded on The Nasdaq Global Market since May 4, 2017 under the symbol URGN. Prior to such time, there was no public market for our ordinary shares. The following graph shows the value of an investment of $100 from May 4, 2017 (the date our ordinary shares commenced trading on The Nasdaq Global Market) through December 31, 2018, in our ordinary shares, the Nasdaq Biotechnology Index, the Standard & Poor's 500 Index (S&P 500), and Nasdaq Composite Index. The historical share price performance of our common shares shown in the performance graph is not necessarily indicative of future stock price performance.



	Cumulative Total Return date ended							
	5/4/2017 (Inception)	6/30/2017	9/30/2017	12/31/2017	3/31/2018	6/30/2018	9/30/2018	12/31/2018
Urogen Pharma	$ 100.00	$ 129.18	$ 225.46	$ 266.17	$ 355.44	$ 355.94	$ 337.84	$ 308.01
Nasdaq Biotechnology	100.00	103.83	111.75	107.38	107.31	110.48	122.70	97.37
S&P	100.00	101.42	105.43	111.89	110.52	113.76	121.95	104.91
Nasdaq Composite	100.00	101.07	106.92	113.63	116.26	123.62	132.44	109.22

Holders

As of February 22, 2019 there were approximately 27 registered holders of record of our ordinary shares.

Dividend Policy

We have not paid any dividends on our ordinary shares since our inception and do not expect to pay dividends on our ordinary shares in the foreseeable future. We currently intend to retain all available funds as well as future earnings, if any, to fund the development and expansion of our operations. Any future determination to pay dividends will be made at the discretion of our board of directors.

Use of Proceeds from Initial Public Offering of Ordinary Shares

In May 2017, we completed our initial public offering, or IPO, and sold 5,144,378 shares of our ordinary shares at a price of $13.00 per share. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately $60.8 million. The offering commenced on May 1, 2017 and did not terminate before all of the securities registered in the registration statement were sold. The effective date of the registration statement, File No. 333-217201, for our ordinary shares was May 3, 2017. Jefferies LLC and Cowen and Company, LLC acted as joint book-running managers for the IPO, Raymond James & Associates, Inc. and Oppenheimer & Co. Inc acted as co-managers.

None of the net proceeds of our offering were paid directly or indirectly to any of our directors or executive officers, to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

As of December 31, 2018, we have used approximately $35.8 million of the net proceeds from our IPO primarily to fund our UGN-101 clinical program and other programs as well as working capital, including general operating expenses, as further described under the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing elsewhere in this Annual Report.

The remaining net proceeds from our IPO will be used, together with our cash and cash equivalents and marketable securities, to fund continued advancement of our product pipeline, with the balance to be used to fund working capital and other general corporate purposes, which may include licensing, acquiring or investing in additional businesses, technologies, products, or assets of other products, businesses or technologies.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

None.

Item 6. Selected Financial Data

The following selected financial data has been derived from our audited financial statements, including the consolidated balance sheets at December 31, 2018 and 2017 and the related consolidated statements of operations for each of the three years ended December 31, 2018 and related notes appearing elsewhere in this Annual Report. The consolidated statement of operations data for the years ended December 31, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016, 2015 and 2014 are derived from our audited consolidated financial statements that are not included in this Annual Report. Our historical results are not necessarily indicative of the results that can be expected in the future. The selected historical financial data below should be read in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes appearing elsewhere in this Annual Report.

	Years Ended December 31,				
	2018	2017	2016	2015	2014
Statements of operations data:	(in thousands, except share and per share data)				
Revenues	$ 1,128	$ 8,158	$ 17,530	$ —	$ —
Cost of revenue	1,803	600	28	—	—
Gross profit	(675)	7,558	17,502	—	—
Research and development expenses, net	36,934	18,697	10,287	10,515	3,479
General and administrative expenses	39,571	8,811	6,417	1,895	890
Operating (loss) income	(77,180)	(19,950)	798	(12,410)	(4,369)
Finance (income) expenses, net	(1,648)	31	2,739	279	107
Loss before income taxes	(75,532)	(19,981)	(1,941)	(12,689)	(4,476)
Income tax expense	125	19	—	—	—
Net loss	$ (75,657)	$ (20,000)	$ (1,941)	$ (12,689)	$ (4,476)
Loss per ordinary share, basic and diluted	$ (4.80)	$ (2.14)	$ (1.91)	$ (5.88)	$ (6.34)
Weighted average number of ordinary shares outstanding used in computing loss per share	15,754,193	9,716,790	2,305,503	2,300,959	719,059

	As of December 31,				
	2018	2017	2016	2015	2014
			(in thousands)		
Balance sheet data:					
Cash and equivalents, short-term investments	$ 101,318	$ 73,000	$ 21,362	$ 17,975	$ 3,870
Working capital	88,778	67,437	18,904	16,894	3,397
Total assets	103,559	75,550	23,056	19,930	4,359
Total liabilities	13,465	7,035	6,749	3,109	1,196
Total shareholders' equity	$ 90,094	$ 68,515	$ 16,307	$ 16,281	$ 3,163

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with "Selected Financial Data" and the historical consolidated financial statements and the notes thereto included in "Financial Statements and Supplementary Data". This discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. You should carefully read "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

Overview

We are a clinical stage biopharmaceutical company focused on developing novel therapies designed to change the standard of care for urological pathologies. We have an innovative and broad pipeline of product candidates that we believe can overcome the deficiencies of current treatment options for a variety of urological conditions with a focus on uro-oncology. Our lead product candidates, UGN-101 and UGN-102, are proprietary formulations of the chemotherapy drug mitomycin, a generic drug, which is currently used off-label for urothelial cancer treatment only in a water-based formulation as an adjuvant, or supplemental post-surgery, therapy. We are developing our product candidates as chemoablation agents, which means they are designed to remove tumors by non-surgical means, to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma, or LG UTUC, and low-grade bladder cancer, including non-muscle invasive bladder cancer, or LG NMIBC. We believe that UGN-101 and UGN-102, which are both local drug therapies, have the potential to significantly improve patients' quality of life by replacing costly, sub-optimal and burdensome tumor resection and kidney removal surgeries as the first-line standard of care. UGN-101 and UGN-102 may also reduce the need for bladder and upper urinary tract surgeries, including removal of the upper urinary tract, which are major surgical procedures typically performed when local endoscopic tumor resection fails to control the disease progression. Additionally, we believe that our product candidates, which are based on novel formulations of previously approved drugs, may qualify for streamlined regulatory pathways to market approval.

We estimate that the prevalence of LG UTUC in the United States is approximately 6,000 to 8,000; the prevalence of LG NMIBC is approximately 80,000; and the prevalence of carcinoma in situ (CIS) bladder cancer is approximately 2,000.

Our lead product candidates, UGN-101 and UGN-102, are formulated using our proprietary reverse thermally triggered hydrogel, or RTGel, technology. 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 without compromising the safety of the patient or interfering with the natural flow of fluids from the urinary tract to the bladder. Our formulations are designed to achieve this by increasing the dwell time as well as the tissue coverage of the active drug throughout the organ. 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. No drugs have been approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of non-muscle invasive bladder cancer, or NMIBC, in more than 15 years.

Our clinical stage pipeline also includes UGN-201, our proprietary immunotherapy product candidate for the treatment of high-grade NMIBC, which may include Carcinoma in Situ, or CIS. UGN-201 is a novel, liquid formulation of Imiquimod, a generic toll-like receptor 7, or TLR7, agonist. 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 or chemotherapy drugs like UGN-102, could represent a valid alternative to the current standard of care for the post-TURBT adjuvant treatment of high-grade NMIBC.

BotuGel is our proprietary novel RTGel-based formulation of BOTOX, a branded drug, that we believe can potentially serve as an effective treatment option for patients suffering from overactive bladder. In October 2016, we announced the licensing of the worldwide rights to RTGel in combination with neurotoxins, including BOTOX, to Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc, or the Allergan Agreement. 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 the RTGel in combination with BOTOX. In October 2017, Allergan commenced a Phase 2 clinical trial of BotuGel for the treatment of overactive bladder.

Our Research and Development and License Agreements

We entered into an exclusive license agreement with Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc in October 2016, which we refer to as the Allergan Agreement. Allergan paid us a nonrefundable upfront license fee of $17.5 million, and we are eligible to receive additional milestone payments upon the successful completion of certain development, regulatory and commercial milestones. Under the Allergan 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, which we refer to collectively

as 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 July 2017, Allergan notified us that they had submitted their Investigational New Drug, or IND, application for BotuGel, our proprietary novel RTGel-based formulation of BOTOX for the treatment of overactive bladder, to the FDA. The submission of the IND triggered the second milestone under the Allergan Agreement, pursuant to which we received a payment of $7.5 million in August 2017. Allergan commenced a Phase 2 clinical trial of BotuGel in October 2017, pursuant to Allergan Agreement.

For additional information regarding our research and development and license agreements, see Note 6 to our financial statements appearing elsewhere in this Annual Report.

Components of Operating Results

Revenues

We do not currently have any products approved for sale and, to date, we have not recognized any revenues from sales of UGN-101, UGN-102 or UGN-201. For the year ended December 31, 2018, we recognized revenues of $1.1 million from RTGel sales under the Allergan Agreement. For the year ended December 31, 2017, we recognized revenues of $7.5 million under the Allergan Agreement upon the achievement of a milestone in August 2017 as well as sales of RTGel to Allergan, per the Allergan Agreement. 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 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, to the extent any are successfully commercialized. If we fail to achieve clinical success and/or to obtain regulatory approval of any of our product candidates in a timely manner, our ability to generate future revenue will be impaired.

Research and Development Expenses, Net

Research and development expenses 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 CROs, subcontractors, suppliers and consultants, preclinical studies and clinical trials;
- expenses incurred to acquire, develop and manufacture preclinical study and clinical trial materials; 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. In light of the fact that 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 preclinical study and clinical trial expenses based on the services performed pursuant to contracts with research institutions and contract research organizations that conduct and manage preclinical 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, or the R&D Law, from the Israel Innovation Authority in Israel, or 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. Through December 31, 2018, we had received grants in the aggregate amount of $2.1 million.

The IIA may also impose certain conditions on any arrangement under which it permits us to transfer IIA-funded technology outside of the State of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of the State of Israel of IIA-funded technology (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to IIA. The restrictions under the R&D Law will continue to apply even after we have repaid the full amount of royalties due to the IIA. If we fail to satisfy the conditions of the R&D Law, we may be required to refund the amounts of the grants previously received, together with interest and penalties.

A recipient of a grant from the IIA is obligated to pay royalties generally at a rate of 3% to 5% on revenues from sales of products developed in whole or in part with IIA-funded technology, up to the amount of the grant related to any such products plus accrued interest. As of December 31, 2018, we have accrued $0.8 million in royalties due to the IIA, which has been recorded in cost of revenues in our results of operations for the year ended December 31, 2018. Under the R&D Law, a company that received grants from the IIA may not transfer IIA-funded technology or manufacture products developed with IIA-funded technology outside of the State of Israel without first obtaining the approval of the IIA. We may be required to pay increased royalties of up to 300% of the amount of the original grant and other amounts; if we do not receive such approvals, we may be required to pay significant penalties. Under applicable accounting rules, we deduct the IIA grants from research and development expenses as the applicable costs are incurred. We also had a preclinical collaboration for BotuGel with Allergan into which we initially entered into in February 2014. We deduct amounts received from the preclinical collaboration with Allergan from our research and development expenses as the applicable costs are incurred. As a result, our research and development expenses are shown on our financial statements net of the IIA grants and amounts received from the preclinical collaboration.

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 preclinical 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 preclinical 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 preclinical 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;
- 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.

Because UGN-101 and UGN-102 are still in clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of 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.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including share-based compensation, related to directors, executive, finance, business development, investor relations, and human resource functions, facility costs and external professional service costs, including legal, accounting and audit 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 our continued research and development programs and the potential approval and commercialization of our product candidates. 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. The increased costs associated with being a public company include expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, insurance, executive compensation, investor relations costs, and other costs associated with being a public company.

In addition, if any of our product candidates receives regulatory approval and if we invest in building a commercial infrastructure to support the marketing of our products, we expect to incur greater expenses.

Finance Expenses, Net

Finance expenses, net, consisted primarily of finance expenses on warrants offset by 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 $72.1 million as of December 31, 2018. 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.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following table sets forth our results of operations for the years ended December 31, 2018 and 2017.

	Year Ended December 31,		
	2018	2017	Change
	(in thousands)		
Revenues	$ 1,128	$ 8,158	$ (7,030)
Cost of revenue	1,803	600	1,203
Gross profit	(675)	7,558	(8,233)
Operating expenses:			
Research and development	36,934	18,697	18,237
General and administrative	39,571	8,811	30,760
Total operating expenses	76,505	27,508	48,997
Operating (loss) income	(77,180)	(19,950)	(57,230)
Finance (income) expenses, net	(1,648)	31	(1,679)
Loss before income taxes	(75,532)	(19,981)	(55,551)
Income tax expense	125	19	106
Net loss	$ (75,657)	$ (20,000)	$ (55,657)

Revenues

Revenues were $1.1 million and $8.2 million for the years ended December 31, 2018 and 2017, respectively. The decrease of $7.0 million was primarily due to the decreased revenue recognized under the Allergan Agreement.

Research and Development Expenses

Research and development expenses increased by $18.2 million to $36.9 million in the year ended December 31, 2018 from $18.7 million in the year ended December 31, 2017. Approximately $8.1 million of the increase was attributable to share-based compensation, including $2.4 million in modification costs relating to senior management severance packages and $5.7 million in new grants to executive management and employees. The remaining increase of $10.1 million is mainly comprised of $4.1 million in increased headcount and related costs to support increased clinical trial activities, a $2.5 million increase in direct costs associated with the UGN-101 Phase 3 clinical trial, a $2.7 million increase due to increased clinical activity of the UGN-102 Phase 2b clinical trial and approximately a $0.6 million increase in allocated overhead costs to support the growth of our U.S. operations. Total non-cash research and development share-based compensation expense was $12.0 million and $3.9 million for the years ended December 31, 2018 and 2017, respectively.

General and Administrative Expenses

General and administrative expenses were $39.6 million and $8.8 million for the years ended December 31, 2018 and 2017, respectively. The increase in general and administrative expenses of $30.8 million resulted primarily from an increase in share-based compensation expense of $16.2 million, including $7.5 million in modification costs relating to senior management severance packages and $8.7 million in new grants to executive management and employees. The remaining increase resulted primarily from a $5.3 million increase in payroll and recruitment costs due to headcount and related costs to support our growing business, an increase of $4.4 million in commercial services, an increase of $3.2 million in consultant and directors' fees and an increase of $1.4 million to support the growth of our U.S. operations. Total non-cash general and administrative share-based compensation expense was $18.6 million and $2.4 million for the years ended December 31, 2018 and 2017, respectively.

Finance (Income) Expenses, Net

Finance (income) expenses, net was ($1.6 million) and $31,000 for the years ended December 31, 2018 and 2017, respectively. The increase of $1.7 million in finance income was primarily due to increased interest earned on our cash balances.

Comparison of the Years Ended December 31, 2017 and 2016

The following table sets forth our results of operations for the years ended December 31, 2017 and 2016.

	Year Ended December 31,		
	2017	2016	Change
Revenues	$ 8,158	$ 17,530	$ (9,372)
Cost of revenue	600	28	572
Gross profit	7,558	17,502	(9,944)
Operating expenses:			
Research and development	18,697	10,287	8,410
General and administrative	8,811	6,417	2,394
Total operating expenses	27,508	16,704	10,804
Operating (loss) income	(19,950)	798	(20,748)
Finance (income) expenses, net	31	2,739	(2,708)
Loss before income taxes	(19,981)	(1,941)	(18,040)
Income tax expense	19	—	19
Net loss	$ (20,000)	$ (1,941)	$ (18,059)

Revenues

Our total revenues decreased by $9.3 million to $8.2 million in the year ended December 31, 2017 from $17.5 million in the year ended December 31, 2016. This decrease is mainly due to the difference in proceeds of $7.5 million and $17.5 million received from Allergan upon the achievement of certain milestones under the Allergan Agreement in each of the years ended December 31, 2017 and 2016, respectively.

Research and Development Expenses

Research and development expenses increased by $8.4 million to $18.7 million in the year ended December 31, 2017 from $10.3 million in the year ended December 31, 2016. The increase was attributable mainly to an increase in direct costs associated with the UGN-101 Phase 3 clinical trial of approximately $3.1 million, an increase of approximately $2.8 million of share-based compensation expenses related to an increase in personnel and the grant date fair value of ordinary shares, and an increase of approximately $2.5 million in headcount, consulting and related costs to support increased clinical trial activities. Total non-cash research and development share-based compensation expense for the year ended December 31, 2017 was $3.9 million.

General and Administrative Expenses

General and administrative expenses increased by approximately $2.4 million to $8.8 million in the year ended December 31, 2017 from $6.4 million in the year ended December 31, 2016. The increase in general and administrative expenses resulted primarily from an increase in share-based compensation expense of approximately $1.6 million related to an increase in personnel and the grant date fair value of ordinary shares, an increase of $1.3 million in payroll and recruitment costs due to headcount and related costs to support our growing business, an increase of $0.9 million in professional service expenses, commercial services, director and officer insurance premiums, and other costs associated with being a public company, and an increase of $0.3 million in rent and office maintenance related to our new office in New York. These increases were offset by $1.7 million of initial public offering, or IPO, expenses in the statement of operations in 2016. Total non-cash general and administrative share-based compensation expense for the year ended December 31, 2017 was $2.4 million.

Finance Expenses, Net

Finance expenses, net were $31,000 and $2.7 million for the years ended December 31, 2017 and 2016, respectively. The decrease in finance expenses, net, was primarily due to the recording of the increase in fair value of the Preferred A-1 warrants to the income statement in 2016. The warrants converted to Preferred A-1 shares upon the closing of the IPO in May 2017. There was minimal change in the fair value of the warrants in 2017 prior to conversion.

Liquidity and Capital Resources

As of December 31, 2018, we had $101.3 million in cash, 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. We believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating and capital expenditure requirements for at least the next 12 months.

Through December 31, 2018, we funded our operations primarily through public equity offerings, private placements of equity securities and through the upfront payment received under the Allergan Agreement. In May 2017, we raised $60.8 million, net of issuance costs and underwriting discounts and commissions, in our IPO on the Nasdaq Global Market. In August 2017, we received $7.5 million from Allergan upon the achievement of a milestone under the Allergan Agreement. In addition, during the year ended December 31, 2016, we recorded $1.7 million in general and administrative expenses related to IPO costs, in accordance with SEC staff Bulletin Topic 5A.

In January 2018, we completed an underwritten public offering of 1,682,926 of our ordinary shares, including 219,512 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 us from the offering were approximately $64.0 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

In January 2019, we completed an underwritten public offering of 4,207,317 of our 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 us from the offering were approximately $161.8 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

We have incurred losses since our inception and negative cash flows from our operations, and as of December 31, 2018 we had an accumulated deficit of $122.9 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, 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.

Because UGN-101 and UGN-102 are still in clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of 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.

Cash Flows

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

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (37,334)	$ (9,568)	$ 4,189
Investing activities	35,287	(36,277)	(719)
Financing activities	66,421	61,585	(9)
Net change in cash and cash equivalents	$ 64,374	$ 15,740	$ 3,461

Operating Activities

Net cash used in operating activities was $37.3 million during the year ended December 31, 2018, compared to $9.6 million during the year ended December 31, 2017. The $27.7 million increase was attributable primarily to the increase of $55.7 million in the net loss for the year, partly offset by a $24.3 million increase in share-based compensation expense and a net increase in operating assets and liabilities of $3.6 million.

Net cash used in operating activities was $9.6 million during the year ended December 31, 2017, compared to $4.2 million provided by operating activities during the year ended December 31, 2016. The increase in cash used in operating activities was attributable primarily to the receipt of the different milestone payments from Allergan of $7.5 million in 2017 and $17.5 million in 2016 and an increase in expenditures related to the UGN-101 Phase 3 clinical trial of approximately $3.1 million, as well as an increase in personnel related costs to support our growing business and service provider costs related to becoming a public company. These increases were offset by the recording of $1.7 million of IPO expenses in 2016.

Investing Activities

Net cash provided by investing activities was $35.3 million during the year ended December 31, 2018, compared to $36.3 million used in investing activities during the year ended December 31, 2017. The increase of $71.6 million is primarily related to our investment in highly liquid, short term money market funds.

Net cash used in investing activities was $36.3 million during the year ended December 31, 2017, compared to $0.7 million during the year ended December 31, 2016. The increase of $35.6 million is primarily related to our investment in highly liquid, short term money market funds.

Financing Activities

Net cash provided by financing activities was $66.4 million during the year ended December 31, 2018, compared to $61.6 million during the year ended December 31, 2017. The increase is primarily related to the increased net proceeds received from our January 2018 underwritten offering as compared to the net proceeds received from our IPO in May 2017.

Net cash provided by financing activities was $61.6 million during the year ended December 31, 2017, compared to cash used in financing activities of $0.1 million during the year ended December 31, 2016. The difference is primarily related to the net proceeds received from our IPO in May 2017.

Funding Requirements

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

- the progress, timing and completion of clinical trials for UGN-101 and UGN-102;
- preclinical studies and clinical trials for UGN-201 or any of our other product candidates;

- the costs related to obtaining regulatory approval for UGN-101, UGN-102 and UGN-201 and any of our other product candidates, and any delays we may encounter as a result of regulatory requirements or adverse clinical trial results with respect to any of these product candidates;
- selling, marketing and patent-related activities undertaken in connection with the commercialization of UGN-101 and UGN-102 and any of our other product candidates, and costs involved in the development of an effective sales and marketing organization;
- the costs involved in filing and prosecuting patent applications and obtaining, maintaining and enforcing patents or defending against claims or infringements raised by third parties, and license royalties or other amounts we may be required to pay to obtain rights to third party intellectual property rights;
- potential new product candidates we identify and attempt to develop; and
- revenues we may derive either directly or in the form of royalty payments from future sales of UGN-101, UGN-102, UGN-201, BotuGel and any other product candidates.

Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Until such time, if ever, as we can generate substantial product revenue, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

For more information as to the risks associated with our future funding needs, see “Item 1.A – Risk Factors.” 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.”

Contractual Obligations and Commitments

The obligations detailed below do not include grants received from the IIA pursuant to which we will owe royalties or reimbursement upon commercialization of our product candidates. As of December 31, 2018, the maximum royalty amount payable by us under these funding arrangements is $2.1 million, excluding interest. Under the R&D Law, a company that received grants from the IIA may not transfer IIA-funded technology or manufacture products developed with IIA-funded technology outside of the State of Israel without first obtaining the approval of the IIA. We may be required to pay increased royalties of up to 300% of the amount of the original grant and other amounts; if we do not receive such approvals, we may be required to pay significant penalties.

The following summarizes our significant contractual obligations as of December 31, 2018:

	Payments Due By Period				
	Less Than 1 Year	1 To 3 Years	3 To 5 Years	Greater Than 5 Years	Total
	(in thousands)				
Operating lease obligations (1)	$ 1,136	$ 1,927	$ 868	$ 58	$ 3,989

(1) Operating lease obligations consist of payments pursuant to lease agreements for our Israeli offices and laboratory facility and our New York offices. In November 2014, we entered into a lease agreement for our Israeli offices effective from February 1, 2015 for a period of three years, with an option to extend the lease agreement by an additional three years. In April 2016, we signed an addendum to the November 2014 lease agreement in order to increase the office space rented and extend the rental period. In November 2017, we signed an additional addendum to the November 2014 lease agreement in order to increase the office space rented. The lease agreement is effective until September 2019.

In September 2017, Urogen Pharma, Inc. entered into a new lease agreement for its current New York office for a period of approximately 41 months, which period commenced in October 2017. The new lease agreement will terminate on February 1, 2021, unless earlier terminated in accordance with its terms.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of revenue and expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles generally accepted in the United States that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 3 to our financial statements appearing elsewhere in this Annual Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Revenues

We derive virtually all of our revenues from a license and supply agreement with Allergan. Under the agreement, we grant Allergan an exclusive license to develop, commercialize, and otherwise exploit products that contain RTGel and agrees to supply Allergan with pre-clinical and clinical quantities of the RTGel product, also referred to as the RTGel vials. The license agreement contains up-front license fees, future supply fees, development, regulatory, and sales-based milestone payments, and sales-based royalty payments.

We determined that Allergan is our customer and the license and supply agreements are in scope of accounting standards codification ("ASC") 606, which we adopted as of January 1, 2018. We adopted ASC 606 under the modified retrospective method, which did not have a material impact on the Consolidated Statements of Operations. Previously, we analyzed revenues under ASC 605, which states that revenue is recognized only when all of the following conditions have been met: (i) there is persuasive evidence of an arrangement; (ii) delivery has occurred: (iii) the fee is fixed or determinable: and (iv) collectability of the fee is reasonably assured. The adoption of ASC 606 did not have a material impact on the timing and manner of recognized revenues.

Under ASC 606, in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements with Allergan, we performed the following steps:

1) Identification of the contract;
2) Determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
3) Measurement of the transaction price, including the constraint on variable consideration;
4) Allocation of the transaction price to the performance obligations;
5) Recognition of revenue when or as the Company satisfies each performance obligation.

The license agreement contains two performance obligations: (a) the license component and (b) Allergan's right to require supply services of RTGel vials from us. The license component has standalone value (and therefore is accounted for separately from the supply services) since Allergan can use the license for its intended purposes without the Company's supply services.

In an arrangement with multiple goods and services, a good or service that is promised to a customer shall be considered a separate performance obligation if all of the following criteria are met:

1) The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct); and
2) The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract).

Allocating the Consideration in the Arrangement

Since the license to our intellectual property was determined to be functional and distinct from the other performance obligations identified in the arrangement, we recognized revenues from non-refundable, up-front fees allocated to the license when the license was transferred to Allergan and Allergan was able to use and benefit from the license. During the year ended December 31, 2016, we received consideration in an amount of $17.5 million for both the license of the intellectual property as well as Allergan's right to future supply services (which would be provided in consideration for future payments to us according to the pricing stipulated in the supply agreement). We determined that the pricing of the supply services represented their standalone selling price. Accordingly, we allocated the entire upfront fee of $17.5 million to the license performance obligation.

Development and Regulatory Milestone Payments

At the inception of an arrangement that includes development milestone payments, we evaluate whether the development milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated development milestone value is included in the transaction price. Development milestone payments that are not within our control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The milestones are allocated entirely to the license performance obligation, as (1) the terms of milestone and royalty payments relate specifically to the license and (2) allocating milestones and royalties to the license performance obligation is consistent with the overall allocation objective, because management's estimate of the supply fee approximates the standalone selling price for RTGel vials and management's estimate of milestones and royalties approximates the standalone selling price of the license. During the year ended December 31, 2017, we recognized revenue of $7.5 million related to a development milestone payment resulting from Allergan's submission of an IND application for our RTGel in combination with Allergan's BOTOX for the treatment of overactive bladder to the U.S. FDA.

Royalties Based on Allergan's Revenue

We are also entitled to royalties based on Allergan's revenue from its product, however, these amounts would only be recognized when the conditions are met.

Supply of RTGel

We recognize revenue related to the supply of RTGel at a point in time, upon delivery to Allergan. During the years ended December 31, 2018 and 2017, we recognized $1.1 million and $0.7 million of revenue related to RTGel vials supplied to Allergan, respectively. There were no material RTGel vial sales during the year ended December 31, 2016.

Shipping and handling costs associated with supply of RTGel vials are accounted for as a fulfillment cost and are in included in cost of revenues.

See Note 6 appearing elsewhere in this Annual Report for further discussion regarding revenue recognized during the year ended December 31, 2018.

Research and Development

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 preclinical studies, clinical trials, manufacturing costs and professional services. The costs of services performed by others in connection with the research and development activities of an entity, including research and development conducted by others on behalf of the entity, shall be included in research and development costs. Grants received from the Israel Innovation Authority, f/k/a the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor (the "IIA") are recognized when the grant becomes receivable, provided there is reasonable assurance that we will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The grant is deducted from the research and development expenses as the applicable costs are incurred. In the year ended December 31, 2016, research and development expenses increased by $0.2 million as a result of our decision not to pursue one of its research programs that had been approved as a result of other financing opportunities. For the year ended December 31, 2016 an amount of $0.1 million was received from Allergan, in connection with the pre-clinical collaboration agreement signed in August 2015 and deducted from the research and development expenses.

The costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are research and development costs at the time the costs are incurred.

Share-Based Compensation

We account for employees' and directors' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period. As of December 31, 2016, we have early adopted the policy to account for forfeitures as they occur according to the FASB's Accounting Standards Update (ASU) 2016-09, Improvements to Employee Share-Based Payment Accounting. The adjustment for the beginning of the period was not material and therefore it was not reflected in the consolidated statements of changes in shareholders' equity.

We 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. Performance based awards are expensed over the requisite service period when the achievement of performance criteria is probable.

Equity awards granted to non-employees are re-measured at each reporting period at fair value until the commitment date had been reached which is usually the date the service is completed. The fair value of equity awards is charged to the statement of operations over the service period using the straight-line method.

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 7A. Quantitative and Qualitative Disclosures about Market Risks

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. As of December 31, 2018, we had $101.3 million in cash and cash equivalents. We invest our cash primarily in money market accounts, but from time to time may invest in commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. If a 10% change in interest rates were to have occurred on December 31, 2018, this change would not have had a material effect on the fair value of our cash and cash equivalents 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 years ended December 31, 2018, 2017 or 2016.

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 level of devaluation of the dollar against the NIS in 2017 was 9.8%. 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 8. Financial Statements and Supplementary Data

UroGen Pharma, Ltd.

Index to financial statements

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of UroGen Pharma, Ltd.

Opinion on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of UroGen Pharma Ltd. and its subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, changes in shareholders equity and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinion

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying *Management's Annual Report on Internal Control over Financial Reporting.* Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed 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. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Tel Aviv, Israel
February 28, 2019

/s/Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited

We have served as the Company's auditor since 2010.

UROGEN PHARMA, LTD.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

	December 31,	
	2018	2017
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 101,318	$ 36,999
Short-term investments	—	36,001
Restricted deposit	253	198
Inventory	—	316
Prepaid expenses and other current assets	672	958
TOTAL CURRENT ASSETS	102,243	74,472
NON-CURRENT ASSETS		
Property and equipment, net	948	805
Restricted deposit	51	29
Other non-current assets	317	244
TOTAL ASSETS	$ 103,559	$ 75,550
Liabilities and Shareholder's equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 8,540	$ 4,435
Employee related accrued expenses	4,925	1,950
Deferred revenues	—	650
TOTAL CURRENT LIABILITIES	13,465	7,035
TOTAL LIABILITIES	13,465	7,035
COMMITMENTS AND CONTINGENCIES (Note 12)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.01 par value; 100,000,000 shares authorized at December 31, 2018 and 2017; 16,214,883 and 13,751,390 shares issued and outstanding as of December 31, 2018 and 2017, respectively	44	37
Additional paid-in capital	212,921	115,692
Accumulated deficit	(122,871)	(47,214)
TOTAL SHAREHOLDERS' EQUITY	90,094	68,515
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 103,559	$ 75,550

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

UROGEN PHARMA, LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2018	2017	2016
REVENUES	$ 1,128	$ 8,158	$ 17,530
COST OF REVENUES	1,803	600	28
GROSS (LOSS) PROFIT	(675)	7,558	17,502
OPERATING EXPENSES:			
RESEARCH AND DEVELOPMENT EXPENSES, NET	36,934	18,697	10,287
GENERAL AND ADMINISTRATIVE EXPENSES	39,571	8,811	6,417
OPERATING (LOSS) INCOME	(77,180)	(19,950)	798
FINANCE (INCOME) EXPENSES, NET	(1,648)	31	2,739
LOSS BEFORE INCOME TAXES	(75,532)	(19,981)	(1,941)
INCOME TAX EXPENSE	125	19	—
NET LOSS	$ (75,657)	$ (20,000)	$ (1,941)
LOSS PER ORDINARY SHARE BASIC AND DILUTED	$ (4.80)	$ (2.14)	$ (1.91)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE	15,754,193	9,716,790	2,305,503

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

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

	Ordinary Shares		Preferred Shares		Additional paid-in capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount	Amounts		
BALANCE AS OF JANUARY 1, 2016	2,300,959	$ 6	5,193,427	$ 13	$ 41,535	$ (25,273)	$ 16,281
CHANGES DURING 2016							
Exercise of options into ordinary shares	4,784	*			*		*
Share-based compensation					1,967		1,967
Net loss						(1,941)	(1,941)
BALANCE AS OF JANUARY 1, 2017	2,305,743	$ 6	5,193,427	$ 13	$ 43,502	$ (27,214)	$ 16,307
CHANGES DURING 2017							
Exercise of options into ordinary shares	743,806	2			402		404
Share-based compensation					6,300		6,300
Exercise of warrants into preferred shares			364,036	1	4,731		4,732
Exercise of preferred shares into ordinary shares	5,557,463	14	(5,557,463)	(14)			—
IPO, net of issuance expense and underwriters discounts of $6,105	5,144,378	15			60,757		60,772
Net loss						(20,000)	(20,000)
BALANCE AS OF JANUARY 1, 2018	13,751,390	$ 37	—	$ —	$ 115,692	$ (47,214)	$ 68,515
CHANGES DURING 2018							
Exercise of options into ordinary shares	780,567	2			2,399		2,401
Share-based compensation					30,642		30,642
Issuance of ordinary shares in public offering, net of issuance expenses	1,682,926	5			64,188		64,193
Net loss						(75,657)	(75,657)
BALANCE AS OF DECEMBER 31, 2018	16,214,883	$ 44	—	$ —	$ 212,921	$ (122,871)	$ 90,094

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

UROGEN PHARMA, LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (75,657)	$ (20,000)	$ (1,941)
Adjustment to reconcile net loss to net cash from operating activities:			
Depreciation and amortization	417	207	213
Stock-based compensation	30,642	6,300	1,967
Fair value adjustment of warrants for preferred shares	—	168	2,740
Realized loss on sale of short-term investment	100	—	—
Changes in operating assets and liabilities:			
Decrease (increase) in inventory	316	(211)	(105)
Decrease (increase) in accounts receivable	—	83	(83)
Decrease (increase) in prepaid expenses and other current assets	318	(562)	739
Increase in accounts payable and accrued expenses	4,205	2,534	481
(Decrease) increase in deferred revenues	(650)	650	—
Increase in employee related accrued expenses	2,975	1,263	178
Net cash (used in) provided by operating activities	(37,334)	(9,568)	4,189
CASH FLOWS FROM INVESTING ACTIVITIES:			
Short-term investments	35,901	(36,001)	—
Change in restricted deposit	(54)	(5)	(24)
Purchase of property and equipment	(560)	(271)	(695)
Net cash provided by (used in) investing activities	35,287	(36,277)	(719)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of options into ordinary shares	2,401	404	—
Proceeds from exercise of warrants for preferred shares	—	382	570
Payment of deferred equity offering cost	—	—	(579)
Issuance of ordinary shares, net of issuance expenses	64,235	60,841	—
Issuance cost for secondary offering	(215)	(42)	—
Net cash provided by (used in) financing activities	66,421	61,585	(9)
INCREASE IN CASH AND CASH EQUIVALENTS	64,374	15,740	3,461
CASH, CASH EQUIVALENTS AND RESTRICED CASH AT BEGINNING OF THE YEAR	37,197	21,457	17,996
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE YEAR	$ 101,571	$ 37,197	$ 21,457
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Non-cash issuance cost	$ 102	$ 202	$ 181
Exercise of warrants to preferred shares	$ —	$ 4,732	$ —

The accompanying notes are an integral part of these 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 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 clinical stage biopharmaceutical company focused on developing novel therapies designed to change the standard of care for urological pathologies.

As of the date of issuance of the consolidated financial statements, the Company has the ability to fund its planned operations for at least the next 12 months. However, the Company's product candidates may never achieve commercialization and it will continue to incur losses for the foreseeable future. Therefore, in order to fund the Company's research and development expenses, general and administrative expenses and capital expenditures until such time that the Company can generate substantial revenues, the Company may need to raise additional funds.

NOTE 2-BASIS OF PRESENTATION AND MANAGEMENT PLANS

The Company has not generated any revenue from the sale of products since its inception. The Company has experienced net losses since its inception and has an accumulated deficit of $122.9 million and $47.2 million as of December 31, 2018 and 2017, respectively. The Company expects to incur losses and have negative net cash flows from operating activities as it expands its portfolio and engages in further research and development activities, particularly conducting preclinical studies and clinical trials.

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States.

The success of the Company depends on its ability to develop its technologies to the point of U.S. Food and Drug Administration ("FDA") approval and subsequent revenue generation or through the sale, merger, or other transfer of all or substantially all of the Company's assets and, accordingly, to raise enough capital to finance these developmental efforts. In the future, management will need to raise additional capital to finance the continued operating and capital requirements of the Company. Any amounts raised will be used to further develop the Company's technologies, acquire additional product licenses and for other working capital purposes. 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 will be forced to reevaluate its planned business operations.

NOTE 3-SIGNIFICANT ACCOUNTING POLICIES AND SUPPLEMENTAL FINANCIAL INFORMATION

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation, the fair value of the warrants for preferred shares and timing of revenue recognition.

Functional Currency

The U.S. dollar ("Dollar") is the currency of the primary economic environment in which the operations of the Company and subsidiary 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 consolidated statements of operations as "financial (income) expenses."

Cash and Cash Equivalents

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.

Short-Term Investments

The Company from time to time invests in short-term investments that consist of mutual and bond funds. While these investments are considered highly liquid and available to fund current operations, there is more than an insignificant risk of change in value due to interest rate, quoted price, or penalty on withdrawal and are therefore classified as short-term investments.

We classify our short-term investments as available-for-sale in accordance with FASB ASC Topic 320, "Investments — Debt and Equity Securities". Available-for-sale securities are carried at fair value with unrealized gains and losses reported in other comprehensive income/loss within shareholders' equity. The change in value for the year ended December 31, 2018 was $0.1 million.

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. Substantially all 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.

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 FDIC and concentrated within a limited number of financial institutions. The accounts are monitored by management to mitigate the risk.

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents and short-term investments. The Company deposits cash and cash equivalents with highly rated financial institutions, and, as a matter of policy, limits the amounts of credit exposure to any single financial institution. The Company has not experienced any credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

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 we operate. 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. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained upon examination by the taxing authorities based on the technical merits of the position. If this threshold is met, the second step is to measure the tax benefit as the largest amount that is more likely than not of being realized upon ultimate settlement. As of December 31, 2018 and 2017, the Company had not accrued a provision for uncertain tax positions. See Note 10 for further discussion related to income taxes.

Property and Equipment

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

Annual rates of depreciation are as follows:

	%
Computers and software	33
Laboratory equipment	15-30
Furniture	6-15
Manufacturing equipment	50

Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or lease terms. See Note 5 for further discussion regarding property and equipment.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following as of December 31, 2018 and 2017, respectively (in thousands):

	December 31, 2018	December 31, 2017
Accounts payable	$ 4,272	$ 2,839
Accrued clinical expenses	673	384
Accrued research and development costs	780	233
Accrued general and administrative expenses	1,029	239
Accrued other expense	1,786	740
Total accrued expenses and other current liabilities	$ 8,540	$ 4,435

Revenues

The Company derives virtually all of its revenues from its license and supply agreement with Allergan. Under the agreement, the Company grants Allergan an exclusive license to develop, commercialize, and otherwise exploit products that contain RTGel and agrees to supply Allergan with pre-clinical and clinical quantities of the RTGel product, also referred to as the RTGel vials. The license agreement contains up-front license fees, future supply fees, development, regulatory, and sales-based milestone payments, and sales-based royalty payments.

The Company determined that Allergan is its customer and the license and supply agreements are in scope of ASC 606, which was adopted as of January 1, 2018. The Company adopted ASC 606 under the modified retrospective method, which did not have a material impact on the Consolidated Statements of Operations. Previously, we analyzed revenues under ASC 605, which states that revenue is recognized only when all of the following conditions have been met: (i) there is persuasive evidence of an arrangement; (ii) delivery has occurred: (iii) the fee is fixed or determinable: and (iv) collectability of the fee is reasonably assured. The adoption of ASC 606 did not have a material impact on the timing and manner of recognized revenues.

Under ASC 606,in determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements with Allergan, the Company performs the following steps:

1) Identification of the contract;
2) Determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
3) Measurement of the transaction price, including the constraint on variable consideration;
4) Allocation of the transaction price to the performance obligations;
5) Recognition of revenue when or as the Company satisfies each performance obligation.

The license agreement contains two performance obligations: (a) the license component and (b) Allergan's right to require supply services of RTGel vials from the Company. The license component has standalone value (and therefore is accounted for separately from the supply services) since Allergan can use the license for its intended purposes without the Company's supply services.

In an arrangement with multiple goods and services, a good or service that is promised to a customer shall be considered a separate performance obligation if all of the following criteria are met:

1) The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct); and
2) The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract).

Allocating the Consideration in the Arrangement

Since the license to the Company's intellectual property was determined to be functional and distinct from the other performance obligations identified in the arrangement, the Company recognized revenues from non-refundable, up-front fees allocated to the license when the license was transferred to Allergan and Allergan was able to use and benefit from the license. During the year ended December 31, 2016, the Company received consideration in an amount of $17.5 million for both the license of the intellectual property as well as Allergan's right to future supply services (which would be provided in consideration for future payments to the Company according to the pricing stipulated in the supply agreement). The Company determined that the pricing of the supply services represented their standalone selling price. Accordingly, the Company allocated the entire upfront fee of $17.5 million to the license performance obligation.

Development and Regulatory Milestone Payments

At the inception of an arrangement that includes development milestone payments, the Company evaluates whether the development milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated development milestone value is included in the transaction price. Development milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The milestones are allocated entirely to the license performance obligation, as (1) the terms of milestone and royalty payments relate specifically to the license and (2) allocating milestones and royalties to the license performance obligation is consistent with the overall allocation objective, because management's estimate of the supply fee approximates the standalone selling price for RTGel vials and management's estimate of milestones and royalties approximates the standalone selling price of the license. During the year ended December 31, 2017, the Company recognized revenue of $7.5 million related to a development milestone payment resulting from Allergan's submission of an IND application for the Company's RTGel in combination with Allergan's BOTOX for the treatment of overactive bladder to the U.S. FDA.

Royalties Based on Allergan's Revenue

We arealso entitled to royalties based on Allergan's revenue from its product, however, these amounts would only be recognized when the conditions are met.

Supply of RTGel to Allergan

The Company recognizes revenue related to supply of RTGel at a point in time, upon delivery to Allergan. During the years ended December 31, 2018 and 2017, the Company recognized $1.1 million and $0.7 million of revenue related to RTGel vials supplied to Allergan, respectively. There were no material RTGel vial sales during the year ended December 31, 2016.

Shipping and handling costs associated with supply of RTGel vials are accounted for as a fulfillment cost and are in included in cost of revenues.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including share-based compensation, for personnel in executive, finance, accounting, legal, investor relations, facilities, business development and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to corporate matters, insurance, public company expenses relating to maintaining compliance with Nasdaq listing rules and SEC requirements, insurance and investor relations costs, and fees for accounting and consulting services. 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.

Research and Development

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 preclinical studies, clinical trials, manufacturing costs and professional services. The costs of services performed by others in connection with the research and development activities of an entity, including research and development conducted by others on behalf of the entity, 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.

Grants received from the Israel Innovation Authority, f/k/a the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor (the "IIA") are recognized when the grant becomes receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The grant is deducted from the research and development expenses as the applicable costs are incurred. In the year ended December 31, 2016, the Company had an increase of $0.2 million to its research and development expenses as a result of its decision not to pursue one of its research programs that had been approved as a result of other financing opportunities. For the year ended December 31, 2016 an amount of $0.1 million was received from Allergan, in connection with the pre-clinical collaboration agreement signed in August 2015 and deducted from the research and development expenses.

The costs of intangibles that are purchased from others for a particular research and development project and that have no alternative future uses (in other research and development projects or otherwise) and therefore no separate economic values are research and development costs at the time the costs are incurred.

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 stock options is determined using the Black-Scholes option-pricing model. The fair value of a restricted stock unit equaled the closing price of our ordinary shares on the grant date.

As of December 31, 2016, the Company has early adopted the policy to account for forfeitures as they occur according to the FASB's Accounting Standards Update (ASU) 2016-09, Improvements to Employee Share-Based Payment Accounting.

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.

Equity awards granted to non-employees are re-measured at each reporting period at fair value until the commitment date had been reached which is usually the date the service is completed. The fair value of equity awards is charged to the statement of operations over the service period using the straight-line method.

Finance (Income) Expense

	Year Ended December 31,		
	2018	2017	2016
Changes in fair value of warrants for preferred shares	$ —	$ 168	$ 2,740
Interest income on cash and cash equivalents	(1,872)	(125)	(1)
Realized loss on sale of short-term investment	100	—	—
Other finance expenses	124	(12)	—
Total finance (income) expense	$ (1,648)	$ 31	$ 2,739

Net Loss per Common Share

Basic net loss per share is computed by dividing the net loss attributable to common shareholders by the weighted-average number of common 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 common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. In addition, the net loss attributable to common shareholders is adjusted for Series A and A-1 Preferred Stock dividends for the periods in which Series A and A-1 Preferred Stock is outstanding.

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

The following table summarizes the calculation of basic and diluted loss per common share for the periods presented (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2018	2017	2016
Basic and diluted:			
Loss attributable to equity holders of the Company	$ 75,657	$ 20,000	$ 1,941
Dividend accumulated for preferred shares during the period	$ —	$ 825	$ 2,467
Loss attributable to equity holders of the Company, after deducting dividend accumulated for preferred shares	$ 75,657	$ 20,825	$ 4,408
Weighted-average number of ordinary shares	15,754,193	9,716,790	2,305,503
Loss per ordinary share	$ 4.80	$ 2.14	$ 1.91

Recent Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, "Compensation-Stock Compensation" (“Topic 718” or “ASU 2018-07”) to improve the usefulness of information provided to users of financial statements while reducing cost and complexity in financial reporting and provide guidance aligning the measurement and classification for share-based payments to nonemployees with the guidance for share-based payments to employees. Under the guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date. This standard is effective for fiscal years beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The adoption of ASU 2018-07 will not have an impact on the Company’s Consolidated Statements of Operations.

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, "Leases" ("Topic 842"). Topic 842 supersedes existing guidance in Leases ("Topic 840"). Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. Topic 842 requires lessees to recognize right-of-use ("ROU") assets and lease liabilities on the balance sheet for leases with lease terms greater than twelve months, including those classified as operating leases. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The lease liability will be measured at the present value of the unpaid lease payments and the ROU asset will be derived from the calculation of the lease liability. Lease payments will include fixed and in-substance fixed payments, variable payments based on an index or rate, exercise price of purchase options that are reasonably certain to be exercised, termination penalties, and probable amounts the lessee will owe under a residual value guarantee. Topic 842 also requires lessees to disclose key information about leasing arrangements. Lessor accounting will remain largely unchanged. The guidance is effective for annual periods beginning after December 15, 2018, with early adoption permitted.

The Company will apply the modified retrospective transition method and elect the transition option to use the effective date of January 1, 2019 as the date of initial application ("Transition Date"). Consequently, financial information will not be updated, and the disclosures required under the Topic 842 will not be provided for dates and periods before January 1, 2019.

Topic 842 provides a number of optional practical expedients in transition. The Company expects to elect the 'package of practical expedients', which permits not to reassess under Topic 842 its prior conclusions about lease identification, lease classification, and initial direct costs. The Company does not expect to elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to the Company. As a result, the Company will in effect, continue to account for existing leases – i.e. leases for which the commencement date is before January 1, 2019 – in accordance with Topic 840 throughout the entire lease term, including periods after the effective date, with the exception that the Company will apply the new balance sheet recognition guidance for operating leases and apply Topic 842 for remeasurements and modifications after the Transition Date.

While continuing to assess all the effects of adoption, the Company expects that Topic 842 will have a material effect on its financial statements. On adoption, the Company currently expects to recognize additional operating lease liabilities of approximately $3.5 million, with corresponding ROU asset for existing operating leases. The Company does not expect a material impact on its Consolidated Statements of Operations or its Consolidated Statements of Cash Flows.

NOTE 4-FAIR VALUE MEASUREMENTS AND INVESTMENTS IN MARKETABLE SECURITIES

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, Level 2, and Level 3 fair value measurement criteria as of December 31, 2018 are as follows (in thousands):

	Balance as of December 31, 2018	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds(1)	$ 89,965	$ 89,965	$ —	$ —

(1) Included within cash and cash equivalents on the Company's consolidated balance sheets.

Assets and liabilities measured at fair value on a recurring basis based on Level 1, Level 2, and Level 3 fair value measurement criteria as of December 31, 2017 are as follows (in thousands):

	Balance as of December 31, 2017	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds(1)	$ 26,127	$ 26,127	$ —	$ —
Short-term investments	36,001	—	36,001	—

(1) Included within cash and cash equivalents on the Company's consolidated balance sheets.

The Company's investments in money market funds are valued based on publicly available quoted market prices for identical securities as of December 31, 2018 and 2017.

NOTE 5-PROPERTY AND EQUIPMENT

Property and equipment, consists of the following as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Laboratory equipment	$ 241	$ 223
Computer equipment and software	271	167
Furniture	395	234
Leasehold improvements	561	531
Manufacturing equipment	227	227
	1,695	1,382
Less: accumulated depreciation and amortization	(747)	(577)
Property and equipment, net	$ 948	$ 805

Depreciation and amortization expense was $0.4 million $0.2 million and $0.2 million for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 6-ALLERGAN LICENSE AGREEMENT

In October 2016, the Company entered into the Allergan Agreement with Allergan and granted Allergan 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 our trademarks as required for Allergan to practice its exclusive license with respect to the Licensed Products.

Under the Allergan Agreement, Allergan is solely responsible, at its expense, for developing the Licensed Products and obtaining all regulatory approvals for Licensed Products worldwide. Allergan is also solely responsible, at its expense, for commercializing the Licensed Products worldwide 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 to us if there is a material supply failure from us. Prior to completion of the first Phase 2 clinical trial, Allergan has the right to request that the Company transfers to Allergan our manufacturing process for RTGel and Allergan will assume the responsibility to manufacture RTGel and Licensed Product for its own development and commercialization activities.

Allergan paid the Company a nonrefundable upfront license fee of $17.5 million upon signing the agreement, and, in the third quarter of 2017, the Company received an additional $7.5 million milestone payment upon the submission by Allergan of an IND to the FDA for a Licensed Product. In October 2017, Allergan began a Phase 2 study of RTGel in combination with BOTOX for the treatment of overactive bladder. Additionally, during the years ended December 31, 2018 and 2017 the Company recognized revenue of $1.1 million and $0.7 million related to RTGel that was supplied to Allergan, respectively.

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, including $20.0 million upon initiation of a Phase 3 clinical trial for a Licensed Product for overactive bladder; $15.0 million upon initiation of a Phase 3 clinical trial for a Licensed Product for a specified second indication; $50.0 million and $25.0 million upon the first commercial sale of a Licensed Product for overactive bladder in the United States and the European Union, respectively; $25.0 million and $15.0 million upon the first commercial sale of a Licensed Product for a specified second indication in the United States and the European Union, respectively; and $50.0 million upon net sales of all Licensed Products of $500.0 million. 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 our 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 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.

The Company plans to continue to research, develop and commercialize other products combining RTGel with other active ingredients, except that there are certain restrictions with respect to the overactive bladder and neurogenic detrusor overactivity indications. Neurogenic detrusor overactivity is when a known neurologic abnormality impairs the signaling systems between the bladder and the central nervous system, and the brain is unable to inhibit the detrusor muscles controlling urination.

Either party may terminate the Allergan Agreement for uncured material breach by the other party and for the insolvency of the other party. The Company may terminate the Allergan 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 the Company, its affiliates or licensees against Allergan, its affiliates or sublicensees. In addition, Allergan may unilaterally terminate the Allergan Agreement for any reason upon advance notice. If Allergan has the right to terminate the Allergan Agreement due to an uncured material breach by the Company, 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 Agreement, Allergan will assign or grant a right of reference to any regulatory documentation related to RTGel to the Company, all rights and licenses to Allergan will terminate, and the license Allergan granted to us under their improvements to RTGel will continue.

NOTE 7-EMPLOYEE RIGHTS UPON RETIREMENT

The Company is required by law to make severance payments upon dismissal of an employee or upon termination of employment in certain other circumstances.

The Company operates a number of post-employment defined contribution plans. A defined contribution plan is a program that benefits an employee after termination of employment, under which the Company regularly makes fixed payments to a separate and independent entity so that the Company has no legal or constructive obligation to pay additional contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods. The fund assets are not included in the Company's financial position.

The Company operates pension and severance compensation plans subject to Section 14 of the Israeli Severance Pay Law, 5723-1963. The plans are funded through payments to insurance companies or pension funds administered by trustees. In accordance with its terms, the plans meet the definition of a defined contribution plan, as defined above.

NOTE 8-SHAREHOLDERS' EQUITY

Ordinary Shares

The Company had 100.0 million ordinary shares authorized for issuance as of December 31, 2018 and 2017, respectively. The Company had 16.2 million and 13.8 million ordinary shares issued and outstanding as of December 31, 2018 and 2017, 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. Since its inception, the Company has not declared any dividends.

In May 2017, the Company completed an IPO on the Nasdaq Global Market, in which it issued 5,144,378 ordinary shares, at a public offering price of $13.00 per share, in consideration for $60.8 million, net of underwriting discounts and commissions and issuance costs, including exercise of the underwriters' option to purchase additional 671,005 ordinary shares at the IPO price.

Upon completion of the IPO, the Company converted all outstanding warrants for Preferred A-1 shares into 364,036 Preferred A-1 shares of the Company (see below). Subsequently, the Company converted all outstanding Preferred A and Preferred A-1 shares into ordinary shares at a ratio of 1:1. As of December 31, 2017, the Company's share capital was composed entirely of ordinary shares.

In January 2018, the Company completed an underwritten public offering of 1,682,926 of its ordinary shares, including 219,512 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 public offering were approximately $64.2 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

See Note 13 for further discussion regarding an underwritten public offering of ordinary shares that the Company completed in January 2019.

Warrants for Preferred A-1 Shares

In 2014, as part of a share purchase agreement, the Company issued warrants (the "A-1 warrants") for preferred shares. The warrants were exercisable for Series A-1 preferred shares, in consideration for cash representing the exercise price. The A-1 warrants were measured at fair value in every reporting period, and changes in their fair value were recognized in earnings within finance expenses, net.

In connection with the completion of the IPO, the Company converted all outstanding warrants into 364,036 Preferred A-1 shares of the Company and subsequently converted all of its preferred shares, including the Preferred A-1 shares, into ordinary shares.

The Company's warrants outstanding prior to the IPO were exercisable for Series A-1 preferred shares at an exercise price of $7.81 per share. Prior to the IPO, such warrants were exercisable for 728,312 Preferred A-1 shares.

Series A Preferred Shares

In October 2015 the Company entered into an asset purchase agreement with Telormedix SA ("TMX") pursuant to which the Company purchased all of the intellectual property assets of TMX (in process R&D) in consideration for 691,200 Series A preferred shares of the

Company at a price per share of $5.94, which were subsequently converted into ordinary shares on the date of the IPO. The Company will issue additional shares upon the occurrence of each of three milestones as set in the agreement. The Company has deemed the probability of achieving these milestones to be remote. The acquired intellectual property costs totaling $4.1 million were expensed as incurred to research and development costs in accordance with ASC 730, as the intellectual property is purchased from others for a particular research and development project and has no alternative future uses and therefore no separate economic value.

On April 19, 2017, the Company's board of directors and shareholders approved an aggregate 3.2 for-1 share split of the Company's ordinary, Preferred A and Preferred A-1 shares. The share split was effected on April 19, 2017 by the issuance of 2.2 ordinary shares for each outstanding ordinary, Preferred A and Preferred A-1 share held immediately prior to the share split.

Upon the completion of the IPO, all Series A preferred shares converted to ordinary shares on a 1:1 ratio. Prior to the IPO, the Series A preferred shares were classified within permanent equity as they were not subject to liability classification under the scope of ASC 480, and meet all the requirements of equity classification under ASC 480-10-S99.

NOTE 9-SHARE-BASED COMPENSATION

In October 2010, the Company's Board of Directors 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 stock options and RSU grants upon commencement of employment. Eligible employees may also receive a grant of stock options or RSUs annually. Non-employee members of our Board of Directors and any new, future directors may receive a grant of RSUs and/or stock options annually. The term of any stock 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 stock of the Company, the exercise price shall not be less than 110% of the fair market value of a common share of stock on the date of grant.

The Company's RSU and stock 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 equal quarterly amounts for the two years following the one-year anniversary of the grant date. Stock options generally vest in a 33% increment upon the first anniversary of the grant date, and in equal quarterly amounts for the three years following the one-year anniversary of the grant date.

The expected volatility is based on 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 Company's Board of Directors adopted the 2017 Equity Incentive Plan ("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, restricted stock unit awards, performance stock awards, performance cash awards, and other forms of stock 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 our board of directors. The maximum number of ordinary shares that may be issued upon the exercise of incentive 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 filed a registration statement on Form S-8 increasing the amount of registered ordinary shares of the Company's 2017 Plan by 1,900,000 to 3,550,167.

In April 2017, the Company's board of directors approved modifications of performance conditions for 67,200 restricted stock units and contingent options for executive management. The Company recorded an expense of $0.5 million under general and administrative expenses with respect to these modifications.

During the year ended December 31, 2018, the Company recorded $7.2 million in general and administrative and research and development expenses in the Company's Statements of Operations for the year ended December 31, 2018 related to the stock option modifications related to the termination of certain senior executives, based on the executive's respective allocations.

On January 2, 2019, the Company announced the resignation of its CEO, and the Company's board of directors approved a severance package, which included a combination of cash and modifications to grants of his related option awards in the amount of $3.4 million. The cash element followed the termination section in the CEO employment agreement, and the options element included acceleration to certain grants of his related option awards. The fair value of the modifications to these option awards was estimated at $2.8 million. The entire severance package was recorded in general and administrative and research and development expenses, based on salary allocations respectively, in the Company's Statements of Operations for the year ended December 31, 2018.

In August 2018, in addition to the modifications, one senior executive was granted 10,466 RSUs in which no compensation expense was taken because the award vests upon a future performance condition that is not currently probable of occurring.

For the years ended December 31, 2018 and 2017, the Company granted options to certain employees and non-employees as follows:

Options granted to employees and directors:

Set forth below are grants made by the Company to employees and directors as of December 31, 2018. The majority of options vest over three years and expire on the tenth anniversary of the date of grant.

a) During 2018, the Company granted 1,155,000 options to employees and directors with exercise prices ranging from $38.64 to $59.23 per share.

b) During 2017, the Company granted 589,600 options to employees and directors with exercise prices ranging from $1.78 to $39.26 per share.

c) During 2016, the Company granted 404,813 options to employees and directors with exercise prices ranging from $5 to $5.94 per share.

The fair value of options granted to employees and directors during 2018, 2017 and 2016 was $39.3 million, $10.9 million and $0.9 million, respectively.

The total unrecognized compensation cost of employee and director options at December 31, 2018 is $26.5 million, which is expected to be recognized over a weighted average period of 2.2 years.

The fair value of options granted to employees and directors was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	2018	2017	2016
Value of ordinary shares	$38.64-59.23	$13.00-39.26	$2.98-5.54
Dividend yield	0%	0%	0%
Expected volatility	72.59%-79.37%	71.53%-76.32%	74.8%-80%
Risk-free interest rate	2.30%-3.07%	1.85%-2.47%	1.4%–2.13%
Expected term	5.4-10 years	5.5-10 years	7 years

Options granted to consultants and other service providers:

Set forth below are grants made by the Company to consultants and service providers as of December 31, 2018. The majority of the options vest over a period of three years and expire on the seventh anniversary of the date of grant.

a) During 2018, the Company granted 40,000 options to consultants and service providers with exercise prices ranging from $43.67 to $59.23 per share.

b) During 2017, there were no new grants issued to consultants and service providers.

c) During 2016, the Company granted 132,032 options to consultants and service providers with exercise prices ranging from $0 to $5.94 per share.

The fair value as of December 31, 2018, 2017 and 2016 of options granted to consultants and service providers during 2018, 2017 and 2016 was $1.0 million, $0 and $0.7 million, respectively.

The fair value of options granted to consultants and other service providers was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	2018	2017	2016
Value of ordinary shares	$43.06-49.69	$1.58-37.21	$1.58-7.96
Dividend yield	0%	0%	0%
Expected volatility	72.00%-82.04%	68.45%-74.50%	72.72%-80%
Risk-free interest rate	1.72%-2.98%	1.38%-2.26%	1.56%-2.27%
Expected term	0.2-9.5 years	3.9-5.9 years	5.8-8.5 years

The following table summarizes the number of options outstanding under the Plan for the years ended December 31, 2018, 2017 and 2016, and related information:

	Employees and Directors		Consultants and Service providers	
	Number of options	Weighted Average price per share	Number of options	Weighted Average price per share
Outstanding as of January 1, 2016	1,411,400	$ 4.70	513,238	$ 3.48
Granted	404,813	$ 5.50	132,032	$ 7.15
Canceled/Forfeited	(60,800)	$ 5.94	(6,000)	$ 1.58
Exercised	—	$ —	(4,784)	$ 2.45
Outstanding as of December 31, 2016	1,755,413	$ 4.84	634,486	$ 4.27
Granted	589,600 *	$ 23.95	—	$ —
Canceled/Forfeited	(39,500)	$ 5.77	(5,686)	$ 2.93
Exercised	(560,243)	$ 4.39	(130,038)	$ 2.92
Outstanding as of December 31, 2017	1,745,270	$ 11.42	498,762	$ 4.64
Granted	1,155,000	$ 47.18	40,000	$ 47.56
Canceled/Forfeited	(153,313)	$ 35.19	(13,836)	$ 37.38
Exercised	(659,434)	$ 9.37	(89,468)	$ 6.20
Outstanding as of December 31, 2018	2,087,523	$ 30.11	435,458	$ 7.22

* Including 9,600 ordinary shares issuable upon the vesting of options granted in 2016, which were contingent upon the closing of the IPO

The intrinsic value of stock options exercised by employees and directors was $27.5 million, $17.9 million, and $0 for the years ended December 31, 2018, 2017, and 2016, respectively. The intrinsic value of stock options exercised by consultants and service providers was $4.1 million, $3.5 million, and $0.01 million for the years ended December 31, 2018, 2017, and 2016, respectively.

The following table summarizes the outstanding and exercisable options as of December 31, 2018:

	Options outstanding		Options exercisable	
Exercise price per share	Number of options outstanding at end of year	Weighted average remaining contractual life	Number of options exercisable at end of year	Weighted average remaining contractual life
$0.00 - 10.00	1,023,791	3.38	814,479	3.20
$10.01 - 20.00	215,079	6.71	140,078	5.79
$20.01 - 30.00	100,000	8.82	33,334	8.82
$30.01 - 40.00	225,000	6.18	114,998	3.40
$40.01 - 50.00	742,111	8.80	157,720	6.90
$50.01 - 59.23	217,000	9.37	36,499	9.43
	2,522,981		1,297,108	

The aggregate intrinsic value of the total vested and exercisable options and vested and not released restricted stock units as of December 31, 2018 is $38.9 million.

The following table summarizes information about RSU activity as of December 31, 2018:

	Outstanding Restricted Stock Units
Outstanding as of January 1, 2016	275,200
Granted	—
Vested and released	—
Forfeited	—
Outstanding as of December 31, 2016	275,200
Granted	123,300 *
Vested and released	(121,940)
Forfeited	—
Outstanding as of December 31, 2017	276,560
Granted	116,493
Vested and released	(118,447)
Forfeited	(10,907)
Outstanding as of December 31, 2018	263,699

* Including 28,800 ordinary shares issuable upon the vesting of options granted in 2016, which were contingent upon the closing of the IPO

The Company has not previously separately disclosed the table information shown above. The fair value of RSUs granted during 2018, 2017 and 2016 was $5.7 million, $3.3 million, and $0, respectively. The total unrecognized compensation cost of RSUs at December 31, 2018 is $5.2 million with a weighted average recognition period of 2.1 years.

The following table illustrates the effect of share-based compensation on the statements of operations:

	Year ended December 31,		
	2018	2017	2016
Research and development expenses	$ 12,038	$ 3,923	$ 1,167
General and administrative expenses	18,604	2,377	800
	$ 30,642	$ 6,300	$ 1,967

NOTE 10-INCOME TAXES

The Company is taxed under Israeli tax laws:

Corporate tax rate

Presented hereunder are the tax rates relevant to the Company in the years 2016-2018:

2016 – 25%

2017 – 24%

2018 – 23%

On January 4, 2016 the Knesset plenum passed the Law for the Amendment of the Income Tax Ordinance (Amendment 216) - 2016, by which, inter alia, the corporate tax rate would be reduced by 1.5% to a rate of 25% as from January 1, 2016.

Furthermore, on December 22, 2016 the Knesset plenum passed the Economic Efficiency Law (Legislative Amendments for Achieving Budget Objectives in the Years 2017 and 2018) – 2016, by which, inter alia, the corporate tax rate would be reduced from 25% to 23% in two steps. The first step will be to a rate of 24% as from January 2017 and the second step will be to a rate of 23% as from January 2018.

As a result of the reduction in the tax rate to 23% in two steps, the deferred tax balances as at December 31, 2018 were calculated according to the new tax rate specified in the Economic Efficiency Law (Legislative Amendments for Achieving Budget Objectives in the Years 2017 and 2018), at the tax rate expected to apply on the date of reversal.

Current taxes for the reported periods are calculated according to the tax rates presented above.

Income Tax Regulations (Rules on Bookkeeping by Foreign Invested Companies and Certain Partnerships and Determination of their Taxable Income), 1986:

As a "Controller Foreign Cooperation" (as defined in the Israeli Law for the Encouragement of Capital Investments-1959), the Company's management has elected to apply Income Tax Regulations (Rules for Maintaining Accounting Records of Foreign Invested Companies and Certain Partnerships and Determining Their Taxable Income) – 1986, from January 2018. Accordingly, its taxable income or loss is calculated in US Dollars.

Law for the Encouragement of Industry (Taxation), 1969:

The Company is an “Industrial Company” under the Law for the Encouragement of Industry (Taxation), 1969 and, therefore, is entitled to certain tax benefits, mainly are as follows:

- Amortization in three equal annual portions of issuance expenses when registering shares for trading as from the date the shares of the company were registered.
- An 8-year period of amortization for acquired patents and know-how used in the process of development performed by the enterprise.

Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company and its subsidiary deferred tax assets are as follows:

	December 31,		
	2018	2017	2016
In respect of:			
Net operating loss carry forward	$ 16,943	$ 5,844	$ 3,280
Deferred rent	61	46	—
Research and development expenses	3,891	2,887	—
Stock-based compensation	4,769	897	—
Issuance costs	1,367	1,261	—
In-process research and development	629	761	806
Accrued expenses	598	5	—
Depreciation of fixed assets	(93)		
Other	84	24	72
Less—valuation allowance	(28,249)	(11,725)	(4,158)
Net deferred tax assets	$ —	$ —	$ —

The change in valuation allowance for the years ended December 31, 2018 and 2017 were as follows:

	2018	2017	2016
Balance at the beginning of the year	$ (11,725)	$ (4,158)	$ (4,499)
Changes during the year	(16,524)	(7,567)	341
Balance at the end of the year	$ (28,249)	$ (11,725)	$ (4,158)

The main reconciling item between the statutory tax rates of the Company and the effective rate is the share-based compensation and provision for full valuation allowance in respect of tax benefits from carryforward tax losses due to the uncertainty of the realization of such tax benefits.

Regarding the Company's US operations, as of December 31, 2018, UPI had federal tax net operating losses of $1.5 million and state tax net operating losses of $1.7 million in several jurisdictions available to carry forward and reduce future income tax liabilities. The federal and state net operating losses begin to expire after 2036.

The Internal Revenue Code contains provisions that may limit the use of the net operating tax loss carryforward available if significant changes occur in the stock ownership of UPI. In the event UPI has had a change in ownership, utilization of the carry-forwards could be restricted due to the "change in ownership provisions" under Section 382 of the Internal Revenue Code and similar state provisions. Such limitations could result in the expiration of the net operating carry-forwards before their utilization.

Losses for tax purposes carried forward to future years

As of December 31, 2018, the Company had approximately $72.1 million of net carry forward tax losses available to reduce future taxable income without limitation of use.

Tax assessments

UPL has received final tax assessments up to and including 2013 tax year.

NOTE 11-RELATED PARTIES

UPI entered into a lease agreement, dated as of November 2015 and commencing as of May 2016, for office space in New York. UPI shared the office space equitably with Kite Pharma, Inc., a Delaware corporation, which was a cosignatory to such lease agreement. Arie Belldegrun, M.D., UPL's chairman, served as the Chairman and Chief Executive Officer of Kite Pharma, Inc. until his resignation effective as of October 3, 2017, in connection with the acquisition of Kite Pharma, Inc. by Gilead Sciences, Inc.

In April 2018, UPI terminated its lease for offices at 689 Fifth Avenue in New York, and on December 1, 2018, UPI and Kite Pharma, Inc., completed a full assignment and assumption of the lease to Allogene Therapeutics, Inc. of which Arie Belldegrun, M.D., serves as the Chairman of the Board of Directors.

UPI recorded a loss on disposal of fixed assets of $0.2 million for the year ended December 31, 2018, regarding accelerated depreciation on the leasehold improvements associated with the lease, and there is no further liability as of December 31, 2018.

NOTE 12-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 December 31, 2018 and 2017. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Leases

In April 2016, UPL signed an addendum to its November 2014 lease agreement for the Company's principal executive offices located in Israel, in order to increase the office space rented and to extend the rent period until 2019.

UPI entered into a lease agreement for its office for a period of seven years commencing on May 1, 2016. As part of the agreement UPI provided the lessor with a letter of credit which renews on an annual basis. On December 1, 2018 UPI completed a full assignment and assumption of the lease to Allogene Therapeutics, Inc. The letter of credit was returned and there is no further liability to UPI as of December 31, 2018.

In September 2017, UPI entered into a new lease agreement for its New York headquarters. The lease agreement commenced in October 2017 and shall terminate in February 2021. The remaining contractual obligation is approximately $1.5 million.

In April 2018, UPI entered into a new lease agreement for an office in Los Angeles, CA. The lease commencement date was July 10, 2018 and terminates in March 2024. The contractual obligation for the remainder of the lease is $1.4 million. The landlord provided a tenant allowance for leasehold improvements of $0.2 million that is accounted for as a lease incentive and is being amortized to rent expense ratably over the life of the lease.

Rent expense charged to operations was $1.2 million, $0.6 million, and $0.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

The following table summarizes our lease obligations at December 31, 2018 (in thousands):

YEARS ENDED DECEMBER 31,	Operating Lease
2019	$ 1,136
2020	1,251
2021	676
2022	567
2023	301
2024 and thereafter	58
Total minimum lease payments	$ 3,989

Grants from the 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 Director General Directive 8.2 of Israel by grants provided to Granot Ventures. Since 2008, the funding was provided directly to Company.

The Company is committed to pay royalties to the Government of Israel on proceeds from sales of products in the research and development of which the IIA participates by way of grants. At the time the grants were received, successful development of the related projects was not assured. In the case of failure of a project that was partly financed as above, the Company is not obligated to pay any such royalties. Under the terms of the funding from the IIA, royalties of 3% to 5% are payable on sales of products developed from a project so funded, up to 100% of the amount of the grant received by the Company (dollar linked); with the addition of annual interest at a rate based on 12-month LIBOR. The Company is subject to several conditions, including restrictions on its intellectual property.

As of December 31, 2018, the maximum royalty amount payable by the Company under these funding arrangements is $2.1 million (excluding interest, and inclusive of the $0.8 million in royalties that the Company has accrued as of December 31, 2018). Under the R&D Law, a company that received grants from the IIA may not transfer IIA-funded technology or manufacture products developed with IIA-funded technology outside of the State of Israel without first obtaining the approval of the IIA. We may be required to pay increased royalties of up to 300% of the amount of the original grant and other amounts; if we do not receive such approvals, we may be required to pay significant penalties. As of December 31, 2018, the Company has accrued $0.8 million in royalties due to the IIA, which has been recorded in cost of revenues in our results of operations for the year ended December 31, 2018.

NOTE 13-SUBSEQUENT EVENTS

In January 2019, the Company completed an underwritten public offering of 4,207,317 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 $161.8 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

On January 3, 2019, we appointed Elizabeth Barrett as our President and Chief Executive Officer, replacing Ron Bentsur in those capacities. Concurrently, Ms. Barrett was appointed as a member of our board of directors (the "Board") and Mr. Bentsur resigned from the Board. In connection with Ms. Barrett's employment, she was granted 277,432 options to purchase the Company's ordinary shares, as well as 317,065 RSUs, with a combined fair value of $24.1 million.

NOTE 14-SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for 2018 and 2017 are as follows (in thousands, except per share data):

	2018				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Total revenues	$ 481	$ 364	$ 283	$ —	$ 1,128
Total operating expenses	$ 13,691	$ 18,480	$ 20,317	$ 24,017	$ 76,505
Loss from operations	$ (13,640)	$ (18,434)	$ (21,089)	$ (24,017)	$ (77,180)
Net loss attributable to common shareholders	$ (13,382)	$ (18,026)	$ (20,533)	$ (23,716)	$ (75,657)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.88)	$ (1.14)	$ (1.28)	$ (1.46)	$ (4.80)

	2017				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Total revenues	$ 19	$ —	$ 7,812	$ 327	$ 8,158
Total operating expenses	$ 3,539	$ 5,951	$ 7,820	$ 10,198	$ 27,508
Loss from operations	$ (3,538)	$ (5,951)	$ (303)	$ (10,158)	$ (19,950)
Net loss attributable to common shareholders	$ (3,417)	$ (6,199)	$ (298)	$ (10,086)	$ (20,000)
Net loss per share attributable to common shareholders - basic and diluted	$ (1.74)	$ (0.70)	$ (0.02)	$ (0.74)	$ (2.14)

Net loss per share is computed independently for each of the quarters presented in the tables above. Therefore, the sum of the quarterly per-share calculations will not equal the annual per share calculation.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. 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 December 31, 2018. 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 December 31, 2018, 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.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of our internal control over financial reporting has been audited by Kesselman & Kesselman (a member firm of PricewaterhouseCoopers International Limited, or PwC), an independent registered public accounting firm, as stated in their attestation report herein, which is included under "Item 8 —Financial Statements."

Inherent Limitations of Internal Controls

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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. During the quarter ended December 31, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information required by this Item and not set forth below will be set forth in the section headed "—Election of Directors" and "Information Regarding the Board of Directors and Corporate Governance" in our definitive Proxy Statement for our 2019 Annual Meeting of Shareholders to be filed with the SEC by April 30, 2019 (our "Proxy Statement") and is incorporated in this Annual Report by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Corporate Code of Ethics and Conduct. The Corporate Code of Ethics and Conduct is available on our website at *http://www.urogen.com* under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Shareholders may request a free copy of the Corporate Code of Ethics and Conduct from c/o UroGen Pharma Ltd., 499 Park Avenue, Suite 1200, New York, NY 10022.

Item 11. Executive Compensation

The information required by this Item will be set forth in the section headed "Executive Compensation" in our Proxy Statement and is incorporated in this Annual Report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item will be set forth in the section headed "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement and is incorporated in this Annual Report by reference.

Information regarding our equity compensation plans will be set forth in the section headed "Executive Compensation" in our Proxy Statement and is incorporated in this Annual Report by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this Item will be set forth in the section headed "Transactions With Related Persons" in our Proxy Statement and is incorporated in this Annual Report by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item will be set forth in the section headed "—Ratification of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated in this Annual Report by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Part II, Item 8 above.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

(a)(3) Exhibits.

Exhibit Number	Exhibit 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*	Form of Officer Indemnity and Exculpation Agreement (incorporated by reference to Exhibit 99.2 to the Form 6-K filed on July 13, 2018).
10.2*	Amended and Restated 2010 Israeli Share Option Plan (incorporated by reference to Exhibit 4.2 to the Form 20-F filed on March 15, 2018).
10.3	Investors' Rights Agreement, dated September 18, 2014, as amended on October 1, 2015 and April 12, 2016, among the Registrant and the Registrant's shareholders (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form F-1 (File No. 333-217201)).
10.4	Asset Purchase Agreement, dated October 1, 2015, between the Registrant and Telormedix SA (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form F-1 (File No. 333-217201)).
10.5†	License Agreement, dated as of October 7, 2016, by and between the Registrant and Allergan Pharmaceuticals International Limited (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form F-1 (File No. 333-217201)).
10.6*	2017 Equity Incentive Plan, as amended.
10.7*	2017 Israeli Equity Incentive Sub Plan to the 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form F-1 (File No. 333-217201)).
10.8	Open Market Sales Agreement, dated October 12, 2018, by and between the Registrant and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the Form F-3 filed on October 12, 2019 (File No. 333-227811).
10.9*	Employment Agreement by and between the Registrant and Elizabeth Barrett, dated as of January 3, 2019.
10.10*	Employment Agreement by and between the Registrant and Peter Pfreundschuh, dated as of July 31, 2018.
10.11*	Employment Agreement by and between the Registrant and Stephen Mullennix, dated as of January 17, 2018.
10.12*	Employment Agreement by and between the Registrant and Mark Schoenberg, dated as of December 5, 2017.
10.13*	Separation and Release Agreement between the Registrant and Ron Bentsur, dated as of January 3, 2019.
10.14*	Separation and Agreement between the Company and Gary Titus, dated as of July 11, 2018.
21.1	Subsidiary of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-217201)).
23.1	Consent of Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from the Annual Report on Form 10-K of UroGen Pharma Ltd. for the year ended December 31, 2018, formatted in XBRL (extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Changes in Shareholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.

* Management contract or compensatory plan.

† Registrant has been granted confidential treatment for certain portions of this exhibit. This exhibit omits the information subject to this confidentiality treatment. Omitted portions have been filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

February 28, 2019

By: /s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer

SIGNATURES AND POWER OF ATTORNEY

We, the undersigned directors and officers of UroGen Pharma, Ltd. (the "Company"), hereby severally constitute and appoint Elizabeth Barrett and Peter Pfreundschuh, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Elizabeth Barrett Elizabeth Barrett	Chief Executive Officer, Director *(Principal Executive Officer)*	February 28, 2019
/s/ Peter Pfreundschuh Peter Pfreundschuh	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 28, 2019
/s/ Arie Belldegrun Arie Belldegrun, M.D.	Chairman	February 28, 2019
/s/ Cynthia Butitta Cynthia Butitta	Director	February 28, 2019
/s/ Fred E. Cohen Fred E. Cohen	Director	February 28, 2019
/s/ Kathryn Falberg Kathryn Falberg	Director	February 28, 2019
/s/ Stuart Holden Stuart Holden, M.D.	Director	February 28, 2019
/s/ Ran Nussbaum Ran Nussbaum	Director	February 28, 2019
/s/ Shawn C. Tomasello Shawn C. Tomasello	Director	February 28, 2019

Exhibit 10.6

AMENDMENT TO 2017 EQUITY INCENTIVE PLAN

UroGen Pharma Ltd.

FIRST AMENDMENT TO 2017 EQUITY INCENTIVE PLAN

Effective August 29, 2018

This First Amendment (this "***Amendment***") to the 2017 Equity Incentive Plan (as amended, the "***Plan***") of UroGen Pharma Ltd. (the "***Company***") is effective as of the date specified above and further amends the Plan pursuant to Section 2 thereof.

Unless otherwise expressly provided for in this Amendment, all capitalized words or phrases or other defined terms used in this Amendment will have the same meaning ascribed to them in the Plan.

Section 3(a)(i) of the Plan is amended and restated in its entirety to read as follows:

"(i) Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of Ordinary Shares that may be issued pursuant to Stock Awards from and after the Effective Date will not exceed 3,550,167 shares (the ***"Share Reserve"***)."

UROGEN PHARMA LTD.

2017 EQUITY INCENTIVE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: MARCH 29, 2017 AND MAY 3, 2017
APPROVED BY THE STOCKHOLDERS: APRIL 19, 2017
IPO DATE/EFFECTIVE DATE: MAY 9, 2017

1. GENERAL.

(a) **Eligible Award Recipients.** Employees, Directors and Consultants are eligible to receive Awards.

(b) **Available Awards.** The Plan provides for the grant of the following types of Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards.

(c) **Purpose.** The Plan, through the grant of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate, and provide a means by which the eligible recipients may benefit from increases in value of the Ordinary Shares.

2. ADMINISTRATION.

(a) **Administration by Board.** The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c).

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

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Ordinary Shares under the Award; (E) the number of Ordinary Shares subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to a Stock Award.

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

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

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

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

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and/or bringing the Plan or Awards granted under the Plan into compliance with the requirements for Incentive Stock Options or ensuring that they are exempt from, or compliant with, the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements (taking into account any permissible and effective opting out by the Company from such requirements), and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan that (A) materially increases the number of Ordinary Shares available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, (D) materially reduces the price at which Ordinary Shares may be issued or purchased under the Plan, (E) materially extends the term of the Plan, or (F) materially expands the types of Awards available for issuance under the Plan. Except as otherwise provided in the Plan or an Award Agreement, no amendment of the Plan will materially impair a Participant's rights under an outstanding Award without the Participant's written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 162(m) of the Code regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees, (B) Section 422 of the Code regarding "incentive stock options" and/or (C) Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided, however,* that a Participant's rights under any Award will not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights, and (2) subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (B) to change the terms of an Incentive Stock Option, if such change results in impairment of the Award solely because it impairs the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (C) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code; and/or (D) to comply with other applicable laws or listing requirements.

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

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees, Directors or Consultants who are not United States nationals or who are employed outside the United States (provided that Board approval will not be necessary for

immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction).

(xi) To effect, with the consent of any adversely affected Participant, (A) the reduction of the exercise, purchase or strike price of any outstanding Stock Award; (B) the cancellation of any outstanding Stock Award and the grant in substitution therefor of a new (1) Option or SAR, (2) Restricted Stock Award, (3) Restricted Stock Unit Award, (4) Other Stock Award, (5) cash and/or (6) other valuable consideration determined by the Board, in its sole discretion, with any such substituted award (x) covering the same or a different number of Ordinary Shares as the cancelled Stock Award and (y) granted under the Plan or another equity or compensatory plan of the Company; or (C) any other action that is treated as a repricing under generally accepted accounting principles.

(c) Delegation to Committee.

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

(ii) Section 162(m) and Rule 16b-3 Compliance. The Committee may consist solely of two or more Outside Directors, in accordance with Section 162(m) of the Code, or solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) Delegation to an Officer. The Board may delegate to one (1) or more Officers the authority to do one or both of the following (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by applicable law, other Stock Awards) and, to the extent permitted by applicable law, the terms of such Awards, and (ii) determine the number of Ordinary Shares to be subject to such Stock Awards granted to such Employees; *provided*, *however*, that the Board resolutions regarding such delegation will specify the total number of Ordinary Shares that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on the form of Stock Award Agreement most recently approved for use by the Committee or the Board, unless otherwise provided in the resolutions approving the delegation authority. The Board may not delegate authority to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) to determine Fair Market Value.

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

3. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve. Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of Ordinary Shares that may initially be issued pursuant to Stock Awards will not exceed 1,400,000 shares (the "***Share Reserve***"). The Share Reserve will automatically increase on January 1 of each year, for a period of not more than ten years, commencing on January 1 of the year

following the year in which the IPO Date occurs and ending on (and including) January 1, 2027, to an amount equal to 12% of the total number of Ordinary Shares outstanding on December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1 of a given year to provide that there will be no January increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of Ordinary Shares than would otherwise occur pursuant to the preceding sentence. For clarity, the Share Reserve in this Section 3(a) is a limitation on the number of Ordinary Shares that may be issued pursuant to the Plan. Accordingly, this Section 3(a) does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

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

(c) **Incentive Stock Option Limit.** Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of Ordinary Shares that may be issued pursuant to the exercise of Incentive Stock Options will be 5,600,000 Ordinary Shares.

(d) **Section 162(m) Limitations**. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code, the following limitations shall apply.

(i) A maximum of 230,000 Ordinary Shares subject to Options, SARs and Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the Fair Market Value on the date the Stock Award is granted may be granted to any one Participant during any one calendar year. Notwithstanding the foregoing, if any additional Options, SARs or Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the Fair Market Value on the date the Stock Award are granted to any Participant during any calendar year, compensation attributable to the exercise of such additional Stock Awards will not satisfy the requirements to be considered "qualified performance-based compensation" under Section 162(m) of the Code unless such additional Stock Award is approved by the Company's stockholders.

(ii) A maximum of 230,000 Ordinary Shares subject to Performance Stock Awards may be granted to any one Participant during any one calendar year (whether the grant, vesting or exercise is contingent upon the attainment during the Performance Period of the Performance Goals).

(iii) A maximum of $3.0 million may be granted as a Performance Cash Award to any one Participant during any one calendar year.

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

4. ELIGIBILITY.

(a) **Eligibility for Specific Stock Awards**. Incentive Stock Options may be granted only to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; *provided*, *however*, that Stock Awards may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from Section 409A of the Code, or (iii) the Company, in consultation with its legal counsel, has determined that such Stock Awards comply with the distribution requirements of Section 409A of the Code.

(b) **Ten Percent Stockholders.** A Ten Percent Stockholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five years from the date of grant.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for Ordinary Shares purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, or if an Option is designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; *provided*, *however*, that each Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) **Term.** Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten years from the date of its grant or such shorter period specified in the Award Agreement.

(b) **Exercise Price.** Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Ordinary Shares subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Ordinary Shares subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in Ordinary Shares equivalents.

(c) **Purchase Price for Options.** The purchase price of Ordinary Shares acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by

the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

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

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

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

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

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

(d) **Exercise and Payment of a SAR.** To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of Ordinary Shares equal to the number of Ordinary Share equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Ordinary Share equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Ordinary Shares, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Agreement evidencing such SAR.

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

(i) **Restrictions on Transfer.** An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided in the Plan, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulations Section 1.421-1(b)(2). If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

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

(f) Vesting Generally. The total number of Ordinary Shares subject to an Option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of Ordinary Shares as to which an Option or SAR may be exercised.

(g) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date which occurs ninety (90) days following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR (as applicable) within the applicable time frame, the Option or SAR will terminate.

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

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

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

(k) **Termination for Cause.** Except as explicitly provided otherwise in a Participant's Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon such Participant's termination of Continuous Service, and the Participant will be prohibited from exercising his or her Option or SAR from and after the date of such termination of Continuous Service.

(l) **Non-Exempt Employees**. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any Ordinary Shares until at least six months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Award Agreement in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARS.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. To the extent consistent with the Company's articles of association, at the Board's election, Ordinary Shares may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Ordinary Shares awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the Ordinary Shares held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire Ordinary Shares under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Ordinary Shares awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

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

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

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

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

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

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of Ordinary Shares covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional Ordinary Shares covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

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

(c) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award (covering a number of shares not in excess of that set forth in Section 3(d) above) that is payable (including that may be granted, may vest or may be exercised) contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may but need not require the Participant's completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board or the Committee may determine that cash may be used in payment of Performance Stock Awards.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award (for a dollar value not in excess of that set forth in Section 3(d) above) that is payable contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. The Board or the Committee may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board or the Committee may specify, to be paid in whole or in part in cash or other property.

(iii) Board and Committee Discretion. The Board and the Committee retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for a Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement or the written terms of a Performance Cash Award.

(iv) Section 162(m) Compliance. Unless otherwise permitted in compliance with the requirements of Section 162(m) of the Code with respect to an Award intended to qualify as "performance-based compensation" thereunder, the Committee will establish the Performance Goals applicable to, and the formula for calculating the amount payable under, the Award no later than the earlier of (a) the date which occurs 90 days after the commencement of the applicable Performance Period, and (b) the date on which 25% of the Performance Period has elapsed, and in any event at a time when the achievement of the applicable Performance Goals remains substantially uncertain. Prior to the payment of any compensation under an Award intended to qualify as "performance-based compensation" under Section 162(m) of the Code, the Committee will certify the extent to which any Performance Goals and any other material terms under such Award have been satisfied (other than in cases where such Performance Goals relate solely to the increase in the value of the Ordinary Shares). Notwithstanding satisfaction of, or completion of any Performance Goals, the number of Ordinary Shares, Options, cash or other benefits granted, issued, retainable and/or vested under an Award on account of satisfaction of such Performance Goals may be reduced by the Committee on the basis of such further considerations as the Committee, in its sole discretion, will determine.

(d) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Ordinary Shares, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value of the Ordinary Shares at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of Ordinary Shares (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

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

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

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

8. MISCELLANEOUS.

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

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

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

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

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

(f) **Incentive Stock Option Limitations.** To the extent that the aggregate Fair Market Value (determined at the time of grant) of Ordinary Shares with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds $100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

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

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

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

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

of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

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

(l) **Clawback/Recovery**. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired Ordinary Shares or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company.

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

(a) **Capitalization Adjustments**. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c), (iii) the class(es) and maximum number of securities that may be awarded to any person pursuant to Sections 3(d), and (iv) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) **Dissolution or Liquidation**. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding Ordinary Shares not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the Ordinary Shares subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; *provided*, *however*, that the

Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

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

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

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

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

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

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

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Transaction, over (B) any exercise price payable by such holder in connection with such exercise. For clarity, this payment may be zero ($0) if the value of the property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of Ordinary Shares in connection with the Transaction is delayed as a result of escrows, earn outs, holdbacks or other contingencies.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

(d) **Change in Control.** A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. Plan Term; Earlier Termination or Suspension of the Plan.

The Board may suspend or terminate the Plan at any time. No Incentive Stock Options may be granted after the tenth anniversary of the earlier of (i) the date the Plan is adopted by the Board (the "***Adoption Date***"), or (ii) the date the Plan is approved by the stockholders of the Company. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. Existence of the Plan; Timing of First Grant or Exercise.

The Plan will come into existence on the Adoption Date; *provided, however*, that no Award may be granted prior to the IPO Date (that is, the Effective Date). In addition, no Stock Award will be exercised (or, in the case of a Restricted Stock Award, Restricted Stock Unit Award, Performance Stock Award, or Other Stock Award, no Stock Award will be granted) and no Performance Cash Award will be settled unless and until the Plan has been approved by the stockholders of the Company, which approval will be within 12 months after the date the Plan is adopted by the Board.

12. Choice of Law.

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

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

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

(b) "***Award***" means a Stock Award or a Performance Cash Award.

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

(d) "***Board***" means the Board of Directors of the Company.

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

(f) "***Cause***" will have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term

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

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

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, (C) on account of the acquisition of securities of the Company by any individual who is, on the Adoption Date, either an executive officer or a Director (either, a "***Legacy Investor***") and/or any entity in which a Legacy Investor has a direct or indirect interest (whether in the form of voting rights or participation in profits or capital contributions) of more than 50% (collectively, the "***Legacy Entities***") or on account of the Legacy Entities continuing to hold shares that come to represent more than 50% of the combined voting power of the Company's then outstanding securities as a result of the conversion of any class of the Company's securities into another class of the Company's securities having a different number of votes per share pursuant to the conversion provisions set forth in the Company's articles of association; or (D) solely because the level of Ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

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

more than 50% of the combined voting power of the surviving Entity or its parent are owned by the Legacy Entities;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; *provided, however*, that a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the acquiring Entity or its parent are owned by the Legacy Entities;

(iv) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company will otherwise occur, except for a liquidation into a parent corporation; or

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

Notwithstanding the foregoing definition or any other provision of the Plan, the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company and the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

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

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

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

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

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

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

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

(ii) a sale or other disposition of more than 50% of the outstanding securities of the Company;

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

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

(n) "***Covered Employee***" will have the meaning provided in Section 162(m)(3) of the Code.

(o) "***Director***" means a member of the Board.

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

(q) "***Effective Date***" means the IPO Date.

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

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

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

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

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

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

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

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

(w) "***Incentive Stock Option***" means an option granted pursuant to Section 5 of the Plan that is intended to be, and qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code.

(x) "***IPO Date***" means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Ordinary Shares, pursuant to which the Ordinary Shares are priced for the initial public offering.

(y) "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an

interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(z) "***Nonstatutory Stock Option***" means any Option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

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

(bb) "***Option***" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase Ordinary Shares granted pursuant to the Plan.

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

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

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

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

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

(hh) "***Outside Director***" means a Director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an "affiliated corporation" who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an "affiliated corporation," and does not receive remuneration from the Company or an "affiliated corporation," either directly or indirectly, in any capacity other than as a Director, or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

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

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

(kk) "***Performance Cash Award***" means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).

(ll) "***Performance Criteria***" means the one or more criteria that the Board or the Committee will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Board or the Committee: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) earnings before interest, taxes, depreciation, amortization and legal settlements; (v) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (vi) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (vii) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (viii) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation, other non-cash expenses and changes in deferred revenue; (ix) total stockholder return; (x) return on equity or average stockholder's equity; (xi) return on assets, investment, or capital employed; (xii) stock price; (xiii) margin (including gross margin); (xiv) income (before or after taxes); (xv) operating income; (xvi) operating income after taxes; (xvii) pre-tax profit; (xviii) operating cash flow; (xix) sales or revenue targets; (xx) increases in revenue or product revenue; (xxi) expenses and cost reduction goals; (xxii) improvement in or attainment of working capital levels; (xxiii) economic value added (or an equivalent metric); (xxiv) market share; (xxv) cash flow; (xxvi) cash flow per share; (xxvii) cash balance; (xxviii) cash burn; (xxix) cash collections; (xxx) share price performance; (xxxi) debt reduction; (xxxii) implementation or completion of projects or processes (including, without limitation, clinical trial initiation, clinical trial enrollment and dates, clinical trial results, regulatory filing submissions, regulatory filing acceptances, regulatory or advisory committee interactions, regulatory approvals, and product supply); (xxxiii) stockholders' equity; (xxxiv) capital expenditures; (xxxv) debt levels; (xxxvi) operating profit or net operating profit; (xxxvii) workforce diversity; (xxxviii) growth of net income or operating income; (xxxix) billings; (xl) bookings; (xli) employee retention; (xlii) initiation of studies by specific dates; (xliii) budget management; (xliv) submission to, or approval by, a regulatory body (including, but not limited to the U.S. Food and Drug Administration) of an applicable filing or a product; (xlv) regulatory milestones; (xlvi) progress of internal research or development programs; (xlvii) acquisition of new customers; (xlviii) customer retention and/or repeat order rate; (xlix) improvements in sample and test processing times; (l) progress of partnered programs; (li) partner satisfaction; (lii) timely completion of clinical trials; (liii) submission of pre-market approvals and other regulatory achievements; (liv) milestones related to research development (including, but not limited to, preclinical and clinical studies), product development and manufacturing; (lv) expansion of sales in additional geographies or markets; (lvi) research progress, including the development of programs; (lvii) strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property; and (lviii) and to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board or the Committee.

(mm) "***Performance Goals***" means, for a Performance Period, the one or more goals established by the Board or the Committee for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board or the Committee (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board or the Committee will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "unusual or infrequently occurring items" as determined under generally accepted accounting principles; (6) to exclude the dilutive

effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding Ordinary Shares of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to Ordinary Shareholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item. In addition, the Board or the Committee retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for such Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement or the written terms of a Performance Cash Award.

(nn) "***Performance Period***" means the period of time selected by the Board or the Committee over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board or the Committee.

(oo) "***Performance Stock Award***" means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(pp) "***Plan***" means this UroGen Pharma Ltd. 2017 Equity Incentive Plan, as it may be amended.

(qq) "***Restricted Stock Award***" means an award of Ordinary Shares which is granted pursuant to the terms and conditions of Section 6(a).

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

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

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

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

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

(ww) "***Stock Appreciation Right***" or "***SAR***" means a right to receive the appreciation on Ordinary Shares that is granted pursuant to the terms and conditions of Section 5.

(xx) "***Stock Appreciation Right Agreement***" means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(yy) "***Stock Award***" means any right to receive Ordinary Shares granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award.

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

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

(bbb) "***Ten Percent Stockholder***" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate.

(ccc) "***Transaction***" means a Corporate Transaction or a Change in Control.

Exhibit 10.9

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**"), is hereby made this 3rd day of January, 2019, 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 Elizabeth Barrett (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 Chief Executive Officer. Executive's employment with the Company shall commence on January 3, 2019 (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) Outside activities set forth in Section 12.1 below, 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 the Chief Executive Officer, including, in coordination with department heads, alignment and execution oversight of the Company's key efforts in order to help meet its short and long-term business goals and objectives and measuring and reporting on the Company's operational performance. Executive will report to the Company's Chairman of its Board of Directors. Executive's primary work location will be the Company's New York City facility subject to Section 11 below.

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 $700,000 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. The Company will pay the Executive a one-time signing bonus of $300,000 within 60 days of the Executive's Start Date. (the "signing bonus"), less payroll deductions and all required withholdings. If the Executive resigns from employment with the company without Good Reason or the Company terminates the Executive's employment for Cause, in each case prior to the first anniversary of the Start Date, the Executive must repay the Signing Bonus in full to the Company. If any repayment is due to the Company pursuant to this Section, the Executive agrees that the amount of the repayment due is payable in full immediately via personal check or payroll deduction and the Executive agrees to permit the Company to deduct this amount from any monies or benefits due to the Executive including wages, bonuses, reimbursements and/or expenses and any remaining amounts are the Executive's responsibility payable via personal check.

2.3 Annual Bonus. Executive will be eligible for an annual discretionary bonus, with an annual target of 50% guaranteed with the total bonus for year one at 100% 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 one hundred sixty hours (160) 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. The Company will reimburse Executive for costs of interim health insurance coverage actually incurred by Executive, and not otherwise reimbursed, in the period (if any) between 30 days after termination of Executive's current health insurance plan and being covered by the Company's plan.

4. Equity.

4.1 Subject to approval by the Board of Directors of the Parent, Executive shall be granted 2.00% (or 317,065 shares) restricted stock units of the Parent (the "**RSU**") and an option to purchase 1.75% (or 277,432 shares) 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**"). The RSU and Option 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, as well as the Company's 2017 Equity Incentive Plan. The RSU and Option will vest over 3 years - 33% will vest on the first anniversary of the Start Date of this agreement, and 1/36 of the RSU and Option will vest monthly thereafter for the remaining 24 months. 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.

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 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 twelve (12) 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 the equivalent of 50% of base salary pro rata portion of the annual bonus for the year of termination, which bonus shall be paid only to the extent earned based on actual Company performance (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) All unvested restricted shares and options scheduled to vest within the 12-month period following Executive's last day of employment shall be accelerated and 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 12-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. Except in the event of Executive's death, 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 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) 18 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 18 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 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. Travel and Business Expenses. The Parties agree that Executive is expected to work in the New York City office on a full-time basis. The Company recognizes that at times Company may cover the costs for Executive to stay in a hotel in New York City, provided such costs are incurred in furtherance of, or in connection with, Executive's duties hereunder and are in line with the Company's travel and expense policy. The Parties agree that Executive may occasionally telecommute or perform day-to-day work activities outside of the New York City office. The Company will also reimburse Executive for reasonable travel and other business expenses incurred by Executive in furtherance of, or in connection with, the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

12. Outside Activities During Employment

12.1 Non-Company Business. Except for pre-existing corporate affiliations (including Sage Therapeutics Board of Director and one additional board seat), or 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. Executive agrees that Executive's activities with all non-company business, including activities with pre-existing corporate affiliations, shall not interfere with the performance of Executive's duties and responsibilities as an employee of the Company, conflict in any material way with the business of the Company or violate any of the covenants contained in this Agreement.

13. 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.

14. General Provisions.

14.1 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.

14.2 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.

14.3 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.

14.4 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.

14.5 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.

14.6 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.

14.7 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 his duties hereunder and he may not assign any of his rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

14.8 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.

14.9 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 his capacity as an office holder of the Company, and to include his in the Company's existing D&O insurance policy in accordance with Company policy and applicable laws.

14.10 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 York.

In Witness Whereof, the Parties have executed this Agreement on the day and year first written above.

UroGen Pharma, Ltd.

By /s/Arie Belldegrun
Dr. Arie Belldegrun

Chairman

Executive
/s/Elizabeth Barrett
Elizabeth Barrett

Exhibit 10.10

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**"), is hereby made this 31st day of July, 2018, 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 Peter P. Pfreundschuh (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 Chief Financial Officer and Secretary. Executive's employment with the Company shall commence on August 20, 2018 (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.*, other pre-existing corporate affiliations (including Speratus Therapeutics, Inc. and GitBasic LLC), charitable activities, conferences, events, etc.), subject to Section 12.1 below, 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 Chief Financial Officer, including, in coordination with department heads, alignment and execution oversight of the Company's key efforts in order to help meet its short and long-term business goals and objectives and measuring and reporting on the Company's operational performance. Executive will report to the Company's Chief Executive Officer. Executive's primary work location will be the Company's New York City facility subject to Section 11 below.

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 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 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 one hundred sixty hours (160) 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. The Company will reimburse Executive for costs of interim health insurance coverage actually incurred by Executive, and not otherwise reimbursed, in the period (if any) between 30 days after termination of Executive's current health insurance plan, and being covered by the Company's plan.

4. Equity.

4.1 Subject to approval by the Board of Directors of the Parent, Executive shall be granted an option to purchase 50,000 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 12,500 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, as well as the Company's 2017 Equity Incentive Plan. The Option and RSU will vest over 3 years - 1/3 will vest on the first anniversary of the Start Date of this agreement, and 1/12 of the Option and RSU will vest quarterly thereafter for the remaining eight (8) quarters. 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.

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 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 the equivalent of a six (6) month pro rata portion of the annual bonus for the year of termination, which bonus shall be paid only to the extent earned based on actual Company performance (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 two (2) quarters such that 16.67% 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 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. Travel and Business Expenses. The Parties agree that Executive is expected to work in the New York City office on a full-time basis. To minimize Executive's travel and commuting expenses, the Company agrees to provide Executive with a travel stipend, which shall cover the costs to stay in a pre-approved hotel in New York City for up to three (3) days per week, provided such costs are incurred in furtherance of, or in connection with, Executive's duties hereunder. The Parties agree that Executive may telecommute or perform his day-to-day work activities outside of the New York City office on workdays if Executive's request is approved by the Company, in its sole discretion. The Company will also reimburse Executive for reasonable travel and other business expenses incurred by Executive in furtherance of, or in connection with, the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

12. Outside Activities During Employment

12.1 Non-Company Business. Except for pre-existing corporate affiliations (including Speratus Therapeutics, Inc. and GitBasic LLC), or 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. Executive agrees that Executive's activities with all non-company business, including activities with pre-existing corporate affiliations, shall not interfere with the performance of Executive's duties and responsibilities as an employee of the Company, conflict in any material way with the business of the Company or violate any of the covenants contained in this Agreement.

13. 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.

14. General Provisions.

14.1 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.

14.2 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.

14.3 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.

14.4 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.

14.5 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.

14.6 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.

14.7 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 his duties hereunder and he may not assign any of his rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

14.8 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.

14.9 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 his capacity as an office holder of the Company, and to include his in the Company's existing D&O insurance policy in accordance with Company policy and applicable laws.

14.10 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 York.

In Witness Whereof, the Parties have executed this Agreement on the day and year first written above.

UroGen Pharma, Inc.

By: /s/Ron Bentsur
Ron Bentsur
Chief Executive Officer

Executive

/s/Peter P. Pfreundschuh
Peter P. Pfreundschuh

Exhibit 10.11

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**"), is hereby made this 17th day of January between UroGen Pharma, Inc., (the "**Company**", a wholly-owned subsidiary of UroGen Pharma, Ltd., the "Parent") and Stephen L. Mullennix (the "**Executive**", or "**you**") (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 Chief Operating Officer. Executive's employment with the Company shall commence on February 15, 2018 (the "**Start Date**") and shall be a member of the Senior Management Team. 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 Chief Operating Officer, including, in coordination with department heads, alignment and execution oversight of the Company's key efforts in order to help meet its short and long-term business goals and objectives, implementing procedures and resources to promote improvements in operational processes and employee motivation, and measuring and reporting on the Company's operational performance. Executive will report to the Company's Chief Executive Officer. Your primary work location will initially be your home in the Los Angeles area, until the Company's Los Angeles facility is established, upon which time you will work out of such office. This position will involve travel (about 30% of your time), particularly to the Company's NYC facility and to investor events.

The Company will reimburse you for reasonable travel and other business expenses incurred by you in furtherance of, or in connection with, the performance of your duties hereunder, in accordance with the Company's expense reimbursement policy as in effect from time to time.

The Company approves of your working from your home office subject to the terms set forth below:

- You are expected to devote your time and attention to your job duties on a full-time basis, and maintain satisfactory performance. You are expected to personally perform all work duties for the Company. You will be responsible for establishing and maintaining a proper work environment in which personal distractions, such as non-business telephone calls and visitors, are kept to a minimum. The Company has sole discretion to change the parameters of your work from home arrangement, and to require you to perform your work in one of the Company's Los Angeles based offices at a later date.

- You and the Company agree that you will use the information technology devices, including the computer provided by the Company, to perform your duties. The Company will provide you with, or reimburse you for, basic office supplies, telecommunication and other normal costs associated with operating from a home office. You will be responsible for furnishing your home office and for insuring any office equipment not owned by the Company. Any tax implications related to your home office and personal office equipment will be your responsibility.

- You are expected to comply with all Company policies while working from home. In particular, you must safeguard all Company Confidential Information, and take steps to ensure it is not intermingled or disclosed. You will be covered by the Company's workers' compensation insurance for work-related injuries or illnesses. You are expected to report any job-related accidents that occur while you are performing your job duties for the Company to an appropriate human resources employee or other executive as soon as possible.

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 $375,000 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 $70,000, such payment subject to standard payroll deductions and withholdings. The Signing Bonus shall be paid to Executive on the first regularly-scheduled Company payroll date after the Start Date.

2.3 Annual Bonus. Executive will be eligible for an annual discretionary bonus, with an annual target of 40% 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 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 one hundred sixty hours (160) 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. The Company will reimburse Executive for costs of interim health insurance coverage in the period (if any) between 30 days after termination of Executive's current health insurance plan, and being covered by the Company's plan.

4. Equity.

4.1 Subject to approval by the Board of Directors of the Parent, Executive shall be granted an option to purchase 45,000 ordinary shares in the Parent at the fair market value on the date of grant (the "**Option**") and 12,000 shares of restricted stock of the Parent (the "**RS**"). The Option and RS 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. The Option and RS will vest over 3 years - 1/3 will vest on the first anniversary of the Start Date of this agreement, and 1/12 of the Option and RS will vest quarterly thereafter for the remaining 8 quarters. 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.

4.2 Acceleration. 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 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, then all of the Executive's unvested restricted shares and options, including any unvested portion of the Option and RS, shall be accelerated such that 100% of the unvested options and shares shall be deemed immediately vested and exercisable as of the date of the closing of the Change in Control. Such acceleration shall be in addition to any non-acceleration-related benefits provided in Section 5.2 below.

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 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 nine (9**)** 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 portion of the annual bonus for the year of termination, which bonus shall be paid only to the extent earned based on actual Company performance (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 such that 50% of the then-unvested restricted shares and options shall be deemed immediately vested and exercisable as of Executive's last day of employment.

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 RS, (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 Agreeme**nt"). 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. 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.

8. Definitions.

8.1 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 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.

8.2 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.

8.3 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) following the establishment of the Company's Los Angeles office, the requirement that Executive relocate to a location greater than 30 miles from the Los Angeles office, unless mutually agreed that the Executive will relocate to the Company's NYC office; 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.

9. Proprietary Information Obligations. As a condition of employment, Executive shall execute and abide by the Company's standard form of At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement (the **"Confidentiality Agreement"**).

10. Outside Activities During Employment and Non-Compete

10.1 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.

10.2 Non-Solicitation. The Executive agrees that during the period of his employment by the Company, and for a period of 9 months thereafter, the Executive will not, without the Company's prior written consent, directly or indirectly, by himself or through others, offer, solicit or attempt to solicit, for employment or other engagement, or otherwise contract or seek to contract the services of, any individual who is employed or engaged (whether directly or indirectly) by the Company or induce or entice or attempt to induce or entice such individual to leave such employment or other engagement or otherwise interfere in his/her relationship with the Company, except as part of a general solicitation for employment that is not targeted at any specific individual or organization.

11. Dispute Resolution. To ensure the timely and economical resolution of disputes that may arise in connection with your employment with the Company, you 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, your employment, or the termination of your employment, including but not limited to statutory claims, will be resolved to the fullest extent permitted by law by final, binding and confidential arbitration, by a single arbitrator, in the Los Angeles, California area, or as otherwise agreed upon by you and the Company, conducted by JAMS, Inc. ("**JAMS**") under the then-applicable JAMS rules (available at the following web address: https://www.jamsadr.com/rules-employment, and which will be provided to you on request). By agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. You will have the right to be represented by legal counsel at any arbitration proceeding. In addition, all claims, disputes, or causes of action under this section, whether by you 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 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; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator shall be authorized to award any or all remedies that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS' arbitration fees in excess of the amount of court fees that would be required of you if the dispute were decided in a court of law. Nothing in this letter is intended to prevent either you 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.

12. General Provisions.

12.1 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.

12.2 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.

12.3 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.

12.4 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.

12.5 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.

12.6 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.

12.7 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 his duties hereunder and he may not assign any of his rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.8 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.

12.9 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 his capacity as an office holder of the Company, and to include his in the Company's existing D&O insurance policy in accordance with Company policy and applicable laws.

12.10 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.

In Witness Whereof, the Parties have executed this Agreement on the day and year first written above.

UroGen Pharma, Inc.

By: /s/ Ron Bentsur
Ron Bentsur
Chief Executive Officer

Executive

/s/Stephen L. Mullennix
Stephen L. Mullennix

Exhibit 10.12

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "**Agreement**"), is hereby made this 5th day of December, 2017, by and among UroGen Pharma, Inc., (the "**Company**", a wholly-owned subsidiary of UroGen Pharma, Ltd., the "**Parent**"), the Parent, and Mark P. Schoenberg, MD (the "**Executive**") (collectively, the "**Parties**").

WHEREAS, the Company and Parent (the "**Company Parties**") desire 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 Employment and Position. Executive's employment with the Company shall commence on December 7, 2017 (the "**Start Date**"). Executive currently serves on a consulting basis as the Medical Director of the Company pursuant to a Consulting Agreement dated January 5, 2015 (the "**Consulting Agreement**"). Upon commencement of employment by the Company, the "Term" under the Consulting Agreement will terminate (but the warrant issued thereunder, dated as of January 20, 2016 (the "**Warrant**") will continue to vest as scheduled therein).

During his employment hereunder, Executive will serve as the Chief Medical Officer ("**CMO**") of the Company. For up to a 12-month period after the Start Date (the "**Part Time Period**"), Executive may work in a part-time capacity in his role as CMO. The Parties acknowledge and agree that during the Part Time Period, Executive will have continuing time obligations to his existing employer, the Montefiore Medical Center ("**Montefiore**") and that such work shall not constitute a conflict of interest with Executive's Part Time employment or a breach of this Agreement or any other obligation to the Company Parties. Upon the expiration of the Part Time Period, Executive will become a full-time employee of the Company, devoting substantially all of his business time to the Company without any material service obligations to Montefiore ("**Full Time Basis**"). If following the expiration of the Part Time Period, the Executive decides not to continue as an employee on a Full Time Basis, the Company's Board of Directors, in its sole discretion, will have the right to immediately terminate the Executive's employment without incurring any additional obligations to the Executive.

During Executive's Full Time Basis employment with the Company, Executive will devote his best reasonable efforts and substantially all of his business time and attention to the business of the Company, except for 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 Chief Medical Officer for a company of the size and nature of the Company, including supervision, planning and implementation all clinical, regulatory, publication, KOL relations strategy and activities. Executive will report to the Company's Chief Executive Officer. Executive will be based in the Company's New York City office, however, it is understood that the role will require extensive travel in order to execute the Company's objectives.

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 an annual base salary of $450,000 (the "**Base Salary**"), to be reviewed annually by the Board of Directors for increase only; not subject to decrease at any time or for any reason. During the Part Time Period, however, the annual Base Salary shall be $200,000**.** Base Salary will be 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 cash bonus of $75,000 (the "**Signing Bonus**"), subject to standard payroll deductions and withholdings. The Signing Bonus shall be paid to Executive on the first regularly-scheduled Company payroll date after the Start Date.

2.3 Annual Bonus. Executive will be eligible to receive an annual discretionary bonus (the **"Annual Bonus")** which shall be pro-rated in the case of a partial calendar year. Annual Bonus will be comprised of a minimum annual cash bonus for each calendar year (the "**Guaranteed Bonus**") equal to 20% of Base Salary. An additional cash bonus of up to 20% of Base Salary may be granted by the Board of Directors, in its sole discretion, based upon the achievement of the Company's corporate goals and objectives for such year as approved by the Board of Directors. Any cash bonuses as discussed above shall be based on the reduced Base Salary during the Part Time Period. 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. Executive will not be eligible for, and will not earn, any Annual Bonus (including a prorated bonus) if Executive's employment terminates for any reason before the end of the calendar year. Executive will also participate in annual cash and stock

incentive plans offered to other senior executives (without duplication of the Guaranteed Bonus).

3. Standard Company Benefits. Executive shall be entitled to participate in all employee benefit programs for which Executive is eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees. Executive shall be eligible to accrue a maximum of one-hundred and sixty (160) hours per year (80 hours per year during the Part Time Period), in accordance with the Company's paid-time off accrual policy. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time.

4. Equity.

4.1 Start Date Awards. Within 15 days after the Start Date, subject to approval by the Board of Directors of Parent (the "**Board**"), Parent shall grant Executive 12,500 restricted stock units (the "**Restricted Stock Unit Award**") and an option to purchase 15,000 shares (the "**Option**"), with both vesting over three years (with one-third vested upon the first anniversary of the Start Date, and the balance vesting quarterly for eight equal quarterly installments). The Restricted Stock Unit Award shall be made in the form of the restricted stock unit agreement attached hereto as Exhibit A. The Option shall be made in the form of the stock option agreement attached hereto as Exhibit B, shall have an exercise price equal to the fair market value of the Parent's ordinary shares as of its grant date, and shall have a ten-year term.

4.2 Full Time Basis Awards. In addition, should Executive elect to remain employed by the Company on a Full Time Basis at the end of the Part Time Period, within 15 days after the end of the Part-Time Period, subject to approval by the Board, Parent shall grant Executive an additional 12,500 restricted stock units (the "**Full-Time Restricted Stock Unit Award**") and an option to purchase 15,000 shares (the "**Full-Time Option**"), with both vesting over two years in eight equal quarterly installments. The Full Time Restricted Stock Unit Award shall be made on substantially similar terms and conditions as the Restricted Stock Unit Award, and the Full-Time Option shall be made on substantially similar terms and conditions as the Option, except in each case for such changes that are necessary to comply with changes in applicable law after the Start Date.

4.3 If there is a Change of Control, or if Executive's employment is terminated by the Company without Cause or by him with Good Reason within 60 days before a Change of Control, then all of Executive's unvested restricted stock units, options and warrants, including any unvested portion of the restricted stock units and options described above, shall be accelerated such that 100% of Executive's unvested options, warrants and restricted stock units shall become immediately vested and exercisable as of the date of the closing of the Change of Control.

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 Good Reason or advance notice. Upon his termination of employment for any reason, Executive shall be entitled to payment of Base Salary through the date of his termination of employment (the "**Termination Date**"), any accrued but unused vacation, and any amounts or benefits provided under the then-existing terms of any employee benefit plan, agreement or other arrangement of the Company Parties.

5.2 Termination Without Cause or With Good Reason.

(i) The Company may terminate Executive's employment with the Company at any time without Cause, and Executive may terminate his employment with the Company at any time with Good Reason.

(ii) In the event Executive's employment with the Company is terminated by the Company without Cause or by Executive with Good Reason, provided that Executive remains in material compliance with his obligations under this Agreement, the Company shall provide Executive with the following (the "**Severance Benefits**"):

(a) The Company shall pay Executive, as severance, (x) the equivalent of six (6) months of Executive's Base Salary in effect during the Part Time Period, if the Termination Date occurs during the Part Time Period, and (y) twelve (12) months of Executive's Base Salary in effect thereafter, if the Termination Date occurs after the Part Time Period, 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 Termination Date, provided Executive has met his obligation to execute and deliver (and not revoke) the Release (as discussed in Paragraph 6); and

(b) The vesting of any of Executive's unvested restricted stock units, warrants and options shall be accelerated such that 50% of the then-unvested restricted stock units, warrants and options shall be deemed immediately vested and exercisable as of the Termination Date.

(c) Executive shall receive a pro-rata bonus for the year in which such termination occurs, equal to the product of (x) the Guaranteed Bonus that would have been paid if employment had continued, and (y) a fraction, the numerator of which is the number of days in the calendar year through the Termination Date, and the denominator of which is 365. Such amount shall be paid in cash on the first regular payroll following the sixtieth (60th) day after the Termination Date.

5.3 Termination For Cause or Without Good Reason; Death or Disability.

(i) The Company may terminate Executive's employment with the Company at any time for Cause and Executive may resign at any time without Good Reason. Executive's employment with the Company may also be terminated due to Executive's death or his long term disability (as described in the Company's long term disability plan).

(ii) If Executive resigns without Good Reason or the Company terminates Executive's employment for Cause, then (a) Executive will cease to further vest in the Option and the Restricted Stock Unit Award, (b) all payments of Base Salary 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 Date.

6. Conditions to Receipt of Severance Benefits. Severance Benefits will be subject to Executive signing and not revoking a release of claims in a form provided by the Company within 30 days after the Termination Date (the "**Release**"). The Release shall not impose any additional post-employment restrictive covenant obligations on Executive (other than those already reflected in any proprietary information agreement or similar provision or agreement to which Executive is then subject or a party), shall not require him to release any claims for benefits due under the terms of this Agreement or benefits under the then-existing terms of any agreement, plan or arrangement of the Company Parties or their affiliates, and shall become effective (if not revoked) seven days after Executive's delivery of an executed copy to the Company. If a conforming Release is provided to Executive within 30 days after his Termination Date, no Severance Benefits will be paid or provided until the Release 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 Termination Date.

7. 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 no so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. Notwithstanding anything to the contrary herein, to the extent required to comply with Section 409A, a termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of amounts or benefits upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of 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 upon his Termination Date to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon his "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.

8. Definitions.

8.1 Change of Control. For purposes of this Agreement, **"Change of Control"** shall have the meaning given to such term in the Warrant.

8.2 Cause. For purposes of this Agreement, **"Cause"** for termination will mean Executive's: (a) commission of any felony or crime involving moral turpitude; (b) participation in any fraud against the Company; (c) willful and material breach of his duties to the Company; (d) intentional damage to any property of the Company; (f) misconduct, or other violation of Company policy, that causes material harm to the Company; or (g) material breach of any material written agreement with the Company; provided, however, that a termination for Cause shall not be effective unless (x) notice of the circumstances claimed to constitute Cause is given to Executive within 60 days after the Company becomes aware of such circumstances, and (y) any claimed breach, if curable, remains uncured for 30 days after Executive has received such notice.

8.3 Good Reason. For purposes of this Agreement, "**Good Reason**" means: (a) a material reduction in Executive's duties (including responsibilities and/or authorities) or an adverse change in job position (including an adverse change in title); (b) any material breach by the Parent or the Company of any material written obligation to Executive; or (c) relocation of Executive's principal place of employment to a place that increases Executive's one-way commute by more than fifty (50) miles as compared to Executive's then-current principal place of employment immediately prior to such relocation. In order for Executive to resign with Good Reason, Executive must provide written notice of the event claimed to constitute Good Reason to the Company's Board or Chief Executive Officer within 60 days after he first becomes aware of such event. Executive must then allow the Company at least 30 days from receipt of such written notice (the "**Cure Period**") to cure such event, and if such event is not reasonably cured by the Company within such Cure Period, Executive must then resign from his employment not later than 30 days after the expiration of the Cure Period.

9. Proprietary Information Obligations. As a condition of employment, Executive shall execute and abide by the Company's standard form of Proprietary Information, Inventions, Non-Solicitation and Non-Competition Agreement, in the form attached hereto as Exhibit C (the **"Proprietary Information Agreement"**).

10. Outside Activities During Employment.

10.1 Non-Company Business. Except with the prior written consent of the Company and with respect to other employment allowed during the Part-Time Period, 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.

10.2 No Adverse Interests. Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by him to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise, except that Executive's acquisition or holding of less than 5% of the outstanding shares or units of any outstanding publicly traded securities shall not constitute a violation of this or any similar restriction.

11. Company Party Representations. The Company Parties represent and warrant that (i) they are fully authorized by action of their Board of Directors (and any other governing body or person whose action is required) to enter into this Agreement and perform their obligations under it, (ii) the execution, delivery and performance of this Agreement by them does not violate any applicable law, regulation, order, judgement or decree or an agreement, arrangement, plan or governance document to which any of them are a party or by which they are bound, and (iii) upon the execution and delivery of this Agreement by the Parties, this Agreement shall be their valid and binding obligation, enforceable against them in accordance with its terms, except to the extent that enforceability may be limited by applicable bankruptcy, insolvency or similar laws affecting the enforcement of creditors rights generally.

12. General Provisions.

12.1 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.

12.2 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 Executive's capacity as an office holder of the Company, and to include Executive in the Company's existing D&O insurance policy in accordance with Company policy and applicable laws.

12.3 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.

12.4 Waiver. To be effective, any waiver of any breach of any provisions of this Agreement must be in a writing signed by the Party against whom it is to be enforced, 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.

12.5 Complete Agreement. This Agreement, together with the Proprietary Information Agreement and the other agreements referenced herein, constitutes the entire agreement between the Parties 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 with respect to this Agreement. 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 Executive and a duly authorized officer of the Company.

12.6 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. The Parties agree to accept a signed facsimile or portable document format of this Agreement as a fully executed original.

12.7 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.

12.8 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 his duties hereunder and he may not assign any of his rights hereunder without the written consent of the Company, which shall not be withheld unreasonably.

12.9 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.

12.10 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 York.

In Witness Whereof, the Parties have executed this Agreement on the day and year first written above.

UroGen Pharma, Inc.

By: /s/Ron Bentsur
Ron Bentsur
Chief Executive Officer

UroGen Pharma, LTD.

By: /s/Ron Bentsur

Executive

/s/Mark P. Schoenberg
Mark P. Schoenberg

UROGEN PHARMA LTD.

RESTRICTED STOCK UNIT GRANT NOTICE
(2017 EQUITY INCENTIVE PLAN)

UroGen Pharma Ltd. (the "***Company***"), pursuant to its 2017 Equity Incentive Plan (the "***Plan***"), hereby awards to Participant a Restricted Stock Unit Award for the number of the Company's Ordinary Shares ("***Restricted Stock Units***") set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this "***Restricted Stock Unit Grant Notice***"), and in the Plan and the Restricted Stock Unit Award Agreement (the "***Award Agreement***"), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in this Restricted Stock Unit Grant Notice or the Award Agreement and the Plan, the terms of the Plan shall control.

Participant:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Restricted Stock Units:	_____

Vesting Schedule: [_____, subject to Participant's Continuous Service through each such vesting date.]

Issuance Schedule: Subject to any Capitalization Adjustment, one Ordinary Share (or its cash equivalent, at the discretion of the Company) will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Ordinary Shares pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award, with the exception, if applicable, of (i) restricted stock unit awards or options previously granted and delivered to Participant, (ii) the written employment agreement, offer letter or other written agreement entered into between the Company and Participant specifying the terms that should govern this specific Award, and (iii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law.

By accepting this Award, Participant acknowledges having received and read the Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

UroGen Pharma Ltd.	**Participant**
By: _____	_____
Signature	Signature
Title: _____	Date: _____
Date: _____	

Attachments: Award Agreement and 2017 Equity Incentive Plan

ATTACHMENT I

UROGEN PHARMA LTD.

2017 EQUITY INCENTIVE PLAN
RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Restricted Stock Unit Grant Notice (the "***Grant Notice***") and this Restricted Stock Unit Award Agreement (the "***Agreement***"), UroGen Pharma Ltd. (the "***Company***") has awarded you ("***Participant***") a Restricted Stock Unit Award (the "***Award***") pursuant to the Company's 2017 Equity Incentive Plan (the "***Plan***") for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

1. **GRANT OF THE AWARD.** This Award represents the right to be issued on a future date one (1) Ordinary Share for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of Restricted Stock Units/Ordinary Shares subject to the Award. Notwithstanding the foregoing, the Company reserves the right to issue you the cash equivalent of Ordinary Shares, in part or in full satisfaction of the delivery of Ordinary Shares in connection with the vesting of the Restricted Stock Units, and, to the extent applicable, references in this Agreement and the Grant Notice to Ordinary Shares issuable in connection with your Restricted Stock Units will include the potential issuance of its cash equivalent pursuant to such right. This Award was granted in consideration of your services to the Company.

2. **VESTING.** Subject to the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice. Vesting will cease upon the termination of your Continuous Service and the Restricted Stock Units credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such Award or the Ordinary Shares to be issued in respect of such portion of the Award.

3. **NUMBER OF SHARES.** The number of Restricted Stock Units subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

4. **Securities Law Compliance**. You may not be issued any Ordinary Shares under your Award unless the Ordinary Shares underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Ordinary Shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. **Transfer Restrictions**. Prior to the time that Ordinary Shares have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

(a) **Death**. Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Ordinary Shares or other consideration that vested but was not issued before your death.

(b) **Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Ordinary Shares or other consideration hereunder, pursuant to a domestic relations order, marital settlement agreement or other divorce or separation instrument as permitted by applicable law that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company General Counsel prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

6. **Date of Issuance.**

(a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the Withholding Obligation set forth in Section 11 of this Agreement, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) Ordinary Share for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above, and subject to any different provisions in the Grant Notice). Each issuance date determined by this paragraph is referred to as an "***Original Issuance Date***".

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell Ordinary Shares on an established stock exchange or stock market (including, but not limited to, under a previously established written trading plan that meets the requirements of Rule 10b5-1 under the Exchange Act and was entered into in compliance with the Company's policies (a "***10b5-1 Arrangement***")), *and*

(ii) either (1) a Withholding Obligation does not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Obligation by withholding Ordinary Shares from the shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to enter into a "same day sale" commitment with a broker-dealer pursuant to Section 11 of this Agreement (including, but not limited to, a commitment under a 10b5-1 Arrangement) and (C) not to permit you to pay your Withholding Obligation in cash, then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from the Company's Ordinary Shares in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the Ordinary Shares under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

7. **Dividends.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment; *provided*, *however*, that this sentence will not apply with respect to any Ordinary Shares that are delivered to you in connection with your Award after such shares have been delivered to you.

8. **Restrictive Legends.** The Ordinary Shares issued in respect of your Award shall be endorsed with appropriate legends as determined by the Company.

9. **Execution of Documents.** You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

10. **Award not a Service Contract.**

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ or service of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the vesting schedule provided in the Grant Notice may not be earned unless (in addition to any other conditions described in the Grant Notice and this Agreement) you continue as an employee, director or consultant at the will of the Company and affiliate, as applicable (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "***reorganization***"). You acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to terminate your Continuous Service at any time, with or without your cause or notice, or to conduct a reorganization.

11. **Withholding Obligation.**

(a) On each vesting date, and on or before the time you receive a distribution of the Ordinary Shares in respect of your Restricted Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Ordinary Shares issuable to you and/or otherwise agree to make adequate provision, including in cash, for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "***Withholding Obligation***").

(b) By accepting this Award, you acknowledge and agree that the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Obligation relating to your Restricted Stock Units by any of the following means or by a combination of such means: (i) causing you to pay any portion of the Withholding Obligation in cash; (ii) withholding from any compensation otherwise payable to you by the Company; (iii) withholding Ordinary Shares from the Ordinary Shares issued or otherwise issuable to you in connection with

the Award with a Fair Market Value (measured as of the date Ordinary Shares are issued pursuant to Section 6) equal to the amount of such Withholding Obligation; *provided, however,* that no Ordinary Shares are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Award as a liability for financial accounting purposes); and *provided, further*, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Board or the Company's Compensation Committee; and/or (iv) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***"), pursuant to this authorization and without further consent, whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Obligation and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Obligation directly to the Company and/or its Affiliates. Unless the Withholding Obligation is satisfied, the Company shall have no obligation to deliver to you any Ordinary Shares or any other consideration pursuant to this Award.

(c) In the event the Withholding Obligation arises prior to the delivery to you of Ordinary Shares or it is determined after the delivery of Ordinary Shares to you that the amount of the Withholding Obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. **Tax Consequences.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

13. **Unsecured Obligation.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. **Notices**. Any notice or request required or permitted hereunder shall be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to

participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

15. **Headings**. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

16. **Miscellaneous**.

(a) The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(d) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

17. **Governing Plan Document**. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for "good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

18. **Effect on Other Employee Benefit Plans.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

19. **Severability**. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

20. **Other Documents**. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

21. **Amendment.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

22. **Compliance with Section 409A of the Code.** This Award is intended to be exempt from the application of Section 409A of the Code, including but not limited to by reason of complying with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4) and any ambiguities herein shall be interpreted accordingly. Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and determined to be deferred compensation subject to Section 409A of the Code, this Award shall comply with Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly. If it is determined that the Award is deferred compensation subject to Section 409A and you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "Separation from Service" (as defined in Section 409A), then the issuance of any shares that would otherwise be made upon the date of your Separation from Service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the Separation from Service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

* * * * *

This Restricted Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Restricted Stock Unit Grant Notice to which it is attached.

EXHIBIT B

UROGEN PHARMA LTD.

STOCK OPTION GRANT NOTICE
(2017 EQUITY INCENTIVE PLAN)
(ISRAELI SUB-PLAN TO 2017 EQUITY INCENTIVE PLAN)

UroGen Pharma Ltd. (the "***Company***"), pursuant to its 2017 Equity Incentive Plan and 2017 Israeli Equity Incentive Sub Plan to the 2017 Equity Incentive Plan (together, the "***Plan***"), hereby grants to Optionholder an option to purchase the number of shares of the Company's Ordinary Shares set forth below. This option is subject to all of the terms and conditions as set forth in this Stock Option Grant Notice, in the Option Agreement, the Plan and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement. If there is any conflict between the terms in this Stock Option Grant Notice and the Plan, the terms of this Stock Option Grant Notice will control.

Optionholder:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Shares Subject to Option:	_____
Exercise Price (Per Share):	_____
Total Exercise Price:	_____
Expiration Date:	_____

Type of Grant: ☐ Incentive Stock Option[1] ☐ Nonstatutory Stock Option

☐ Section 3(i)[2]

Exercise Schedule: Same as Vesting Schedule

Vesting Schedule: _____, subject to Optionholder's Continuous Service as of each such date

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[1] If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first *exercisable* for more than $100,000 in value (measured by exercise price) in any calendar year. Any excess over $100,000 is a Nonstatutory Stock Option.

[2] Section 3(i) of the Israeli Income Tax Ordinance [New Version], 5721-1961. Applicable to non-Israeli directors and consultants.

Payment of Exercise Price:

By one or a combination of the following items (described in the Option Agreement):

☐ By cash, check, bank draft or money order payable to the Company
☐ Pursuant to a Regulation T Program if the shares are publicly traded
☐ By delivery of already-owned shares if the shares are publicly traded
☐ If and only to the extent this option is a Nonstatutory Stock Option or Section 3(i) Option, and subject to the Company's consent at the time of exercise, by a "net exercise" arrangement

Additional Terms/Acknowledgements: Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder acknowledges and agrees that this Stock Option Grant Notice and the Option Agreement may not be modified, amended or revised except as provided in the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding this option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of, if applicable, (i) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (ii) any written employment agreement, severance agreement, offer letter or other written agreement entered into between the Company and Participant specifying the terms that should govern this specific option. By accepting this option, Optionholder consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

UROGEN PHARMA LTD.

By: _____
Signature

Title: _____

Date: _____

OPTIONHOLDER:

_____
Signature

Date: _____

ATTACHMENTS: Option Agreement, 2017 Equity Incentive Plan, Israeli Sub-Plan to the 2017 Equity Incentive Plan and Notice of Exercise

Attachment I

UROGEN PHARMA LTD.

OPTION AGREEMENT
(2017 EQUITY INCENTIVE PLAN)
(2017 ISRAELI EQUITY INCENTIVE SUB PLAN TO THE
2017 EQUITY INCENTIVE PLAN)
(INCENTIVE STOCK OPTION; NONSTATUTORY STOCK OPTION OR SECTION 3(I) OPTION)

Pursuant to your Stock Option Grant Notice ("***Grant Notice***") and this Option Agreement, UroGen Pharma Ltd. (the "***Company***") has granted you an option under its 2017 Equity Incentive Plan and the 2017 Israeli Equity Incentive Sub Plan to the 2017 Equity Incentive Plan (together, the "***Plan***") to purchase the number of shares of the Company's Ordinary Shares indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. **NUMBER OF SHARES AND EXERCISE PRICE.** The number of Ordinary Shares subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

2. **METHOD OF PAYMENT.** You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or money order payable to the Company or in any other manner ***permitted by your Grant Notice,*** which may include one or more of the following, as described in more detail below:

(a) Provided that at the time of exercise the Ordinary Shares are publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Ordinary Shares, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a "broker-assisted exercise", "same day sale", or "sell to cover".

(b) Provided that at the time of exercise the Ordinary Shares is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned Ordinary Shares that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of ownership of such Ordinary Shares in a form approved by the Company. You may not exercise your option by delivery to the Company of Ordinary Shares if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

(c) If this option is a Nonstatutory Stock Option or Section 3(i) Option, subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of Ordinary Shares issued upon exercise of your option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment.

3. **WHOLE SHARES.** You may exercise your option only for whole Ordinary Shares.

4. **TERM.** You may not exercise your option before the Date of Grant or after the expiration of the option's term. The term of your option expires, subject to the provisions of Section 5(h) of the Plan, upon the earliest of the following:

(a) upon the termination of your Continuous Service, at the end of the relevant period set forth in Section 5 of the Plan, based on the reason for your termination;

(b) the Expiration Date indicated in your Grant Notice; or

(c) the day before the tenth (10th) anniversary of the Date of Grant.

5. **EXERCISE.**

(a) You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your option, (ii) the lapse of any substantial risk of forfeiture to which the Ordinary Shares are subject at the time of exercise, or (iii) the disposition of shares of Ordinary Shares acquired upon such exercise.

(c) If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within fifteen (15) days after the date of any disposition of any of the Ordinary Shares issued upon exercise of your option that occurs within two (2) years after the Date of Grant or within one (1) year after such Ordinary Shares are transferred upon exercise of your option.

6. **Option not a Service Contract.** Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

7. **Withholding Obligations.**

(a) At the time you exercise your option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "same day sale" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) If this option is a Nonstatutory Stock Option or Section 3(i) Option, then upon your request and subject to approval by the Company, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested Ordinary Shares otherwise issuable to you upon the exercise of your option a number of whole Ordinary Shares having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the maximum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). Notwithstanding the filing of such election, Ordinary Shares shall be withheld solely from fully vested Ordinary Shares determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company will have no obligation to issue a certificate for such Ordinary Shares or release such Ordinary Shares from any escrow provided for herein, if applicable, unless such obligations are satisfied.

8. **Tax Consequences**. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation.

9. **Notices.** Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means.

10. **Governing Plan Document.** Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your option and those of the Plan, the provisions of the Plan will control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

11. **Other Documents.** You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

12. **Effect on Other Employee Benefit Plans.** The value of this option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

13. **Voting Rights.** You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. **Severability.** If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

15. **MISCELLANEOUS.**

(a) The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

(c) You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

(d) This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

***

This Option Agreement will be deemed to be signed by you upon the signing by you of the Stock Option Grant Notice to which it is attached.

ATTACHMENT II

2017 EQUITY INCENTIVE PLAN

2017 ISRAELI EQUITY INCENTIVE SUB PLAN TO THE

2017 EQUITY INCENTIVE PLAN

Attachment III

NOTICE OF EXERCISE

UROGEN PHARMA LTD.

Date of Exercise: _____

This constitutes notice to UroGen Pharma Ltd. (the "***Company***") under my stock option that I elect to purchase the below number of Ordinary Shares of the Company (the "***Shares***") for the price set forth below.

Type of option (check one):	Incentive ☐	Nonstatutory ☐	Section 3(i) ☐
Stock option dated:	_____	_____	_____
Number of Shares as to which option is exercised:	_____	_____	_____
Certificates to be issued in name of:	_____	_____	_____
Total exercise price:	$_____	$_____	$_____
Cash payment delivered herewith:	$_____	$_____	$_____
Value of _____ Shares delivered herewith[3]:	$	$_____]	$]
Value of _____ Shares pursuant to net exercise[4]:	$_____	$_____]	$_____]
Regulation T Program (cashless exercise)[5]:	$_____	$_____]	$_____]

3 Shares must meet the public trading requirements set forth in the option. Shares must be valued in accordance with the terms of the option being exercised, and must be owned free and clear of any liens, claims, encumbrances or security interests. Certificates must be endorsed or accompanied by an executed assignment separate from certificate

4 The option must be a Nonstatutory Stock Option or Section 3(i) Option, and the Company must have established net exercise procedures at the time of exercise, in order to utilize this payment method.

5 Shares must meet the public trading requirements set forth in the option.

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the UroGen Pharma Ltd. 2017 Equity Incentive Plan and Israeli Sub-Plan to the 2017 Equity Incentive Plan, (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this option, and (iii) if this exercise relates to an Incentive Stock Option or Section 3(i) Option, to notify you in writing within fifteen (15) days after the date of any disposition of any of the Shares issued upon exercise of this option that occurs within two (2) years after the date of grant of this option or within one (1) year after such Shares are issued upon exercise of this option.

Very truly yours,

_____

EXHIBIT C

EMPLOYEE PROPRIETARY INFORMATION, INVENTIONS, NON-SOLICITATION AND NON-COMPETITION AGREEMENT

In consideration of my employment or continued employment by UroGen Pharma, Inc., its subsidiaries, parents, affiliates, successors and assigns (together, the "***Company***") and the compensation now and later paid to me, I hereby enter into this Proprietary Information, Inventions, Non-Solicitation and Non-Competition Agreement (the "***Agreement***") and agree as follows:

1. NONDISCLOSURE.

1.1 Recognition of Company's Rights; Nondisclosure. I understand and acknowledge that my employment by the Company creates a relationship of confidence and trust with respect to the Company's Proprietary Information (as defined below) and that the Company has a protectable interest therein. At all times during my employment and thereafter, I will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Company's Proprietary Information, except as such disclosure, use or publication may be required in connection with my work for the Company, or unless an officer of the Company expressly authorizes such in writing. I will obtain the Company's written approval before publishing or submitting for publication any material (written, verbal, or otherwise) that discloses and/or incorporates any Proprietary Information. I hereby assign to the Company any rights I may have or acquire in such Proprietary Information and recognize that all Proprietary Information will be the sole property of the Company and its assigns. I will take all reasonable precautions to prevent the inadvertent or accidental disclosure of Proprietary Information. Notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

1.2 Proprietary Information. The term "**Proprietary Information**" will mean any and all confidential and/or proprietary knowledge, data or information of the Company, its affiliates, parents and subsidiaries, which has economic value as a result of its remaining confidential, whether having existed, now existing, or to be developed during my employment, including information developed by me. By way of illustration but not limitation, "***Proprietary Information***" includes (a) trade secrets, inventions, mask works, ideas, processes, formulas, source and object codes, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques and any other proprietary technology and all Proprietary Rights therein (collectively, "***Inventions***"); (b) information regarding research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, margins, discounts, credit terms, pricing and billing policies, quoting procedures, methods of obtaining business, forecasts, future plans and potential strategies, financial projections and business strategies, operational plans, financing and capital-raising plans, activities and agreements, internal services and operational manuals,

methods of conducting Company business, suppliers and supplier information, and purchasing; (c) information regarding Customers and Potential Customers (as defined below) of the Company, including customer lists, names, representatives, their needs or desires with respect to the types of products or services offered by the Company, proposals, bids, contracts and their contents and parties, the type and quantity of products and services provided or sought to be provided to Customers and Potential Customers of the Company and other non-public information relating to Customers and Potential Customers; (d) information regarding any of the Company's business partners and their services, including names; representatives, proposals, bids, contracts and their contents and parties, the type and quantity of products and services received by the Company, and other non-public information relating to business partners; (e) information regarding personnel, employee lists, compensation, and employee skills; and (f) any other non-public information which a competitor of the Company could use to the competitive disadvantage of the Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which was known to me prior to employment with the Company or which is generally known in the trade or industry through no breach of this Agreement or other act or omission by me. Notwithstanding the foregoing or anything to the contrary in this Agreement or any other agreement between the Company and me, nothing in this Agreement shall limit my right to discuss my employment or report possible violations of law or regulation with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, or other federal government agency or similar state or local agency or to discuss the terms and conditions of my employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act or to the extent that such disclosure is protected under the applicable provisions of law or regulation, including but not limited to "whistleblower" statutes or other similar provisions that protect such disclosure.

1.3 Third Party Information. I understand, in addition, that the Company has received and in the future will receive from third parties their confidential and/or proprietary knowledge, data, or information ("***Third Party Information***"). During my employment and thereafter, I will hold Third Party Information in the strictest confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for the Company) or use, except in connection with my work for the Company, Third Party Information unless expressly authorized by an officer of the Company in writing.

1.4 Term of Nondisclosure Restrictions. I understand that Proprietary Information and Third Party Information is never to be used or disclosed by me, as provided in this Section 1. If, however, a court decides that this Section 1 or any of its provisions is unenforceable for lack of reasonable temporal limitation and the Agreement or its restriction(s) cannot otherwise be enforced, I agree and the Company agrees that the two (2) year period after the date my employment ends will be the temporal limitation relevant to the contested restriction, provided, however, that this sentence will not apply to trade secrets protected without temporal limitation under applicable law.

1.5 No Improper Use of Information of Prior Employers and Others. During my employment by the Company I will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of the Company any unpublished

documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person.

2. Assignment of Inventions.

2.1 Proprietary Rights. The term "***Proprietary Rights***" will mean all trade secrets, patents, copyrights, trade marks, mask works and other intellectual property rights throughout the world.

2.2 Prior Inventions. Inventions, if any, patented or unpatented, which I made prior to the commencement of my employment with the Company are excluded from the scope of this Section 2. To preclude any possible uncertainty, I have set forth on *Exhibit A* (Prior Inventions) attached to this Agreement a complete list of all Inventions that I have, alone or jointly with others, conceived, developed or reduced to practice or caused to be conceived, developed or reduced to practice prior to the commencement of my employment with the Company, that I consider to be my property or the property of third parties, and that I wish to have excluded from the scope of this Agreement (collectively, "***Prior Inventions***"). If disclosure of any such Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to list such Prior Inventions in *Exhibit A* but am only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. A space is provided on *Exhibit A* for such purpose. If no such disclosure is attached, I represent that there are no Prior Inventions. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or machine, the Company is hereby granted and will have a nonexclusive, royalty-free, irrevocable, perpetual, fully-paid, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, make derivative works of, publicly perform, use, sell, import, and exercise any and all present and future rights in such Prior Invention. Notwithstanding the foregoing, I agree that I will not incorporate, or permit to be incorporated, Prior Inventions in any Company Inventions without the Company's prior written consent.

2.3 Assignment of Inventions. Subject to Subsection 2.4, I hereby assign, grant and convey to the Company all my right, title and interest in and to any and all Inventions (and all Proprietary Rights with respect thereto) whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by me, either alone or jointly with others, during the period of my employment with the Company. Inventions assigned to the Company or its designee are referred to as "***Company Inventions***."

2.4 Unassigned/Nonassignable Inventions. I recognize that this Agreement will not be deemed to require assignment of any Invention that I developed entirely on my own time without using the Company's equipment, supplies, facilities, trade secrets, or Proprietary Information, except for those Inventions that either (i) relate to the Company's actual or anticipated business, research or development, or (ii) result from or are connected with work performed by me for the Company. In addition, this Agreement does not apply to any Invention which qualifies fully for protection from assignment to the Company under any specifically applicable state law, regulation, rule, or public policy ("***Specific Inventions Law***").

2.5 Obligation to Keep Company Informed. During the period of my employment and for six (6) months after termination of my employment with the Company, I will promptly disclose to the Company fully and in writing all Inventions

authored, conceived or reduced to practice by me, either alone or jointly with others. In addition, I will promptly disclose to the Company all patent applications filed by me or on my behalf within a year after termination of employment. At the time of each such disclosure, I will advise the Company in writing of any Inventions that I believe fully qualify for protection under the provisions of a Specific Inventions Law; and I will at that time provide to the Company in writing all evidence necessary to substantiate that belief. The Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to the Company pursuant to this Agreement relating to Inventions that qualify fully for protection under a Specific Inventions Law. I will preserve the confidentiality of any Invention that does not fully qualify for protection under a Specific Inventions Law.

2.6 Ownership of Work Product.

a. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

b. I agree that the Company will exclusively own all work product that is made by me (solely or jointly with others) within the scope of my employment, and I hereby irrevocably and unconditionally assign to the Company all right, title, and interest worldwide in and to such work product. I understand and agree that I have no right to publish on, submit for publishing, or use for any publication any work product protected by this Section, except as necessary to perform services for the Company.

2.7 Enforcement of Proprietary Rights. I will assist the Company in every proper way to obtain, and from time to time enforce, United States and foreign Proprietary Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Proprietary Rights to the Company or its designee, including the United States or any third party designated by the Company. My obligation to assist the Company with respect to Proprietary Rights relating to such Company Inventions in any and all countries will continue beyond the termination of my employment, but the Company will compensate me at a reasonable rate after my termination for the time actually spent by me at the Company's request on such assistance.

In the event the Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to the Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Proprietary Rights assigned under this Agreement to the Company.

3. RECORDS. I agree to keep and maintain adequate and current records (in the form of

notes, sketches, drawings and in any other form that may be required by the Company) of all Proprietary Information developed by me and all Company Inventions made by me during the period of my employment at the Company, which records will be available to and remain the sole property of the Company at all times.

4. Duty of Loyalty During Employment. I agree that during the period of my employment by the Company I will not, without the Company's express written consent, directly or indirectly engage in any employment or business activity which is directly or indirectly competitive with, or would otherwise conflict with, my employment by the Company.

5. No Solicitation of Employees, Consultants, Contractors, or Customers or Potential Customers. I agree that during the period of my employment and for the one (1) year period after the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by the Company, I will not, as an officer, director, employee, consultant, owner, partner, or in any other capacity, either directly or through others, except on behalf of the Company:

5.1 solicit, induce, encourage, or participate in soliciting, inducing or encouraging any person known to me to be an employee, consultant, or independent contractor of the Company to terminate his or her relationship with the Company, even if I did not initiate the discussion or seek out the contact;

5.2 solicit, induce, encourage, or participate in soliciting, inducing, or encouraging any person known to me to be an employee, consultant, or independent contractor of the Company to terminate his or her relationship with the Company to render services to me or any other person or entity that researches, develops, markets, sells, performs or provides or is preparing to develop, market, sell, perform or provide Conflicting Services (as defined in Section 6 below);

5.3 hire, employ, or engage in a business venture with as partners or owners or other joint capacity, or attempt to hire, employ, or engage in a business venture as partners or owners or other joint capacity, with any person then employed by the Company or who has left the employment of the Company within the preceding three (3) months to research, develop, market, sell, perform or provide Conflicting Services;

5.4 solicit, induce or attempt to induce any Customer or Potential Customer (as defined below), to terminate, diminish, or materially alter in a manner harmful to the Company its relationship with the Company;

5.5 solicit or assist in the solicitation of any Customer or Potential Customer to induce or attempt to induce such Customer or Potential Customer to purchase or contract for any Conflicting Services; or

5.6 perform, provide or attempt to perform or provide any Conflicting Services for a Customer or Potential Customer.

The parties agree that for purposes of this Agreement, a "***Customer or Potential Customer***" is any person or entity who or which, at any time during the one (1) year period prior to my contact with such person or entity as described in Sections 5.4-5.6 above if such contact occurs during my employment or, if such contact occurs following the termination of my employment, during the one (1) year period prior to the date my employment with the Company ends: (i) contracted for, was billed for, or received from the Company any product, service or process with which I worked directly or indirectly during my employment by the Company or about which I acquired Proprietary Information; or (ii) was in contact with me or in contact with any other employee, owner, or agent of the Company, of which contact I was or should have been aware, concerning the sale or purchase of, or contract for, any product, service

or process with which I worked directly or indirectly during my employment with the Company or about which I acquired Proprietary Information; or (iii) was solicited by the Company in an effort in which I was involved or of which I was aware.

6. NON-COMPETE PROVISION. I agree that for the one (1) year period after the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by the Company, I will not, directly or indirectly, as an officer, director, employee, consultant, owner, partner, or in any other capacity solicit, perform, or provide, or attempt to perform or provide Conflicting Services anywhere in the Restricted Territory, nor will I assist another person to solicit, perform or provide or attempt to perform or provide Conflicting Services anywhere in the Restricted Territory**.**

The parties agree that for purposes of this Agreement, ***"Conflicting Services***" means any product, service, or process or the research and development thereof, of any person or organization other than the Company that directly competes with a product, service, or process, including the research and development thereof, of the Company with which I worked directly or indirectly during my employment by the Company or about which I acquired Proprietary Information during my employment by the Company.

The parties agree that for purposes of this Agreement, ***"Restricted Territory***" means the one hundred (100) mile radius of any of the following locations: (i) any Company business location at which I have worked on a regular or occasional basis during the preceding year; (ii) my home if I work from home on a regular or occasional basis; (iii) any potential business location of the Company under active consideration by the Company to which I have traveled in connection with the consideration of that location; (iv) the primary business location of a Customer or Potential Customer; or (v) any business location of a Customer or Potential Customer where representatives of the Customer or Potential Customer with whom I have been in contact in the preceding year are based.

7. REASONABLENESS OF RESTRICTIONS.

7.1 I agree that I have read this entire Agreement and understand it. I agree that this Agreement does not prevent me from earning a living or pursuing my career. I agree that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Company's legitimate business interests. I represent and agree that I am entering into this Agreement freely and with knowledge of its contents with the intent to be bound by the Agreement and the restrictions contained in it.

7.2 In the event that a court finds this Agreement, or any of its restrictions, to be ambiguous, unenforceable, or invalid, I and the Company agree that the court will read the Agreement as a whole and interpret the restriction(s) at issue to be enforceable and valid to the maximum extent allowed by law.

7.3 If the court declines to enforce this Agreement in the manner provided in subsection 7.2, I and the Company agree that this Agreement will be automatically modified to provide the Company with the maximum protection of its business interests allowed by law and I agree to be bound by this Agreement as modified.

7.4 Furthermore, the parties agree that the market for the Company's products is worldwide. If, however, after applying the provisions of subsections 7.2 and 7.3, a court still decides that this Agreement or any of its restrictions is unenforceable for lack of reasonable geographic limitation and the Agreement or restriction(s) cannot otherwise be enforced, the parties hereby agree that the fifty (50) mile radius from any location at which I worked for the Company on either a regular or occasional basis during the one (1) year immediately preceding termination of my

employment with the Company shall be the geographic limitation relevant to the contested restriction.

8. No Conflicting Agreement or Obligation. I represent that my performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement to keep in confidence information acquired by me in confidence or in trust prior to my employment by the Company. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict with this Agreement.

9. Return of Company Property. When I leave the employ of the Company, I will deliver to the Company any and all drawings, notes, memoranda, specifications, devices, formulas, and documents, together with all copies thereof, and any other material containing or disclosing any Company Inventions, Third Party Information or Proprietary Information of the Company. I further agree that any property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company personnel at any time with or without notice. Prior to leaving, I will cooperate with the Company in completing and signing the Company's termination statement if requested to do so by the Company.

10. Legal and Equitable Remedies.

10.1 I agree that it may be impossible to assess the damages caused by my violation of this Agreement or any of its terms. I agree that any threatened or actual violation of this Agreement or any of its terms will constitute immediate and irreparable injury to the Company and the Company will have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach or threatened breach of this Agreement.

10.2 I agree that if the Company is successful in whole or in part in any legal or equitable action against me under this Agreement, the Company will be entitled to payment of all costs, including reasonable attorney's fees, from me.

10.3 In the event the Company enforces this Agreement through a court order, I agree that the restrictions of Sections 5 and 6 will remain in effect for a period of twelve (12) months from the effective date of the Order enforcing the Agreement.

11. Notices. Any notices required or permitted under this Agreement will be given to the Company at its headquarters location at the time notice is given, labeled "Attention Chief Executive Officer," and to me at my address as listed on the Company payroll, or at such other address as the Company or I may designate by written notice to the other. Notice will be effective upon receipt or refusal of delivery. If delivered by certified or registered mail, notice will be considered to have been given five (5) business days after it was mailed, as evidenced by the postmark. If delivered by courier or express mail service, notice will be considered to have been given on the delivery date reflected by the courier or express mail service receipt.

12. Publication of This Agreement to Subsequent Employer or Business Associates of Employee.

12.1 If I am offered employment or the opportunity to enter into any business venture as owner, partner, consultant or other capacity while the restrictions described in Sections 5 and 6 of this Agreement are in effect I agree to inform my potential employer, partner, co-owner and/or others involved in managing the business with which I have an opportunity to be associated of my obligations under this Agreement and also agree to provide such person or persons with a copy of this Agreement.

12.2 I agree to inform the Company of all employment and business ventures which I enter into while the restrictions described in Sections 5 and 6 of this Agreement are in effect and I also authorize the Company to provide copies of this Agreement to my employer, partner, co-owner and/or others involved in managing the business with which I am employed or associated and to make such persons aware of my obligations under this Agreement.

13. GENERAL PROVISIONS.

13.1 Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by and construed according to the laws of the State of New York as such laws are applied to agreements entered into and to be performed entirely within New York between New York residents. I hereby expressly consent to the personal jurisdiction and venue of the state and federal courts located in New York for any lawsuit filed there against me by Company arising from or related to this Agreement.

13.2 Severability. In case any one or more of the provisions, subsections, or sentences contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained in this Agreement. If moreover, any one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it will then appear.

13.3 Successors and Assigns. This Agreement is for my benefit and the benefit of the Company, its successors, assigns, parent corporations, subsidiaries, affiliates, and purchasers, and will be binding upon my heirs, executors, administrators and other legal representatives.

13.4 Survival. The provisions of this Agreement will survive the termination of my employment, regardless of the reason, and the assignment of this Agreement by the Company to any successor in interest or other assignee.

13.5 Employment At-Will. I agree and understand that nothing in this Agreement will change my at-will employment status or confer any right with respect to continuation of employment by the Company, nor will it interfere in any way with my right or the Company's right to terminate my employment at any time, with or without cause or advance notice.

13.6 Waiver. No waiver by the Company of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by the Company of any right under this Agreement will be construed as a waiver of any other right. The Company will not be required to give notice to enforce strict adherence to all terms of this Agreement.

13.7 Advice of Counsel. I ACKNOWLEDGE THAT, IN EXECUTING THIS AGREEMENT, I HAVE HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND I HAVE READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT WILL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION OF THIS AGREEMENT.

13.8 Entire Agreement. The obligations pursuant to Sections 1 and 2 (except Subsections 2.4 and 2.6(a)) of this Agreement will apply to any time during

which I was previously engaged, or am in the future engaged, by the Company as a consultant if no other agreement governs nondisclosure and assignment of inventions during such period. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter of this Agreement and supersedes and merges all prior discussions between us. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

[signatures to follow on next page]

This Agreement will be effective as of _____ __, 20___.

I HAVE READ THIS AGREEMENT CAREFULLY AND UNDERSTAND ITS TERMS. I HAVE COMPLETELY FILLED OUT EXHIBIT A TO THIS AGREEMENT.

_____

(Signature)

_____

(Printed Name)

ACCEPTED AND AGREED TO:

UROGEN PHARMA, INC.

By: _____

EXHIBIT A

PRIOR INVENTIONS

TO: **UROGEN PHARMA, INC.**

FROM: _____

DATE: _____

SUBJECT: **Prior Inventions**

1. Except as listed in Section 2 below, the following is a complete list of all inventions or improvements relevant to the subject matter of my employment by UroGen Pharma, Inc., (the "***Company***") that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

☐ No inventions or improvements.

☐ See below:

_____

_____

_____

☐ Additional sheets attached.

2. Due to a prior confidentiality agreement, I cannot complete the disclosure under Section 1 above with respect to inventions or improvements generally listed below, the proprietary rights and duty of confidentiality with respect to which I owe to the following party(ies):

	Invention or Improvement	**Party(ies)**	**Relationship**
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____

☐ Additional sheets attached.

Exhibit 10.13

SEPARATION AND RELEASE AGREEMENT

This Separation and Release Agreement (the "***Agreement***") is made and entered into effective as of January 3, 2019 by and between UroGen Pharma Ltd. ("***Company***") of the first part and Ron Bentsur ("***Bentsur***") of the second part.

WHEREAS Bentsur currently serves as the Chief Executive Officer of Company and member of the board of directors of Company ("***Board***") pursuant to that certain employment agreement dated August 15, 2015, which the parties, from time to time, extended and updated verbally and/or by conduct, and as amended as of September 1, 2017 and by resolutions of the Board, the Compensation, Nominating and Corporate Governance Committee of the Board and the shareholders of the Company (collectively, "***Employment Agreement***"), all capitalized terms used herein (including in the preamble to the Agreement) and not otherwise defined shall have the respective meaning ascribed to them in the Employment Agreement; and

WHEREAS The parties have agreed that Bentsur will cease his employment with the Company and resign from the Board as of January 3, 2019 ("***Separation Date***").

NOW, THEREFORE in consideration of the premises herein, and the mutual promises and undertakings herein contained and set forth, and for other good and valuable consideration, made over by each party to the other, the receipt of which is hereby acknowledged, it is covenanted and agreed as follows.

1. Termination of Employment.

1.1. The Company and Bentsur hereby agree to terminate the Employment Agreement, the employer-employee relationship and all positions at Company held by Bentsur on the Separation Date, subject to and in accordance with the terms and conditions set forth in this Agreement and Bentsur hereby waives any entitlement to notice pursuant to the Employment Agreement and/or by applicable law.

1.2. The Company and Bentsur hereby agree that on the Separation Date Bentsur hereby resigns from the Board. It is agreed that execution of this Agreement shall serve as resignation notice.

1.3. As of the Separation Date, Bentsur's salary and wages shall cease, and any entitlement or claim Bentsur has or might have had under the Employment Agreement terminates, except as otherwise described in this Agreement. On the Separation Date, the Company will pay Bentsur all accrued salary, all accrued and unused paid time off and all accrued recuperation payments earned through the Separation Date, subject to standard payroll deductions and withholdings. Bentsur is entitled to these payments regardless of whether or not he signs this Agreement.

1.4. Bentsur agrees that, within thirty (30) days after the Separation Date, he will submit his final documented expense reimbursement statement reflecting all business expenses he incurred through the Separation Date, if any, for which he seeks reimbursement. The Company will reimburse Bentsur for these expenses pursuant to its regular business practice.

1.5. Within fifteen (15) days after the Separation Date Company will deliver to Bentsur a letter addressed to the Advanced Study Fund ("Advanced Study Fund") authorizing it to release to Bentsur all monies accumulated in the Advanced Study Fund in his name.

1.6. Within fifteen (15) days after the Separation Date Company will deliver to Bentsur (i) a letter addressed to the insurance agent, authorizing the insurance company and/or the pension fund, as the case may be, to release to Bentsur all monies accumulated in the manager's insurance policy ("Policy") and/or pension fund in his name, as the case may be, including the compensatory and severance pay components of the Policy, and (ii) a dully signed Income Tax Authority Form 161 (Employer Notice of Employee's Termination of Employment).

1.7. The unvested portion of the Restricted Share Units and options to purchase Ordinary Shares of the Company NIS 0.01 each, as detailed in Exhibit 1.7 (the "Options") which the Company granted to Bentsur pursuant to its 2010 Israeli Share Option Plan ("2010 Plan") and 2017 Equity Incentive Plan and Israeli Sub-Plan to the 2017 Equity Incentive Plan ("2017 Plan"), respectively (2010 Plan and 2017 Plan together, "Plans") which would have vested during the 12 (twelve) month period following the Separation Date, shall vest immediately upon the Separation Date ("Accelerated Vesting"), provided, however, that Bentsur may sell the shares underlined by the Accelerated Vesting ("Option Shares") as follows: (i) fifty percent (50%) of the Option Shares as of the three-month anniversary of the Separation Date; and (ii) the remaining fifty percent (50%) of the Option Shares as of the six- month anniversary of Separation Date, all as set forth in the Lock-up Agreement, Exhibit A hereto. Bentsur shall have 12 (twelve) months to exercise the Options subject to Accelerated Vesting and all his other vested and unexercised options. It is agreed, notwithstanding the Plans, to set December 31, 2019 as the expire date for all Options granted to Bentsur on July 13, 2017 and January 10, 2018 ("Expire Date").

1.8. Within 15 (fifteen) days of the Separation Date the Company shall pay Bentsur a one-time payment of US$ 401,250 which equals to 9 (nine) months of Base Salary (75% (seventy-five percent) of the US$ 535,000 annual base salary ("Annual Base Salary")).

1.9. The Company shall pay Bentsur the Annual Bonus due for the year of 2018 in the amount equal to the percentage of goals and objectives achieved for the year 2018 multiplied by 50% (fifty percent) of the Annual Base Salary. Company shall pay Bentsur the Annual Bonus concurrently with payment of the 2018 annual bonus to the other officers of the Company, and no later than March 15, 2019.

2. No Other Compensation and Benefits. By signing this Agreement, Bentsur agrees that, except as otherwise provided in this Agreement, he has received all amounts and other benefits owed to him from the Company including, but not limited to, salary payments, annual leave, recuperation pay, severance pay and sick leave, prior written notice, overtime, and reimbursement of expenses. Bentsur agrees and understands that he will not be entitled to any other compensation or benefits, except for those explicitly described in this Agreement or as otherwise required by law. More specifically, Bentsur agrees that the payments and benefits set forth above, together with any amounts or benefits previously provided to him by the Company, shall be complete and constitute unconditional payment, settlement, satisfaction and accord with respect to any obligations and liabilities that the Company or any affiliate thereof may owe him.

3. Taxation. Bentsur shall be responsible for paying his share of all taxes applicable to him with respect to all amounts, payments, and benefits set forth herein in accordance with applicable laws and regulations.

4. Return of Company Property. Within 15 (fifteen) days of the Separation Date, except as otherwise allowed by Company provided herein, Bentsur shall have returned to Company all other Company documents (and all copies thereof) and other Company property in his possession or control, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, contact information, financial information, specifications, training materials, computer-recorded information, tangible property including, but not limited to, credit cards, entry cards,

identification badges and keys; and any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). In addition, if Bentsur has used any personally owned computer, server, e-mail system, mobile phone, portable electronic device (e.g., smartphone, iPad or the like), (collectively, "***Personal Systems***") to receive, store, prepare or transmit any Company confidential or proprietary data, materials or information, then Bentsur agrees that, upon request by the Company, he will provide the Company reasonable access to such Personal Systems to ensure such Company confidential or proprietary information is permanently deleted and expunged.

5. Confidentiality.

5.1. Company and Bentsur agree that neither party shall, as the case may be, voluntarily disclose, or cause to be disclosed, the terms of this Agreement nor the events that led to the execution of this Agreement, except to their respective attorneys, accountants and/or tax advisors, to tax authorities or to the extent otherwise required by law, exercise of each of the parties' rights under this Agreement, or for any due diligence process. In particular, and without limitation, Bentsur agrees not to disclose the terms of this Agreement to any current or former Company employee. Bentsur undertakes to fulfill, at all times after the termination of his employment, all of the obligations imposed on Bentsur by those provisions of the Confidentiality, Proprietary Rights and Non-Competition Undertaking, Schedule B to the Employment Agreement, Exhibit 5.1 hereto, intended to survive termination of the Employment Agreement.

5.2. It is agreed that for a period of 4 (four) months from the Separation Date, Bentsur shall not assume any new formal roles (director or officer) in any entity in the life science space.

6. Release of Claims.

General Release. After having examined the aforesaid accounting and all relevant data, and being fully cognizant of his rights, Bentsur hereby confirms, declares and undertakes that upon receipt of the sums and rights set forth in the Agreement:

6.1. Bentsur has received from Company all amounts due to me, pursuant to all applicable law in relation to the Employment Agreement and in relation to the termination of the Employment Agreement and Bentsur's employment by Company in a timely manner; including without limitation, Bentsur's wages in full, any amounts in due redemption of unused annual leave, sick leave pay, recuperation pay, severance pay, and any other amounts or rights due to him in accordance with the Employment Agreement and its termination.

6.2. By virtue of any law, contract or custom and/or by virtue of any manner of claim, Bentsur further confirms in connection with the Option that he is aware that pursuant to the Plans, and subject to Section 1.7 hereof, any options granted to him by the Company that have vested as of the Separation Date must be exercised until the Expire Date, and that in the event they are not so exercised, they shall lapse as of said date, and he hereby waives any claims in connection with any options that have lapsed in accordance with the foregoing.

6.3. Neither he nor any one coming in his stead have, nor will he nor anyone coming in his stead have in the future, any claims and/or contentions of any kind or type, against the Company, its shareholders, managers, or employees, or its successors in connection with the Employment Agreement and/or its termination.

6.4. He hereby waives any claim and/or contention of any kind and type that he has or shall have, if, and to the extent he has, or shall have, against the Company including such claims and/or contentions, in connection with the period of his employment with the Company and/or the

termination of the Employment Agreement and any tax implications that may arise with the Expire Date.

7. Continuing Obligations; Non-Disparagement.

7.1. Bentsur undertakes to provide free of charge transition support and other assistance as may be reasonably required by the newly appointed Chief Executive Officer of Company ("CEO") for the period of six (6) months following the Separation Date ("Consulting Services"). Bentsur (i) shall render the Consulting Services on an as needed basis. Bentsur shall devote such attention and business time as may be reasonably required to discharge and fulfill the Consulting Services, (ii) acknowledges that time is of the essence with respect to any reasonable timetable as established between the parties from time to time, (iii) will make its best efforts to comply with the obligations set forth in any such timetable, (i) shall act at all times without any conflict of interests with the Company, (v) shall attend telephone or video meetings with shareholders, the CEO and officers of the Company, and/or any other meeting as reasonably necessary, and (vi) shall be available as reasonably required to meet with investors in Israel and at Company expense and upon reasonable notice with investors worldwide.

7.2. Bentsur also agrees not to disparage the Company, its officers, directors, employees, shareholders, and agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation; provided that he may respond accurately and fully to any question, inquiry or request for information when required by legal process. Bentsur agrees to direct employment verification requests to HR@urogen.com. In response to inquiries from any future employer or third parties, the Company will limit information provided to (a) Bentsur' dates of employment, and (b) the positions that Bentsur held, and shall inform the inquiring party it is Company policy to provide only this information.

8. Miscellaneous

8.1. Bentsur understands and agrees that the promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by Company to him or to any other person, and that Company makes no such admission.

8.2. The execution, validity, interpretation and performance of this Agreement shall be determined and governed exclusively by the laws of the State of Israel, without reference to the principles of conflict of laws. Each party hereby irrevocably submits to the sole and exclusive jurisdiction of the courts in the District of Tel Aviv in any action, proceeding or dispute arising out of or relating to this Agreement and/or the Employment Agreement.

8.3. This Agreement represents the complete agreement between Bentsur and Company concerning the subject matter hereof and supersede all prior agreements or understandings, written or oral, between Bentsur and Company concerning the subject matter hereof except those agreements and documents expressly referred to in this Agreement. No attempted modification or waiver of any of the provisions of this Agreement shall be binding on any party hereto unless in writing and signed by Bentsur and Company. This Agreement is binding upon and inures to the benefit of the parties' heirs, successors, and assignees.

8.4. All notices or other communications hereunder shall be in writing and shall be given in person, or by registered mail, postage prepaid, to the parties at the addresses first stated above (or at such other addresses for a party as shall be specified by like notice). All such notices and other communications shall be deemed to have been given and received on the fifth (5th) day following such mailing.

8.5. This Agreement may be executed by facsimile signature and in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signed versions of this Agreement that included digitized signature images or digital signatures (certificates) transmitted by facsimile, email, portable document format (PDF) or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement and/or its document security features shall have the same effect as the physical delivery of the paper document bearing original signature.

8.6. This Agreement has been entered into voluntarily and not as a result of coercion, duress, or undue influence. Bentsur acknowledges that he has read and fully understands the terms of this Agreement and has been advised to consult with an attorney before executing this Agreement.

[Signature Page Follows]

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

UroGen Pharma Ltd.

By: /s/Peter P. Pfreundschuh
Chief Financial Officer

Date: January 2, 2019

/s/Ron Bentsur
Ron Bentsur
Date: January 2, 2019

Exhibit 1.7 - Option Grants
Exhibit 5.1 - Non-Compete and Proprietary Information Agreement

Exhibit 1.7

Option Grants

RSUs and Options Grant Date	**Exercise Price**	**Unvested RSUs/Options**	**Due to vest within 12 months form Separation Date**	**Plan**
August 15, 2015	RSU	41,067	41,067	2010 Plan
July 13, 2017	$19.55	40,000	26,667	2017 Plan
January 10, 2018	$43.67	34,723	16,666	2017 Plan

Exhibit 5.1

Confidentiality, Proprietary Rights and Non-Competition Undertaking

Exhibit 10.14

SEPARATION AND RELEASE AGREEMENT

This Separation and Release Agreement (the "***Agreement***") is made and entered into by and between UroGen Pharma Ltd. ("***Company***") of the first part and Gary S. Titus ("***Titus***") of the second part.

WHEREAS Titus has been serving as the Chief Financial Officer of the Company ("***Position***") pursuant to that certain letter agreement made and entered into by Company and Titus on June 8, 2015 ("***Employment Agreement***"); and

WHEREAS The parties have agreed that Titus will cease his employment with the Company as of July 1, 2018 ("***Separation Date***"); and

WHEREAS Titus has further agreed to consult with the Company following the Separation Date.

NOW, THEREFORE in consideration of the premises herein, and the mutual promises and undertakings herein contained and set forth, and for other good and valuable consideration, made over by each party to the other, the receipt of which is hereby acknowledged, it is covenanted and agreed as follows.

1. Termination of Employment.

1.1. The Company and Titus hereby agree to terminate the Employment Agreement and the Employer-Employee relationship on the Separation Date, subject to and in accordance with the terms and conditions set forth in this Agreement and Titus hereby waives any entitlement to notice pursuant to the Employment Agreement.

1.2. As of the Separation Date, Titus's salary and wages shall cease, and any entitlement or claim Titus has or might have had under the Employment Agreement terminate, except as otherwise described in this Agreement. On the Separation Date, the Company will pay Titus all accrued salary and all accrued and unused paid time off earned through the Separation Date, subject to standard payroll deductions and withholdings. Titus is entitled to these payments regardless of whether or not he signs this Agreement.

1.3. Titus agrees that, within fifteen (15) days after the Separation Date, he will submit his final documented expense reimbursement statement reflecting all business expenses he incurred through the Separation Date, if any, for which he seeks reimbursement. The Company will reimburse Titus for these expenses pursuant to its regular business practice.

2. Severance.

2.1. Although the Company has no obligation to do so, if Titus: (i) signs and returns this Agreement to the Company on or within twenty-one (21) days after the Separation Date; (ii) allows the releases contained herein to become effective; (iii) remains available during the Consulting Period to provide the Consulting Services (as defined below); and (iv) complies with all of his legal and contractual obligations to the Company, then the Company will provide Titus with the following severance benefits (collectively, the "***Severance Benefits***"):

2.1.1. The Company will pay Titus an amount equivalent to six (6) months of Titus' current base salary (in the total amount of $175,000), as well as an amount equivalent to 50% of Titus's 2018 annual target bonus (in the total amount of $70,000), for total gross severance payments of $245,000, subject to standard payroll deductions and withholdings (the "***Severance Payment***"). The Severance Payment will be paid to Titus as a one-time lump sum payment on the Company's first regularly-scheduled payroll date falling after the Effective Date (as defined in Paragraph 7.4).

2.1.2. To the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, Titus will be eligible to continue his group health insurance benefits at his own expense, subject to the further provisions in this paragraph. Later, Titus may be able to convert to an individual policy through the provider of the Company's health insurance, if he wishes. If Titus timely elects continued coverage under COBRA, the Company will pay for the COBRA premiums to continue Titus' health insurance coverage (including coverage for eligible dependents, if applicable) ("***COBRA Premiums***") through the period (the "***COBRA Premium Period***") starting on the Separation Date and ending on the earliest to occur of: (i) the end of the six (6) month period following the Separation Date; (ii) the date Titus becomes eligible for group health insurance coverage through a new employer; or (iii) the date Titus ceases to be eligible for COBRA continuation coverage for any reason. Titus must timely pay the premiums, and then provide the Company with proof of same to obtain reimbursement for his COBRA premiums under this Section 2.1.2. In the event Titus becomes covered under another employer's group health plan or otherwise ceases to be eligible for COBRA during the COBRA Premium Period, he must immediately notify the Company of such event. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that it cannot pay the COBRA Premiums without a substantial risk of violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company instead shall pay Titus, on the first day of each calendar month, a fully taxable cash payment equal to the applicable COBRA premiums for that month for the remainder of the COBRA Premium Period, which Titus may (but is not obligated to) use toward the cost of COBRA premiums.

2.1.3. For the period of six (6) months following the Separation Date, or until otherwise terminated as provided herein (with such actual period, the "***Consulting Period***"), the Company shall engage Titus to provide transition support and other assistance as may be reasonably required by the Company from time to time (the "***Consulting Services***"). The Consulting Services shall include, among other things, being available to answer questions and provide information to the Company about areas for which Titus was responsible and assisting in the transfer of third-party relationships to the Company. Titus shall act as an independent contractor during the Consulting Period and shall not be an employee of the Company or have authority to bind the Company on any matter. During the Consulting Period, Titus shall, however, be permitted to hold himself out as an independent advisor to the Company. Titus agrees and understands that his Proprietary Information and Inventions Agreement (attached as Exhibit A) remains in full force and effect during the Consulting Period and thereafter and he agrees to comply with the restrictions and obligations contained therein. Titus shall not receive compensation from the Company for providing the Consulting Services and will not be eligible to participate in any of the Company's benefit plans or offerings. Either party may terminate the Consulting Period for convenience at any time for any reason upon thirty (30) days advance written notice to the other party. The Company may terminate the Consulting Agreement for Cause immediately upon written notice to Titus (a "***Termination for Cause***"), and Titus may terminate the Consulting Period immediately for Good Reason upon written

notice to the Company (a "***Termination for Good Reason***"). The Consulting Period may also be terminated immediately for any reason upon written agreement of both parties. For purposes of this Agreement, "***Cause***" shall mean a breach of this Agreement or the Proprietary Information and Inventions Agreement by Titus. For purposes of this Agreement, "***Good Reason***" shall mean a breach of this Agreement by the Company.

2.1.4. Titus was granted options to purchase shares of the Company's common stock as detailed in **Exhibit B** (the "***Options***"), pursuant to the Company's 2010 and 2017 equity incentive plans (the "***Plans***"). Notwithstanding anything to the contrary in the Plans or other award agreements, the Options shall continue to vest during the Consulting Period. Upon a Qualifying Termination of the Consulting Period, the vesting of the Options shall accelerate as follows: (a) the vesting of the Option shall accelerate as to the number of Options that would have otherwise vested had Titus remained in service to the Company until the natural expiration of the Consulting Period, if applicable; and (b) fifty percent (50%) of the remaining unvested Options, after taking into account the Options subject to accelerated vesting pursuant to (a), will vest immediately as of the date of such Qualifying Termination (collectively, the "***Accelerated Vesting***"). Upon the termination of the Consulting Period for any reason other than a Qualifying Termination, continued vesting of the Option shall cease as of the date of such termination and Titus shall not be eligible to receive the Accelerated Vesting. For purposes of this Agreement, a "***Qualifying Termination***" shall mean: (i) termination of the Consulting Period upon the natural expiration of the six-month term; (ii) termination of the Consulting Period by Titus for Good Reason; or (iii) termination of the Consulting Period by the Company for any reason other than Cause. The Accelerated Vesting will be applied to the oldest Option grants on "first-granted-first-exercised" basis until fully utilized. The Options shall otherwise continue to be governed in all respects by the terms of the applicable grant notices, stock option agreements, and the Plans.

3. Other Compensation and Benefits. By signing this Agreement, Titus agrees that, except as otherwise provided in this Agreement, he has received all amounts and other benefits owed to him from the Company including, but not limited to, salary payments, annual leave and sick leave, prior written notice, overtime, and reimbursement of expenses. Titus agrees and understands that he will not be entitled to any other compensation or benefits, except for those explicitly described in this Agreement or as otherwise required by law. More specifically, Titus agrees that the payments and benefits set forth above, together with any amounts or benefits previously provided to him by the Company, shall be complete and unconditional payment, settlement, satisfaction and accord with respect to any obligations and liabilities that the Company or any affiliate thereof may owe him.

4. Taxation. Titus shall be responsible for paying his share of all taxes applicable to him with respect to all amounts, payments, and benefits set forth herein in accordance with applicable laws and regulations.

5. Return of Company Property. During the Consulting Period, Titus shall be permitted to retain access to his Company computer and company email account in order to facilitate the Consulting Services. Titus shall, upon request, provide the Company with access to his Company computer, Company accounts, and other Company-issued devices or property. Except as otherwise provided herein, on the Separation Date, Titus shall have returned to the Company all other Company documents (and all copies thereof) and other Company property in his possession or control, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, contact information, financial information, specifications, training materials, computer-recorded information, tangible property including,

but not limited to, credit cards, entry cards, identification badges and keys; and any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). In addition, if Titus has used any personally owned computer, server, e-mail system, mobile phone, portable electronic device (e.g., smartphone, iPad or the like), (collectively, "***Personal Systems***") to receive, store, prepare or transmit any Company confidential or proprietary data, materials or information, then Titus agrees that, upon request by the Company, he will provide the Company reasonable access to such Personal Systems to ensure such Company confidential or proprietary information is permanently deleted and expunged. Upon the termination of the Consulting Period, Titus shall return to the Company all remaining Company property in his possession, and understands and agrees he is not authorized to possess any Company property thereafter, except as specifically authorized by the Company. **Titus' timely compliance with this paragraph is a condition precedent to his receipt of the Severance Benefits described above.**

6. Confidentiality. Company and Titus agree that neither party shall, as the case may be, voluntarily disclose, or cause to be disclosed, the terms of this Agreement nor the events that led to the execution of this Agreement, except to their respective attorneys, accountants and/or tax advisors, to tax authorities or to the extent otherwise required by law, exercise of each of the parties' rights under this Agreement, or for any due diligence process. In particular, and without limitation, Titus agrees not to disclose the terms of this Agreement to any current or former Company employee. Notwithstanding any provision in this Agreement to the contrary, nothing herein shall prevent Titus from disclosing the fact or terms of this Agreement as part of any government investigation, or prohibit Titus from filing a charge, complaint, or report with, or otherwise communicating with, providing information to, or cooperating, or participating with any investigation or proceeding by or before the Equal Employment Opportunity Commission, the United States Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, or any other federal, state or local government agency or commission.

7. RELEASE OF CLAIMS.

7.1. General Release. In exchange for the consideration provided to Titus under this Agreement to which he would not otherwise be entitled, Titus hereby generally and completely releases the Company, and its affiliated, related, parent and subsidiary entities, and its and their current and former directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns (collectively, the "***Released Parties***") from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to or on the date Titus signs this Agreement (collectively, the "***Released Claims***").

7.2. Scope of Release. The Released Claims include, but are not limited to: (i) all claims arising out of or in any way related to Titus' employment with the Company, or the termination of that employment; (ii) all claims related to Titus' compensation or benefits from the Company, including salary, bonuses, commissions, vacation, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age

Discrimination in Employment Act of 1967 (as amended) (the "***ADEA***"), the California Labor Code (as amended), and the California Fair Employment and Housing Act (as amended).

7.3. Excluded Claims. Notwithstanding the foregoing, the following are not included in the Released Claims (the "***Excluded Claims***"): (i) any rights or claims for indemnification Titus may have pursuant to any written indemnification agreement with the Company to which Titus is a party or under applicable law; (ii) any rights which are not waivable as a matter of law; and (iii) any claims for breach of this Agreement. In addition, nothing in this Agreement prevents Titus from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the California Department of Fair Employment and Housing, or any other government agency, except that Titus acknowledges and agrees that he hereby waives his right to any monetary benefits in connection with any such claim, charge, or proceeding. Additionally, while this Agreement does not limit Titus' right to receive an award for information provided to the Securities and Exchange Commission, he is otherwise waiving, to the fullest extent permitted by law, any and all rights he may have to individual relief based on any claims that he has released and any rights he has waived by signing this Agreement.

7.4. ADEA Waiver. Titus acknowledges that he is knowingly and voluntarily waiving and releasing any rights he may have under the ADEA, and that the consideration given for the waiver and release in this Agreement is in addition to anything of value to which he is already entitled. Titus further acknowledges that he has been advised, as required by the ADEA, that: (i) his waiver and release do not apply to any rights or claims that may arise after the date that he signs this Agreement; (ii) he should consult with an attorney prior to signing this Agreement (although he may choose voluntarily not to do so); (iii) he has twenty-one (21) days to consider this Agreement (although he may choose voluntarily to sign it earlier); (iv) he has seven (7) days following the date he signs this Agreement to revoke it (by providing written notice of his revocation to Stephen Mullennix); and (v) this Agreement will not be effective until the date upon which the revocation period has expired, which will be the eighth day after the date that this Agreement is signed by Titus provided that he does not revoke it (the "***Effective Date***").

8. SECTION 1542 WAIVER. In giving the release herein, which includes claims which may be unknown to Titus at present, Titus acknowledges that he has read and understands Section 1542 of the California Civil Code, which reads as follows:

> **"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."**

Titus hereby expressly waives and relinquishes all rights and benefits under that section and any law of any other jurisdiction of similar effect with respect to Titus' release of claims herein, including but not limited to his release of unknown claims.

9. Continuing Obligations; Non-Disparagement. Titus acknowledges and agrees that he is bound by the Proprietary Information and Inventions Agreement attached as Exhibit A (the "PIIA") and that the PIIA shall inure to the benefit of the Company as if it were an original party thereto. Titus agrees to abide by the continuing obligations in the PIIA, whether during the Consulting Period or thereafter. Titus also agrees not to disparage the Company, its officers, directors, employees, shareholders, and agents, in any manner likely to be harmful to its or

their business, business reputation, or personal reputation; provided that he may respond accurately and fully to any question, inquiry or request for information when required by legal process. Titus agrees to direct employment verification requests to HR@urogen.com. In response to inquiries from any future employer or third parties, the Company will limit information provided to (a) Titus' dates of employment, and (b) the positions that Titus held, and shall inform the inquiring party it is Company policy to provide only this information. Should any Company officers be asked directly about the reasons for Titus separation, they will respond substantially as follows: "Gary was with UroGen through a significant period of growth and value generation and we thank him for his service. As the Company entered its next phase of growth it was mutually agreed that Gary would move on and the Company would go in another direction."

10. Arbitration. To ensure the timely and economical resolution of disputes that may arise between Titus and the Company (including the Released Parties), the parties agree that any and all disputes, claims, or causes of action, whether arising from or relating to the Consulting Period, the enforcement, breach, performance, negotiation, execution, or interpretation of this Agreement, or otherwise, will be resolved to the fullest extent permitted by law by final, binding, and confidential arbitration, by a single arbitrator, in the Reno, Nevada area, or as otherwise agreed to by the parties, conducted by JAMS, Inc. ("JAMS") under the then-applicable JAMS rules (available at the following web address: https://www.jamsadr.com/rules-employment, and which will be provided to Titus on request). By agreeing to this arbitration procedure, both Titus and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. Titus will have the right to be represented by legal counsel at any arbitration proceeding. In addition, all claims, disputes, or causes of action under this section, whether by Titus 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. 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; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator shall be authorized to award any or all remedies that Titus or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS' arbitration fees in excess of the amount of court fees that would be required of Titus if the dispute were decided in a court of law. Nothing in this letter is intended to prevent either Titus 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.

I HAVE READ THE FOREGOING AGREEMENT TO ARBITRATE, AND I SPECIFICALLY AND AFFIRMATIVELY CONSENT AND AGREE TO BE BOUND BY THIS PROVISION. I FURTHER ACKNOWLEDGE AND AGREE THAT ACCEPTANCE OF EMPLOYMENT SHALL BE DEEMED TO BE ACCEPTANCE OF THIS ARBITRATION PROVISION.

/s/Gary S. Titus	June 11, 2018
Gary S. Titus	Date

11. Miscellaneous

11.1. Titus understands and agrees that the promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by the Company to him or to any other person, and that the Company makes no such admission.

11.2. The execution, validity, interpretation and performance of this Agreement and the Proprietary Information and Inventions Agreement shall be determined and governed exclusively by the laws of the State of Nevada, without reference to the principles of conflict of laws.

11.3. This Agreement and the Proprietary Information and Inventions Agreement represent the complete agreement between Titus and Company concerning the subject matter hereof and supersede all prior agreements or understandings, written or oral, between Titus and Company concerning the subject matter hereof except those agreements and documents expressly referred to in this Agreement. No attempted modification or waiver of any of the provisions of this Agreement shall be binding on any party hereto unless in writing and signed by Titus and Company. This Agreement is binding upon and inures to the benefit of the parties' heirs, successors, and assignees.

11.4. All notices or other communications hereunder shall be in writing and shall be given in person, or by registered mail, postage prepaid, to the parties at the addresses first stated above (or at such other addresses for a party as shall be specified by like notice). All such notices and other communications shall be deemed to have been given and received on the fifth (5th) day following such mailing.

11.5. This Agreement has been entered into voluntarily and not as a result of coercion, duress, or undue influence. Titus acknowledges that he has read and fully understands the terms of this Agreement and has been advised to consult with an attorney before executing this Agreement.

[Signature Page Follows]

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

UroGen Pharma Ltd.

By: /s/Stephen Mullennix
Stephen Mullennix
Chief Operating and Financial Officer

Date: June 11, 2018

Gary S. Titus
/s/Gary S. Titus
Date: June 11, 2018

Exhibit A: Proprietary Information and Inventions Agreement
Exhibit B: Option Grants

Exhibit A

Proprietary Information and Inventions Agreement

Exhibit B

Option Grants

Shareholder	Original Grant Date	Options Granted
Gary Titus	June 25, 2016	48,000
Gary Titus	October 7, 2015	9,600
Gary Titus	October 7, 2015	54,400
Gary Titus	June 28, 2017	40,000
Gary Titus	January 10, 2018	20,000

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-227812, 333-222955, 333-221212 and 333-218992) of UroGen Pharma Ltd. of our report dated February 26, 2019 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

Tel-Aviv, Israel
February 28, 2019

/s/Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

Exhibit 31.1

CERTIFICATIONS

I, Elizabeth Barrett, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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 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: February 28, 2019

/s/ Elizabeth Barrett
Elizabeth Barrett
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Peter Pfreundschuh, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 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 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: February 28, 2019

/s/ Peter Pfreundschuh

Peter Pfreundschuh
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Elizabeth Barrett, Chief Executive Officer of UroGen Pharma Ltd. (the "Company"), and Peter Pfreundschuh, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: February 28, 2019

In Witness Whereof, the undersigned have set their hands hereto as of the 28th day of February, 2019.

/s/ Elizabeth Barrett	/s/ Peter Pfreundschuh
Elizabeth Barrett	Peter Pfreundschuh
Chief Executive Officer	Chief Financial Officer

"This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of UroGen Pharma Ltd. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing."