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, 2019

OR

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

For the transition period from_____to_____

Commission file number: 001-38079

UROGEN PHARMA LTD.

(Exact name of registrant as specified in its charter)

Israel	**98-1460746**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
400 Alexander Park, Princeton, NJ	**08540**
(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	Trading Symbol	Name of exchange on which registered
Ordinary Shares, par value NIS 0.01 per share	URGN	The Nasdaq Stock Market LLC

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 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.

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 28, 2019 totaled approximately $695.3 million based on the closing price for the registrant's ordinary shares on that day as reported by the Nasdaq Stock Market LLC. Such value excludes ordinary shares held by executive officers, directors and certain entities affiliated with directors as of June 28, 2019.

As of February 19, 2020, there were 21,154,965 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 the registrant's fiscal year ended December 31, 2019 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 RTGel and Jelmyto 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 nonclinical 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 expectations regarding the current new drug application, or NDA, review process for UGN-101 or 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 commercial potential and 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;
- the future nonclinical, clinical development of newly licensed products, including UGN-301, and their commercial opportunity; 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 biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases. We have developed RTGel™ reverse-thermal hydrogel, a proprietary sustained release, hydrogel-based platform technology that has the potential to improve therapeutic profiles of existing drugs. Our technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. Our lead investigational candidates, UGN-101 and UGN-102, are designed to ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma, or LG UTUC, and low-grade non-muscle invasive bladder cancer, or LG NMIBC, respectively.

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

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

In December 2019, the FDA accepted for filing and granted priority review for our New Drug Application, or NDA, for UGN-101 (mitomycin gel) for instillation as a potential treatment for patients with LG UTUC. If approved, UGN-101 would be the first non-surgical treatment option for LG UTUC. We are on track for the potential FDA approval and launch of UGN-101 by mid-year 2020. The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of LG UTUC. The NDA is supported by the positive results from the pivotal Phase 3 OLYMPUS clinical trial. Results from a final analysis of the primary endpoint showed that UGN-101 demonstrated a complete response rate of 59% in patients with LG UTUC. In addition, the durability of response was estimated to be 89% at six months and 84% at 12 months by Kaplan Meier analysis. Median time to recurrence was estimated to be 13 months. The most commonly reported treatment emergent adverse events were ureteric stenosis (43.7%), urinary tract infection (32.4%), haematuria (31.0%), flank pain (29.6%) nausea (23.9%), dysuria (21.1%), renal impairment (19.7%) and vomiting (19.7%). The majority of these adverse events were mild to moderate with 8.5% of patients having events of ureteric stenosis reported as severe.

In addition, we are evaluating the safety and efficacy of UGN-102 (mitomycin gel) for intravesical instillation, our novel sustained-release high dose formulation of mitomycin, for the treatment of LG Intermediate Risk NMIBC. In September 2019, we reported the interim data of our Phase 2b OPTIMA II trial of investigational UGN-102 (mitomycin gel) for intravesical instillation for patients with LG Intermediate Risk NMIBC, defined as those with one or two of the following criteria: multifocal disease, large tumors and rapid rates of recurrence. The single-arm, open label trial recently completed enrollment of 63 patients at clinical sites across the United States and Israel. Patients are treated with six weekly instillations of UGN-102 and undergo assessment of complete response, or CR (the primary endpoint) four to six weeks following the last instillation. In an interim cohort of 32 patients, 63% (20/32) achieved a CR. 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 LG Intermediate Risk NMIBC patients.

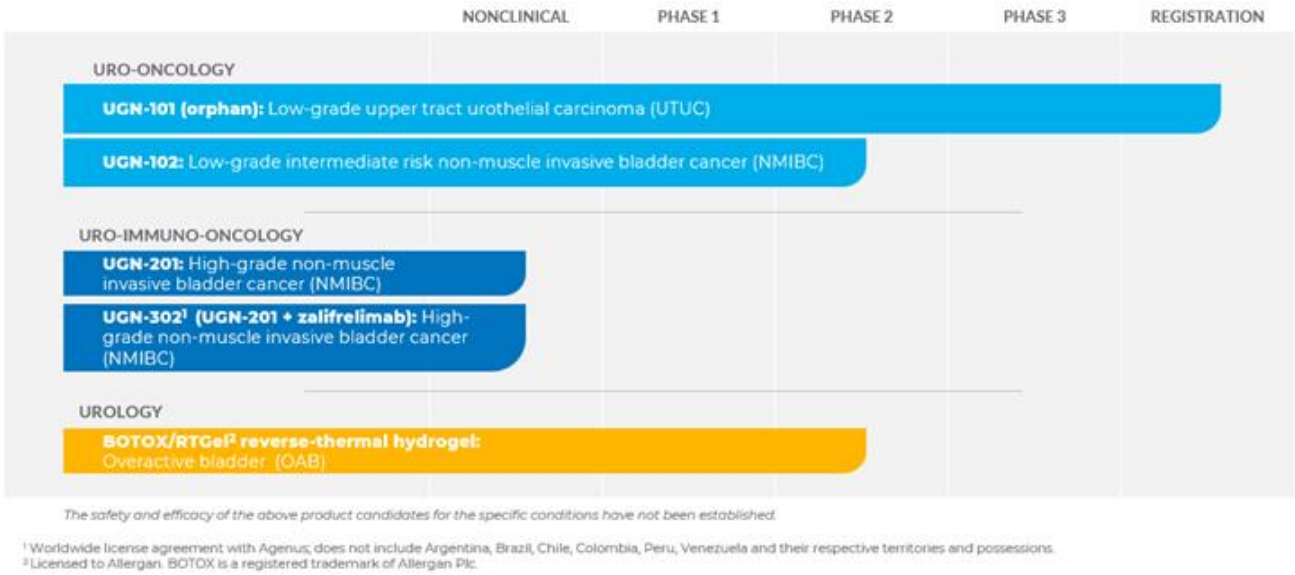
We believe that urothelial cancer, which is comprised of bladder cancer and UTUC, affects a large and underserved patient population. Annual expenditures for Medicare alone in the United States for the treatment of urothelial cancer were estimated to have been at least $4.0 billion in 2010 and are projected to be at least $5.0 billion in 2020. The majority of the expenditures are spent on tumor resection surgeries such as transurethral resection of bladder tumor, or TURBT. 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 LG NMIBC in the United States was approximately 350,000.

Our clinical stage pipeline also includes UGN-201, our proprietary immunotherapy product candidate, a toll-like receptor 7/8, or TLR 7/8 agonist, which has been evaluated 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 TLR7/8, 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 could represent a valid alternative to the current standard of care for the post-TURBT adjuvant treatment of high-grade NMIBC. In November 2019, we entered into a worldwide license agreement with Agenus Inc. to develop and commercialize zalifrelimab (UGN-301, anti-CTLA-4 antibody) via intravesical delivery in combination with UGN-201 (together referred to as UGN-302) for the treatment of urinary tract cancers, initially in high-grade non-muscle invasive bladder cancer, or HG NMIBC. We believe that the combination treatment makes local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effects.

In October 2016, we granted an exclusive worldwide license to Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc, to research, develop, manufacture, and commercialize pharmaceutical products formulated with our RTGel technology platform and clostridial toxins, including BOTOX®, a branded drug, that we believe can potentially serve as an effective treatment option for patients suffering from overactive bladder, or OAB. In August 2017, we announced that Allergan had submitted an Investigational New Drug application, or IND, to the FDA in order to be able to commence clinical trials in the U.S. using RTGel in combination with BOTOX. In October 2017, Allergan commenced a Phase 2 clinical trial of BOTOX/RTGel for the treatment of OAB, with the potential to evolve from multiple injections of BOTOX into the bladder to a single instillation of the novel formulation.

Our Product Candidate Pipeline

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



The safety and efficacy of the above product candidates for the specific conditions have not been established.

[1] Worldwide license agreement with Agenus; does not include Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions.
[2] Licensed to Allergan. BOTOX is a registered trademark of Allergan Plc.

Uro-Oncological Indications Targeted by Our Product Candidates

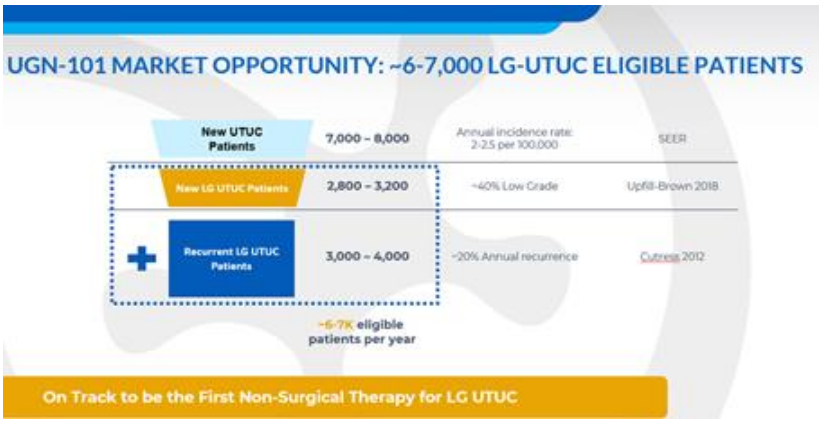
Our product candidates are administered locally using the standard practice of intravesical instillation directly into the bladder or upper urinary tract via a catheter. The instillation into the bladder is expected to take place in a physician's office as a same-day treatment, in comparison with TURBT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

Upper Tract Urothelial Carcinoma (UTUC)

UTUC refers to malignant changes of the urothelium (the epithelial lining) of the upper urinary tract of the calyces, renal pelvis and ureter. LG UTUC managed with endoscopic resection typically exhibits a high rate of local recurrence. HG UTUC is associated with renal parenchymal invasion and the development of metastases. 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 8,000 cases. UTUC is nearly three times more common in men than women and is typically diagnosed in patients in the 6th and 7th decades of life. Tumor grade is the key prognostic factor at the time of diagnosis of UTUC and is assigned based upon microscopic examination of tumor tissue. Approximately 40% of the patients diagnosed annually with UTUC in the United States have LG UTUC.

There are currently no drugs approved by the FDA for the treatment of LG UTUC. Due to the anatomic complexity of the upper urinary tract, complete endoscopic resection of UTUC is technically very challenging. Endoscopic surgical resection of LG UTUC is associated with high rates of local recurrence (50-90%). Consequently, most LG UTUC patients ultimately undergo kidney and ureter removal to control disease (nephroureterectomy).

Endoscopic tumor resection, which aims to be a kidney sparing surgical procedure, is conducted only in patients with low-grade disease and with limited tumor burden (unifocal tumor, low grade histology, less than 2 cm in greatest dimension).



Bladder Cancer

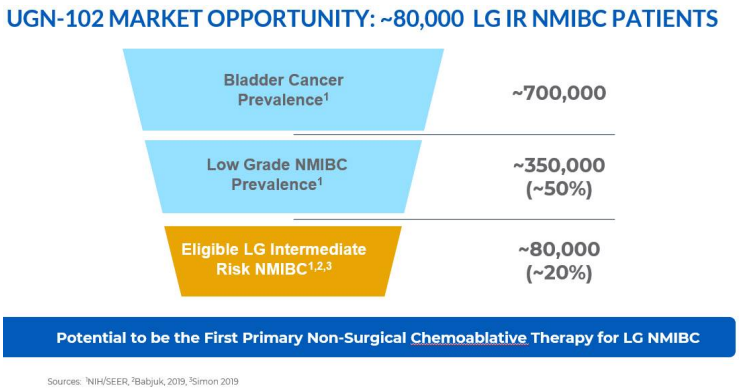
The bladder is a hollow organ in the pelvis with flexible muscular walls. Its main function is to store urine before it leaves the body. Urine is produced by the kidneys and is then carried to the bladder through the upper urinary tract tubes, called ureters. The bladder wall has four main layers. The 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.

Bladder cancer (annual US incidence 80,000, prevalence 700,000) 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, is most commonly diagnosed in 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 physical extent and anatomic location of a tumor is described by clinical staging. The American Joint Committee on Cancer has established an accepted staging system called the tumor, nodes, metastasis, or TNM System. NMIBC includes the clinical stages Ta (papillary urothelial cancer confined to the urothelium), T1 (papillary urothelial cancer invading the lamina propria) and CIS (carcinoma in situ, a form of high-grade NMIBC). NMIBC is associated with high rates of relapse following endoscopic surgery and treatment with aqueous adjuvant topical chemo and immunotherapy. Progression rates to muscle invasion approach 30-50% in patients with high-grade T1 disease associated with CIS. Patients with low-grade NMIBC are treated by chronic endoscopic resection of visible lesions, typically over a period of many years. Patients with LG Intermediate Risk NMIBC have frequent recurrences of disease that can be difficult to control using contemporary standards of care. MIBC which is described as >T2 in the TNM system, is treated with systemic chemo- and/or immunotherapy followed by consolidative radiation therapy or bladder removal surgery (radical cystectomy) in patients with clinically organ-confined disease. Patients presenting with advanced/metastatic bladder cancer have a limited life expectancy.

Non-Muscle Invasive Bladder Cancer

NMIBC can be characterized as low, intermediate, or high risk and can also be characterized as low- or high-grade. Low-grade, intermediate risk tumors are defined as having one of more of following characteristics: tumor larger than 3 cm, multiple tumors in the bladder and a recurrence in less than one year from the prior tumor. We estimate based upon a review of peer-reviewed and publicly available data that approximately 20% of the prevalent NMIBC population (80,000) may be described as intermediate risk in any given year.

The chart below indicates the target patient population for LG NMIBC at intermediate risk of recurrence:



The standard of care for treating LG Intermediate Risk NMIBC patients is TURBT. TURBT is a surgical procedure 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 a treatment for LG 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. A subset of LG NMIBC patients is at risk for frequent local recurrences. Due to lack of treatment options to reduce recurrences in these patients, they are managed with repeat TURBT for each subsequent recurrence.

Recent Developments

In December 2019, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may from time to time offer and sell ordinary shares having an aggregate offering price of up to $100.0 million to or through Cowen, acting as sales agent or principal.

On January 12th, 2020, the Israeli Innovation Authority, or IIA, approved our request to unwind our obligation to the IIA regarding grants that were loaned to us between January 2004 and September 2016. We have previously reported that the repayment of these grants could be up to three-times of the original grants and other amounts. Under the approval from the IIA, we will be required to:

1. Make a one-time payment in 2020, for up to three-times the grants provided (linked to Plan No. 33889) plus annual interest, net of a deduction for the royalties already paid in accordance with Appendix B of the Section 18(F) to Instructions for Benefit Track No. 1 - R&D Fund, or Benefit Track.
2. Make a commitment to continue employment of at least 75% of its base research and development jobs in Israel (at the time of settlement) for a period of at least 3 years, in accordance with Appendix B of the Benefit Track.

The total payment under the IIA approval, net of the royalties already paid, amounts to $6.6 million plus any additional accrued interest since January 2020. We intend to make this payment in the first quarter of 2020.

Subject to payment to the IIA to unwind our obligation, we will have full freedom to transfer IIA-funded technology or manufacture products developed with IIA-funded technology outside of the State of Israel. Other than the commitment to continue employment as discussed above, all other obligations with the IIA will also cease to exist as per the current agreement.

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 repetitive, costly, sub-optimal and burdensome tumor resection procedures that represent the current 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, 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 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 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.

Expertise in developing proprietary formulations of drugs for clinical benefit. We focus on developing proprietary RTGel formulations of previously approved drugs and novel therapeutics which we are investigating, 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 previously approved drugs, 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.

Streamlined development risks and efficiencies for our pipeline product candidates. We expect the approval process for each of our current uro-oncology product candidates to comply with the FDA's 505(b)(2) regulatory pathway, and provide a streamlined, capital efficient pathway 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, Breakthrough Therapy and Priority Review Designations by the FDA.

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 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 35 issued patents worldwide and more than 75 pending patent applications filed worldwide. In the United States, we have 16 granted patents. Most of these patents are directed to protect our lead product candidates UGN-101, UGN-102 and UGN-201 as well as our RTGel technology and our other potential product candidates that are under nonclinical 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 2032. Our pending patent application in the United States is set to expire in 2035, if issued. Additionally, the FDA has granted Orphan Drug Designation to UGN-101 for the treatment of LG UTUC which potentially entitles us to regulatory exclusivity for UGN-101 for seven years following FDA approval.

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 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 are a biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases. Some key growth drivers are as follows:

Establish each of our lead product candidates, UGN-101 and UGN-102, as the treatment in its target indication.

We initiated a rolling submission of the UGN-101 NDA using the 505(b)(2) pathway through submission of nonclinical sections of the NDA to the FDA in December 2018. In December 2019, the FDA accepted our NDA submission and granted Priority Review Designation.

We submitted an IND for UGN-102 in June 2018. We recently completed enrollment in an open-label, single-arm Phase 2b clinical trial to evaluate the efficacy and safety of UGN-102 for the treatment of patients with LG Intermediate Risk NMIBC. 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 standard of care.

Expand our uro-oncology product pipeline.

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 believe that the combination of UGN-201 with additional immunotherapy drugs, such as immune checkpoint inhibitors could represent a valid alternative to the current standard of care for the post-TURBT adjuvant treatment of high-grade NMIBC. In November 2019, we entered into a worldwide license agreement with Agenus Inc. to develop and commercialize zalifrelimab (UGN-301, anti-CTLA-4 antibody) via intravesical delivery in combination with UGN-201 (together, UGN-302) for the treatment of urinary tract cancers, initially in high-grade non-muscle invasive bladder cancer (HG NMIBC). We believe that the combination treatment makes local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effects.

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. 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 BOTOX. 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 BOTOX. 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 as an adjuvant chemotherapy for the treatment of LG NMIBC after TURBT. Mitomycin, a chemotherapy agent, is administered using a water-based solution, which has a relatively short dwell time in the bladder limited to first voiding. Mitomycin often causes temporary irritation of the urinary tract, including the need to urinate frequently and urgently. 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 increased time to recurrence of urothelial 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. Increased dwell time, facilitated by our RTgel preparations UGN-101 and UGN-102, results in increased cell killing and greater efficacy when compared to aqueous solutions of mitomycin.

Limitations of Current Therapies for Upper Tract Urothelial Carcinoma

There are currently no drugs approved by the FDA for the treatment of LG UTUC, representing a significant unmet medical need. The current standard-of-care for the treatment of LG 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.

Our Solution: UGN-101(mitomycin gel) for instillation

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 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 LG UTUC potentially entitles us to regulatory exclusivity for a minimum of seven years following approval by the FDA, if granted. The FDA has also granted Fast Track, Breakthrough and Priority Review Designations.

UGN-101

In the first quarter of 2017, we commenced the OLYMPUS trial, a pivotal, open-label, single-arm Phase 3 clinical trial of UGN-101 for the treatment of LG UTUC. OLYMPUS is a prospective, single-arm study designed to assess the efficacy, safety and tolerability of treatment with UGN-101 instilled in the upper urinary system of patients with noninvasive, LG UTUC. The primary efficacy endpoint is the complete response, or CR, rate, defined as the percentage of patients with a CR at the primary disease evaluation, or 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 were followed for up to 12 months for durability of response.

Eligible consenting patients were treated with UGN-101 once weekly for a total of six times in a retrograde fashion. Patients who demonstrated CR were to be treated with UGN-101 once monthly as a maintenance therapy for a total of 11 instillations or up to the first recurrence, whichever came first. An independent Data Monitoring Committee, or DMC, was assigned to this study. Safety and efficacy data are monitored periodically by the DMC as detailed in the DMC charter.

The OLYMPUS trial is being conducted in the United States and Israel. The study completed enrollment in November 2018 with 74 patients enrolled, and 71 patients treated.

Results from a final analysis of the primary endpoint for the OLYMPUS trial were presented at the Company's Investor Day event on September 24, 2019 and showed that investigational UGN-101 demonstrated a 59% CR rate in patients with LG UTUC. Findings were consistent with previously presented results.

The final analysis of the primary endpoint showed that in the OLYMPUS intent-to-treat population, 42 of the 71 patients (59%) achieved a CR. Forty-one patients entered follow-up, which is still ongoing. Durability of response was estimated by Kaplan-Meier to be 89% at 6 months and 84% at 12 months after PDE. The estimated median time-to-recurrence was 13.0 months. Thirty-four of the 71 patients treated in the study were initially characterized by the treating physician as having endoscopically unresectable tumor at baseline. Twenty of 34 patients (59%) achieved a CR at the PDE assessment and 12-month durability was identical for this subgroup.

In OLYMPUS, the most common treatment emergent adverse events were ureteric stenosis (43.7%), urinary tract infection (32.4%), haematuria (31.0%), flank pain (29.6%), nausea (23.9%), dysuria (21.1%), renal impairment (19.7%) and vomiting (19.7%). The majority of these adverse events were mild to moderate with 8.5% of patients having events of ureteric stenosis reported as severe.

The most common treatment emergent serious adverse events were ureteric stenosis (7.0%), hydronephrosis (5.6%), flank pain (4.2%), and urosepsis (4.2%).

The most common treatment emergent serious adverse events are presented in the table below:

	Safety Analysis Set N=71 Relationship to Study Drug				
Preferred Term	**Not Related n (%)**	**Possibly Related n (%)**	**Probably Related n (%)**	**Definitely Related n (%)**	**Total n (%)**
Number of patients reporting at least one serious adverse event	**7(9.9)**	**9(12.7)**	**9(12.7)**	**1(1.4)**	**26(36.6)**
Ureteric stenosis	0(0.0)	2(2.8)	3(4.2)	0(0.0)	5(7.0)
Hydronephrosis	1(1.4)	2(2.8)	1(1.4)	0(0.0)	4(5.6)
Flank pain	1(1.4)	1(1.4)	1(1.4)	0(0.0)	3(4.2)
Urosepsis	0(0.0)	0(0.0)	3(4.2)	0(0.0)	3(4.2)
Chronic obstructive pulmonary disease	2(2.8)	0(0.0)	0(0.0)	0(0.0)	2(2.8)
Dehydration	1(1.4)	1(1.4)	0(0.0)	0(0.0)	2(2.8)
Dyspnoea	2(2.8)	0(0.0)	0(0.0)	0(0.0)	2(2.8)
Haematuria	2(2.8)	0(0.0)	0(0.0)	0(0.0)	2(2.8)
Urinary tract infection	1(1.4)	0(0.0)	1(1.4)	0(0.0)	2(2.8)
Vomiting	1(1.4)	1(1.4)	0(0.0)	0(0.0)	2(2.8)

We have obtained Orphan Drug, Fast Track and Breakthrough Therapy Designations for UGN-101 for the treatment of patients with LG UTUC. We initiated a rolling submission of the UGN-101 NDA using the 505(b)(2) pathway through submission of nonclinical sections to the FDA in December 2018. In December 2019, the FDA accepted our NDA submission and granted Priority Review Designation.

The FDA grants priority review to applications for medicines that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Priority Review Designation shortens the review period of a 505(b)(2) NDA from the standard 10 months to six months from the submission of the NDA. The FDA assigned a Prescription Drug User Fee Act, or PDUFA, action date of April 18, 2020.

We have initiated a retreatment protocol as an extension to OLYMPUS. This trial is designed to evaluate the efficacy and safety of retreatment with UGN-101 in patients treated in the OLYMPUS trial who were found to be a CR at the PDE 1 Visit and were subsequently found to have a documented recurrence of LG UTUC during follow-up. To date, no patients have recurred and entered into the retreatment protocol.

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%). Tumors are graded as low or high, and approximately 70% of NMIBC patients have a tumor that is classified as low-grade. Tumors classified as Ta and CIS are limited to the urothelial layer, and T1 tumors extend to the layer below, which is the lamina propria.

Recurrence, which occurs in approximately 80% of patients, is the primary threat for patients with NMIBC. 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 patients T1 and CIS NMIBC tumors, progression, which occurs in approximately 45% of patients, is the main threat. Treatment ranges from TURBT in NMIBC patients with a low risk of recurrence to cystectomy for the treatment of HG 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 treatment for NMIBC and only three drugs have been approved for NMIBC, all used as adjuvant treatment: Thiotepa, which was approved in 1959, Bacillus of Calmette and Guerin, or BCG, which was approved in 1989; and Valstar® (valrubicin) which was approved in 1998. Mitomycin is the drug used most often for intravesical chemotherapy. It is used 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 (mitomycin gel) for intravesical instillation

UGN-102 is our sustained-release formulation of mitomycin that we are developing for the treatment of LG Intermediate Risk NMIBC as a non-surgical chemoablation alternative to TURBT. It 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 tumor tissue and therefore has the potential to chemoablate both visible and unseen tumors.

Clinical Development of UGN-102

We presented interim results from the Phase 2b OPTIMA II trial of investigational UGN-102 (mitomycin gel) for intravesical instillation for patients with LG Intermediate Risk NMIBC, defined as those with one or two of the following criteria: multifocal disease, large tumors and rapid rates of recurrence. The single-arm, open label study trial completed enrollment of 63 patients at clinical sites across the United States and Israel. Patients were treated with six weekly instillations of UGN-102 and underwent efficacy assessment of CR (the primary endpoint) four to six weeks following the last instillation. In an interim cohort of 32 patients, 63% (20/32) achieved a CR. Patients who were a CR continue to be followed for durability of response, with 12-month durability to be reported at a later time.

In the interim data from OPTIMA II, the most common treatment emergent adverse events observed were dysuria, pollakiuria, fatigue, hematuria and urinary tract infection. The majority of these events were characterized as mild or moderate and transient.

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.

UGN-201(imiquimod)

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 TLR7/8, 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 is a novel, liquid formulation of imiquimod, a generic toll-like receptor 7/8, or TLR7/8, 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. In November of 2019, we entered into a worldwide license agreement with Agenus Inc. to develop and commercialize zalifrelimab (UGN-301, anti-CTLA-4 antibody) via intravesical delivery in combination with UGN-201 (together, UGN-302) for the treatment of urinary tract cancers, initially in HG NMIBC. We believe that the combination treatment makes local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effect.

Other Partnered Programs

We have combined a proprietary novel RTGel formulation with BOTOX®, a branded drug, and we believe that the combination 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 this RTGel formulation in combination with neurotoxins, including BOTOX, to Allergan Pharmaceuticals International Limited ("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 RTGel in combination with BOTOX. In October 2017, Allergan commenced a Phase 2 clinical trial of our proprietary formulation of RTGel combined with BOTOX for the treatment of overactive bladder.

Nonclinical Programs

Using our proprietary RTGel formulation technology, we are pursuing additional nonclinical programs to expand and enhance our uro-oncology product portfolio. In particular, we are pursuing nonclinical 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 and Collaboration Agreements

Allergan Agreement

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 a proprietary RTGel formulation 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 the RTGel formulation for development of Licensed Products through Allergan's Phase 2 APOLLO clinical trial 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 the RTGel formulation 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.

Agenus Agreement

In November 2019, we entered into a license agreement with Agenus Inc. Pursuant to the agreement, Agenus granted us an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary antibody of Agenus known as AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. AGEN1884 is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients and in combination with Agenus' anti-PD-1 antibody in solid tumors. Initially, we plan to develop AGEN1884 in combination with UGN-201 for the treatment of high-grade non-muscle invasive bladder cancer. Our company code for the combination product will be UGN-302.

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

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

Early-Stage Feasibility Evaluation with Janssen Research & Development, LLC

On April 22, 2019, we entered into an agreement with Janssen to conduct an early-stage formulation feasibility evaluation in a therapeutic area of mutual interest. Both parties will each conduct certain activities under the terms of the agreement, and we will incur the costs of our own efforts related to the feasibility evaluation.

Intellectual Property

Our patent estate includes patents and applications with claims directed to our UGN-101, UGN-102, RTGel, BOTOX/RTGel reverse thermal hydrogel, 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 75 patent filings 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 16 issued patents and more than 15 pending patent applications filed in the United States that are directed to methods, systems, compositions and combination products 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. As noted earlier, companies are required as part of the NDA submission process to list patents with the FDA whose claims cover the applicant's product. Accordingly, UroGen has submitted select patents as part of its NDA process.

Our worldwide intellectual property portfolio includes patents and patent applications filed in many jurisdictions 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 internal cavities such as the bladder and/or urinary tract.
- The method for treating bladder cancer, upper urinary tract cancer and urothelial cancer using hydrogel-based compositions.
- The method for treating overactive bladder and IC topically without a need for injections in the bladder wall.
- 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.
- Composition comprising immunomodulators such as aPD1 and/or aCTLA4 for topical/intravesical administration as a monotherapy or a combo-therapy.
- 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, as well as certain other international jurisdictions for "UroGen", “Jelmyto,” “RTGel” 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

We are developing products for patients with LG UTUC, LG NMIBC and HG NMIBC.

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 recurring UTUC. We are not aware of competition in LG UTUC. We do not know whether the competitors in the NMIBC space are already developing, or plan to develop, UTUC treatments. 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.

The standard of care for treating LG NMIBC is repeated TURBT procedures. While effective, patients with Intermediate Risk NMIBC experience frequent recurrences and repeated surgical procedures. Mitomycin is sometimes used off-label as 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 Intermediate Risk 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. Companies such as Lipac Oncology and Spectrum Pharmaceuticals are developing products for LG NMIBC.

The standard of care for treating HG NMIBC patients is the TURBT procedure for papillary tumor resection, followed by post-operative adjuvant BCG. In the case of HG disease without papillary tumor (CIS), BCG is used alone as primary therapy. BCG was approved by the FDA in 1989, since its approval, only two other drugs were approved for HG NMIBC: Valstar, approved by the FDA in 1998; and Keytruda, approved by the FDA in 2020. Valstar is indicated for patients with CIS that do not respond to BCG treatment and is rarely used. Keytruda was approved for CIS with or without papillary involvement for patients who do not respond to BCG treatment. Keytruda was approved in this indication only this year, and it remains to be seen whether the broader urology community will adopt a systemic infused immunotherapy into their clinical management of BCG unresponsive NMIBC. In addition to these approved options, off-label intravesical chemotherapy can be used (such as gemcitabine and cisplatin). If the disease can no longer be controlled, patients will typically proceed to cystectomy, or surgical removal of the bladder, to prevent progression to muscle invasive and metastatic disease. There are several products in the development pipeline, most of which are treatments targeted for high-grade NMIBC patients who have failed BCG treatment and are facing cystectomy. Companies developing these options include AstraZeneca, Merck, BMS, Altor BioScience, FerGene, Vyriad and Sesen Bio. In addition, Janssen recently acquired Taris Biomedical, a company that was developing an extended release chemotherapeutic technology for muscle-invasive bladder cancers closely related to high-grade NMIBC.

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 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 current good manufacturing practices, or cGMP and GCPs; and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

The testing and approval process require substantial time, effort and financial resources. Nonclinical 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 nonclinical tests and nonclinical 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 nonclinical 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 serious adverse events, or 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 nonclinical 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 patents with the FDA which claims cover the applicant's product. The patents chosen as part of this submission do not reflect the entire patent estate or set of product protections associated with this product, which may provide various protections beyond the patents submitted in the NDA application. 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 nonclinical 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 nonclinical 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 that have not previously been approved by the FDA or 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 nonclinical 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 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 federal, state, and foreign 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, as defined by such law, 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. Effective January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. The CCPA 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.

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

There remain 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, several bills affecting the implementation of certain taxes under the ACA has been signed into law. Legislation enacted in 2017 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." In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, 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 2029 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 2020 contains further drug price control measures that could be enacted during the 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 solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional 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 nonclinical 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 the potential FDA approval of UGN-101. The company also intends to negotiate back-up supply agreements with other third-party manufacturers for the commercial production of any approved products, including UGN-101 if approved.

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 nonclinical 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

Our U.S. subsidiary, Urogen Pharma, Inc., was formed to support our U.S. development and potential commercialization efforts. We have established a commercial management team that is preparing our organization for the planned future launch of UGN-101, if approved. This commercial management team is comprised of experienced professionals in sales, sales operations, market access, marketing and medical affairs. In addition, we have established a field-based organization comprised of approximately 80 individuals, including a sales team, reimbursement support team, clinical nurse educators, national account managers and medical liaisons. Pre-launch marketing efforts have focused on disease-state education and building relationships within key potential customer accounts.

If UGN-101 is approved, our sales force will focus on promoting UGN-101.

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 17, 2020, we had 173 employees worldwide, 127 in the United States and 46 in Israel, many of whom hold advanced degrees. None of our employees are 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 400 Alexander Park, Princeton, NJ 08540. 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.

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 U.S. Securities and Exchange Commission, or 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 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 SEC, including the following risk factors which we face. 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 $104.9 million and $75.7 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $228.0 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our ability to ultimately achieve recurring revenues and profitability is dependent upon our ability to successfully complete the development of our product candidates and obtain necessary regulatory approvals for and successfully manufacture, market and commercialize our products.

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

Our future capital requirements depend on many factors, including:

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

In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. To date, we have not obtained 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 nonclinical and clinical development of our lead product candidates, UGN-101 and UGN-102. As of December 31, 2019, we had cash and cash equivalents and marketable securities of $195.6 million. In January 2019, we completed an underwritten public offering in which we received net proceeds of approximately $161.4 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

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

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

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

- delay, limit, reduce or terminate nonclinical studies, clinical trials or other development activities for our product candidates or any of our future product candidates;
- delay, limit, reduce or terminate our other research and development activities; or
- delay, limit, reduce or terminate our establishment or expansion of manufacturing, sales and marketing or distribution capabilities or other activities that may be necessary to commercialize 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 UGN-101 and our other 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 product candidates remain in clinical development and have yet to receive regulatory approval from the U.S. Food and Drug Administration, or the FDA, or any other regulatory agency. We are focusing a significant portion of our activities and resources on UGN-101, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to obtain regulatory approval for and successfully commercialize UGN-101 in the United States and potentially in additional territories. The regulatory approval and successful commercialization of UGN-101 is subject to many risks, including the risks discussed in other risk factors, and UGN-101 may not receive marketing approval from any regulatory agency. The FDA assigned a Prescription Drug User Fee Act, or PDUFA, action date of April 18, 2020 for UGN-101. However, the PDUFA date is only a goal and the FDA does not always meet its PDUFA dates.

Our product candidates' marketability is subject to significant risks associated with successfully completing current and future clinical trials, including:

- 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, and proposed labeling and packaging;
- the FDA's timely review and approval of our New Drug Application, or NDA, for UGN-101;
- the FDA's acceptance that the single pivotal Phase 3 clinical trial for UGN-101, will be sufficient to support FDA approval;
- our ability to successfully complete the FDA requirements related to chemistry, manufacturing and controls, or CMC, for UGN-101, UGN-102 and our other product candidates, and if completed, their sufficiency to support an NDA;
- the FDA's timely acceptance of our Investigational New Drug applications, or INDs, for our product candidates. Without such IND acceptances, we will be unable to commence clinical trials in the United States;
- the FDA's acceptance of the number, design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from nonclinical studies or clinical trials;
- 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 need to schedule an advisory committee meeting, and to conduct such meeting, in a timely manner to evaluate and decide on the approval of our potential future NDA for UGN-102;
- if applicable, the recommendation of the FDA's advisory committee to approve our applications to market UGN-102 and our other product candidates in the United States, without limiting the approved labeling, specifications, distribution or use of the products, or imposing other restrictions;
- the FDA's determination of safety and efficacy of our product candidates;
- the 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, 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 clinical trials and commercial use;
- our ability to obtain, protect and enforce our intellectual property rights with respect to our product candidates; and
- our ability to properly train physicians or nurses for the skillful preparation and administration of 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 low-grade 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 nonclinical 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 nonclinical studies or clinical trials are required;
- 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 the quality of our drug substance or drug product, formulation, labeling, packaging, 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.

Our NDA for UGN-101 for LG UTUC may receive a complete response letter at the conclusion of the 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 nonclinical testing and early clinical trials do not ensure that later clinical trials will be successful. A number of pharmaceutical companies have suffered significant setbacks in clinical trials, including in Phase 3 clinical trials, after promising results in nonclinical testing and early clinical trials. These setbacks have included negative safety and efficacy observations in later clinical trials, including previously unreported adverse effects. To date, our clinical trials and other programs have involved small patient populations and because of the small sample size, the results of these clinical trials may be subject to substantial variability and may not be indicative of future results. For instance, only 22 patients were enrolled in the UGN-101 Compassionate Use Program and only 71 patients were treated in our pivotal Phase 3 OLYMPUS (TC-UT-03) clinical trial for UGN-101; to date, no patients have recurred and entered our Phase 3b extension trial retreatment protocol. In our Phase 3 Clinical Trial TC-UT-03, we observed several adverse events, such as ureteric stenosis, urinary tract infection, hematuria, flank pain, nausea and dysuria and serious adverse events, including ureteric stenosis, hydronephrosis, flank pain and urosepsis. In addition, we have observed perturbation of laboratory measures of renal and hematopoietic function as well as ureteral stricture and stenosis. These adverse events are known mitomycin or procedure-related adverse events and many are indicated as potential side effects of mitomycin usage on the mitomycin label. However, we cannot assure you that new adverse events related to UGN-101 and UGN-102 that are not directly attributable to mitomycin specifically will not occur. Additional safety information for UGN-101 is contained under “Business—Overview— UGN-101(mitomycin gel) for instillation” of this report, presenting the most common treatment emergent serious adverse events occurring in at least two patients, by relationship to study medication. In addition, our clinical trials may not be successful. If our clinical trials do not ultimately indicate that our product candidates are safe and effective for their intended use, the FDA may not approve any NDA that we may submit to market such product candidates, and our business would not be able to generate revenue from the sale of any such product candidates.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change as patient data become available and following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. In particular, interim data may reflect small sample sizes, be subject to substantial variability and may not be indicative of either future interim results or final results. Durability is a key secondary endpoint for our ongoing pivotal Phase 3b open label extension of the OLYMPUS clinical trial. Additional safety information for UGN-101 is contained under “Business—Overview— UGN-101(mitomycin gel) for instillation” of this report, presenting the most common treatment emergent serious adverse events occurring in in at least two patients, by relationship to study medication. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our ordinary shares. See the description of risks under the heading “Risks Related to Ownership of our Ordinary Shares” for additional disclosures related to the risk of volatility in the price of our ordinary shares.

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

Before we can submit an NDA to the FDA or comparable similar applications to foreign regulatory authorities, we must conduct Phase 3 clinical trials, or a pivotal/registration trial equivalent, for each product candidate. Our pivotal clinical trial for UGN-101 evaluated 71 patients, and we completed a rolling submission to the FDA of an NDA for UGN-101 in October 2019. After submission of an NDA, the FDA may raise additional questions on any data contained in the application. These questions may come in the form of information requests or in the NDA 74-day letter as review issues. We must address these questions during the review, but we do not know whether our responses will be acceptable to the FDA. We cannot assure you that the FDA will not decide to require us to perform additional clinical trials, including potentially requiring us to perform an additional pivotal study with a control arm, before approving, or as a condition of approving, our NDA 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, nonclinical, manufacturing, validation or drug product quality studies and submit that data before considering or reconsidering any NDA or comparable foreign regulatory application that we may submit. Depending on the extent of these additional studies, approval of any applications that we submit may be significantly delayed or may cause the termination of such programs or may require us to expend more resources than we have available.

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

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

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

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

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

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

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

If we are unsuccessful in advancing our nonclinical product candidates into clinical trials in a timely fashion, our business may be harmed. Even if we are successful in advancing our nonclinical product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in the 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 nonclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- obtain regulatory approval or feedback on trial design, in order to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites, and have such CROs and sites effect the proper and timely conduct of our clinical trials;
- obtain and maintain institutional review board, or IRB, approval at each clinical trial site;
- identify, recruit and enroll 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 standard of care for certain urothelial cancers. However, there is no guarantee that our product candidates, if approved, would be approved for first-line or even later lines of therapy, and, that prior to any such approvals, we will not have to conduct additional clinical trials.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers who have previously failed prior treatments, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or third-party market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, our pivotal Phase 3 OLYMPUS clinical trial for UGN-101 was 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 was 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 nonclinical studies and clinical trials or that are not expected with mitomycin treatment or inconsistent with catheter administration procedures. This could prevent us from gaining marketing approval or market acceptance for these product candidates, or from maintaining such approval and acceptance, and could substantially increase commercialization costs and even force us to cease operations.

As with most pharmaceutical products, 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 nonclinical testing, completed Compassionate Use Program for UGN-101 and clinical trials, we have observed several adverse events and serious adverse events, including ureteral stenosis, 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 ureteral stricture and stenosis. These adverse events are known mitomycin or procedure-related adverse events and many are indicated as potential side effects of mitomycin usage on the mitomycin label. Additional safety information for UGN-101 is contained under "Business—Overview— UGN-101(mitomycin gel) for instillation" of this report, presenting the most common treatment emergent serious adverse events occurring in at least two patients, by relationship to study medication. 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 nonclinical studies or clinical trials or restrict or cease the distribution or use of the product; and
- our being sued and held liable for harm caused to patients.

Any of these events could prevent us from achieving 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 treatment of LG UTUC, and in the case of UGN-102, for the treatment of LG Intermediate Risk NMIBC, and for other therapeutic indications that we may seek to pursue with any of our product candidates. Physicians treating LG UTUC and LG Intermediate Risk NMIBC have never had to consider treatments other than surgery. The degree and rate of physician and patient adoption of our product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved;
- the approved labeling and packaging for our products, including the degree of product preparation and administration convenience and ease of use that is afforded to physicians by the approved labeling and product packaging;

- the prevalence and severity of adverse side effects and the level of risk/reward observed in our clinical trials;
- sufficient patient satisfaction with the results and administration of our 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 Intermediate Risk 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 nonclinical 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 Intermediate Risk NMIBC, another key element of our strategy is to discover, develop and commercialize a portfolio of products to serve additional therapeutic markets. We are seeking to do so through our internal research programs, but our resources are limited, and those that we have are geared towards clinical testing and seeking regulatory approval of UGN-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. 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 (durvalumab) and Keytruda (pembrolizumab) for the treatment of locally advanced or metastatic bladder cancer, a form of muscle invasive bladder cancer.

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

We are also aware that other companies, such as Taris and Lipac are conducting, or have recently conducted clinical trials for product candidates for the treatment of LG Intermediate Risk NMIBC, including carcinoma in situ, or CIS. Outside of these indications where we are developing products, we are aware of other companies doing work in both bladder and upper tract cancers, but these are with agents or on targets in high-grade, metastatic, or muscle invasive cancers. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective, easier to administer or less costly than our product candidates.

In addition, we face competition from existing standards of treatment, including transurethral resection of bladder tumor, or TURBT, surgery for bladder cancer. If we are not able to demonstrate that our product candidates are at least as safe and effective as such courses of treatment, medical professionals may not adopt our product candidates in replacement of the existing standard of care, which is first-line tumor surgical procedures.

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

Our strategy is to build a fully integrated biopharmaceutical company to successfully execute the commercial launch of UGN-101 in the United States, if approved. We have established a commercial management team that is preparing our organization for the planned future launch of UGN-101, if approved, and have also established a field-based organization comprised of approximately 80 individuals, including a sales team, reimbursement support team, clinical nurse educators, national account managers and a medical liaisons. However, in order to successfully market UGN-101, if approved, we must continue to build our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. This involves many challenges, such as recruiting and retaining talented personnel, training employees, setting the appropriate system of incentives, managing additional headcount and integrating new business units into an existing corporate infrastructure. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully develop this capability. While we recently established a field-based sales organization, we will need to conduct further activities to develop our sales force in order to successfully execute the commercial launch of UGN-101, if approved. Additionally, even after initial development of our sales force and the commercial launch of UGN-101, we will need to maintain and further develop our sales force, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to effectively develop and maintain our commercial team, including our sales force, our ability to effectively commercialize UGN-101 would be limited, and we would not be able to generate product revenues successfully. Moreover, as an organization, we have no experience in marketing or distributing products, and we cannot be certain that we will successfully develop this capability. 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 and maintain an effective sales and marketing infrastructure, we will be unable to successfully commercialize our product candidates, which in turn would have an adverse effect on our business, financial condition and results of operations.

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 a proprietary RTGel formulation and clostridial toxins (including BOTOX), alone or in combination with certain other active ingredients, which we refer to collectively as the Licensed Products. Either party may terminate the Allergan 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 a proprietary formulation of RTGel in combination with BOTOX, 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 report also apply to the activities of our collaborators.

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

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

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

We 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 nonclinical 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 nonclinical studies, clinical trials and commercial use, should our drug candidates receive regulatory approval. We currently depend on Teva Pharmaceuticals Industries Ltd., or Teva, as our single-source supplier of mitomycin active pharmaceutical ingredient, or API, for UGN-101 and UGN-102. 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 our proprietary 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 nonclinical 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, logistics breakdowns, labor shortages, natural disasters, power failures, production failures or product recalls and numerous other factors could prevent us from realizing the intended benefits of our sales strategy and have a material adverse effect on our business. Further, 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.

In addition to mitomycin, we currently use other single-source suppliers relative to production of the RTGel products, the ureteral catheter and injector which are included within the planned UGN-101 product package. Both the ureteral catheter and injector are used as part of the delivery of UGN-101. Although we are in the process of negotiating supply agreements with these single-source suppliers for commercial supply, we do not yet have any supply agreements with these single-source suppliers and may not be able to establish supply agreements on a timely basis, on favorable terms, or at all.

We are assessing second-source suppliers regarding all key components of UGN-101 and are advancing these conversations as a means to ensure both a second source and potential future reductions in cost of goods sold. However, there can be no assurance that we will be able to secure any second-source suppliers for these key components on a timely basis, on favorable terms, or at all.

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 rely on third parties and consultants to assist us in conducting our clinical trials for our product candidates. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize UGN-101, UGN-102 or any of our other product candidates.

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

We and the third parties upon whom we rely are required to comply with Good Clinical Practice, or GCP, regulations, which are regulations and guidelines enforced by regulatory authorities around the world for products in clinical development. Regulatory authorities enforce these GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or our third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and our submission of marketing applications may be delayed, or the regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, a regulatory authority will determine that any of our clinical trials comply or complied with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under current 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.

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

As of February 17, 2020 we had 173 employees, 46 of whom are based in Israel and 127 are based in the United States. We will need to continue to expand our development, quality, managerial, operational, finance, marketing sales, and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

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

As we continue to grow as an organization, including by expanding our development efforts and building out our commercial capabilities in anticipation of commercial launch of UGN-101, if approved, we will evaluate, and may implement, changes to our organization that may be appropriate in order to properly manage and direct our growth and transformation into a commercial-stage company. Due to our limited financial resources and our limited experience in managing a larger company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion or other significant changes to our organization could delay the execution of our development, commercialization and strategic objectives or disrupt our operations; and if we are not successful in commercializing our 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 significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

The U.S. dollar is our functional and reporting currency. However, a significant portion of our operating expenses are incurred in New Israeli Shekels, or NIS, which is the lawful currency of the State of Israel. As a result, we are exposed to the risks that the NIS may appreciate relative to the dollar, or, if the NIS instead devalues relative to the dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. We cannot predict any future trends in the rate of inflation in Israel or the rate of devaluation (if any) of the NIS against the dollar. For example, although the dollar appreciated against the NIS in 2018 by 8.1%, the dollar depreciated against the NIS in 2019 by 7.8%.. If the dollar cost of our operations in Israel 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, as well as other intellectual property advancements.

We seek patent protection for our product candidates, and we have established several patent families comprised of issued patents and pending patent applications covering our proprietary RTGel technology, the pharmaceutical compositions, methods of use and manufacturing aspects of our product candidates. In the United States, we currently have 16 granted patents that are directed to protect our lead product candidates, UGN-101, UGN-102, a proprietary RTGel technology, various local compositions comprising different active ingredients, inter alia compositions comprising a Botulinium Toxin, UGN-201 and future product candidates that are under company research. These patents claim methods, systems, combination products and novel compositions for treating different diseases, especially cancer in internal cavities, in particular urinary tract cancer. These issued patents are expected to expire between 2024 and 2032. Moreover, our IP portfolio includes more than 45 pending patent applications filed worldwide that are directed to cover various methods, systems and compositions for treating cancer locally, by intravesical means, utilize various active ingredients and the combinations thereof. These patent applications, if issued, set to expire between 2031 and 2036.

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

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

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

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

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

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

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

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

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

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

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

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

Our trade secrets may not have sufficient intellectual property protection.

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

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, advisors, and any other third parties that have access to our proprietary know-how, information or technology, for example, third parties involved in the formulation and manufacture of our product candidates, and third parties involved in our clinical trials to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed

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

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

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

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

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

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

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

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

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

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

candidates, our competitors might be able to enter the market earlier than should otherwise have been the case, which could harm our business.

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

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

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

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

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

We filed applications for trademarks (Jelmyto ™, RTGel ™**)** that identify our branding elements, UGN-101 and our unique technology platform in the United States, Europe and Japan. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy.

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

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

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.

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 nonclinical and clinical data that we would need to generate in order to obtain FDA approval. However, while we believe that our product candidates are reformulations of existing drugs and, therefore, will not be treated as new chemical entities, or NCEs, the submission of an NDA under the Section 505(b)(2) pathway does not preclude the FDA from determining that the product candidate that is the subject of such submission is an NCE and therefore not eligible for review under such regulatory pathway.

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

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

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

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

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

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

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report annually certain financial arrangements with physicians and teaching hospitals; as defined in the ACA and its implementing regulations, including reporting any payment or "transfer of value" provided to physicians 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 remain 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, bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." For example, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, 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 2029 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 2020 contains further drug price control measures that could be enacted during the 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. The HHS has started soliciting feedback on some of these measures and is concurrently implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump Administration have both stated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. If healthcare policies or reforms intended to curb healthcare costs are adopted, or if we experience negative publicity with respect to the pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for any approved products may be limited, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted.

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 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.

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. Conversely, even if we are granted orphan exclusivity, a competitor that demonstrates clinical superiority with the same active moiety may obtain approval prior to expiration of our exclusivity. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate, we are pursuing for a different orphan indication, this may negatively impact the market opportunity for our product candidate. There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, and future challenges could lead to changes that affect the protections afforded our product candidates in ways that are difficult to predict.

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, state, and foreign 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 among other things, unlawful financial inducements paid to prescribers and beneficiaries, as well as impermissible promotional practices, including certain marketing arrangements that rely on volume-based pricing and off-label promotion of FDA-approved products.

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

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

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

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

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

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

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

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

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

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

The European Union, or EU, has established its own data security and privacy legal framework, including but not limited to the European General Data Protection Regulation, or GDPR, which contains provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business to include additional operations outside of the United States and Israel. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Effective January 1, 2020, the CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. The CCPA 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.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of the payer. Additional state laws require pharmaceutical companies to implement a comprehensive compliance program, comply with industry's compliance guidelines and relevant compliance guidance promulgated by the federal government and register pharmaceutical sales representatives and limit expenditure for, or payments to, individual medical or health professionals. In addition, certain state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states; and report pricing with respect to certain drug products.

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 nonclinical 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 December 31, 2019, the holders of up to approximately 3.6 million ordinary shares are entitled to registration rights. In addition, our sale of additional ordinary shares or similar securities in order to raise capital might have a similar negative impact on the share price of our ordinary shares. A decline in the price of our ordinary shares might impede our ability to raise capital through the issuance of additional ordinary shares or other equity securities and may cause you to lose part or all of your investment in our ordinary shares.

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

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

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

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

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

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

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

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a PFIC for U.S. federal income tax purposes. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our common shares from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering.

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

If we are characterized as a PFIC, our U.S. Holders (as defined below) may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. Holders, having interest charges apply to distributions by us and gains from the sales of our shares, and additional reporting requirements under U.S. federal income tax laws and regulations. A U.S. Holder that (i) owns our ordinary shares at any point during a year in which we are characterized as a PFIC and (ii) does not timely make a QEF Election (as described below) will treat such ordinary shares as stock in a PFIC for all subsequent tax years, even if we no longer qualify as a PFIC under the relevant tests in such subsequent tax years. A U.S. Holder may be able to elect out of such treatment if we are no longer characterized as a PFIC by making a "purging election." For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is or is treated as any of the following: (a) an individual who is a citizen or resident of the United States; (b) a corporation, or entity treated as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state thereof, or the District of Columbia; (c) an estate, the income of which is subject to U.S. federal income tax regardless of its source; or (d) a trust that (1) is subject to the supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

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

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

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

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

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

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

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

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

If a U.S. Holder is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). Because our group includes at least one U.S. subsidiary (Urogen Pharma, Inc.), if we were to form or acquire any non-U.S. subsidiaries in the future, they may be treated as controlled foreign corporations of any U.S. Holder owning (directly, indirectly or constructively) at least 10% of the value or voting power of our ordinary shares. A United States shareholder of a controlled foreign corporation may be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. We cannot provide any assurances that we will assist investors in determining whether any non-U.S. subsidiaries that we may form or acquire in the future would be treated as a controlled foreign corporation or whether such investor would be treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any U.S. shareholder information that may be necessary to comply with the reporting and tax paying obligations discussed above. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations with respect to your U.S. federal income tax return for the year for which reporting was due from starting. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares.

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

Under U.S. federal income tax law, federal net operating losses, or NOLs, incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. In addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to utilize its pre-change NOL carryforwards and other pre-change tax attributes to offset future its post-change income or taxes may be limited. We have not performed a detailed analysis to determine whether an ownership change under Section 382 of the Code has occurred for Urogen Pharma, Inc. If we undergo an ownership change, our ability to utilize NOLs and other tax attributes could be limited by Sections 382 and 383 of the Code. Future changes in our share ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes, which could negatively impact our future cash flows. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

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

Risks Related to our Operations in Israel

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

Our research and development facilities are located in Ra'anana, Israel. If these or any future facilities in Israel were to be damaged, destroyed or otherwise unable to operate, whether due to war, acts of hostility, earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, 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, 2019, we had 43 employees based in Israel. Of these employees, some may be military reservists, and may be called upon to perform military reserve duty of up to 36 days per year (and in some cases more) until they reach the age of 40 (and in some cases, up to the age of 45 or older). Additionally, they may be called to active duty at any time under emergency circumstances. In response to increased tension and hostilities in the region, there have been, at times, call-ups of military reservists, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of these employees due to military service. Such disruption could harm our business and operating results.

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

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

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

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

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

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

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

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

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

Risks Related to Our Management and Employees

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

Our success depends upon the continued service and performance of our executive officers who are essential to our growth and development. The loss of one or more of our executive officers could delay or prevent the continued successful implementation of our growth strategy, could affect our ability to manage our company effectively and to carry out our business plan, or could otherwise be detrimental to us. As of February 17, 2020, we had 173 employees. Therefore, knowledge of our product candidates and clinical trials is concentrated among a small number of individuals. Members of our executive team as well as key clinical, scientific, technical and commercial personnel may resign at any time and there can be no assurance that we will be able to continue to retain such personnel. If we cannot recruit suitable replacements in a timely manner, our business will be adversely impacted.

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Effective November 2019, we leased approximately 20,913 square feet of space in Princeton, NJ, which now serves as our principal executive offices and is used for commercial and marketing as well as general and administrative purposes. 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. 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

Market Information

Our ordinary shares have 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.

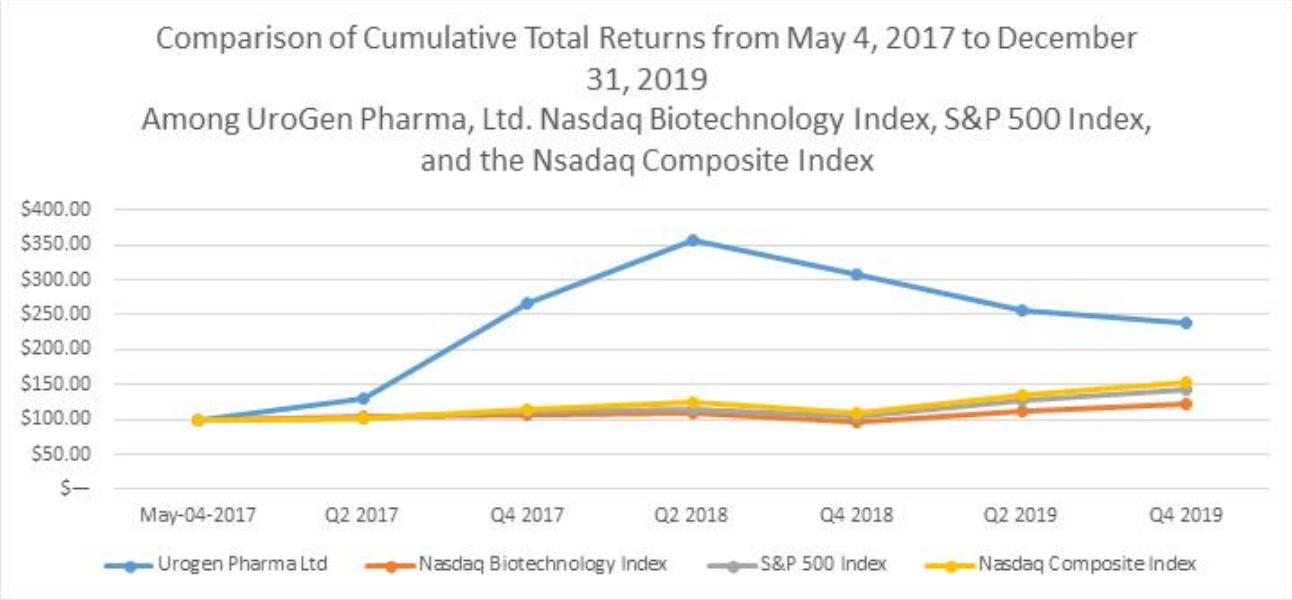
Recent Sales of Unregistered Securities

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.

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, 2019, 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	12/31/2017	6/30/2018	12/31/2018	6/30/2019	12/31/2019
Urogen Pharma	$ 100.00	$ 129.18	$ 266.17	$ 355.94	$ 308.01	$ 257.08	$ 238.70
Nasdaq Biotechnology	100.00	103.83	107.38	110.48	97.37	110.92	122.87
S&P	100.00	101.42	111.89	113.76	104.91	128.55	142.59
Nasdaq Composite	100.00	101.07	113.63	123.62	109.22	134.94	152.03

Holders

As of February 19, 2020, there were approximately 22 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 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, 2019, we have used all of the net proceeds from our IPO primarily to fund our UGN-101 and UGN-102 clinical programs 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.

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 as of December 31, 2019 and 2018 and the related consolidated statements of operations for each of the three years ended December 31, 2019 and related notes appearing elsewhere in this Annual Report. The consolidated statement of operations data for the years ended December 31, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016 and 2015 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,				
	2019	2018	2017	2016	2015
Statements of operations data:	(in thousands, except share and per share data)				
Revenues	$ 18	$ 1,128	$ 8,158	$ 17,530	$ —
Cost of revenue	—	1,803	600	28	—
Gross profit (loss)	18	(675)	7,558	17,502	—
Research and development expenses, net	49,297	36,934	18,697	10,287	10,515
General and administrative expenses	60,199	39,571	8,811	6,417	1,895
Operating (loss) income	(109,478)	(77,180)	(19,950)	798	(12,410)
Interest and other (income) expenses, net	(4,332)	(1,648)	31	2,739	279
Loss before income taxes	(105,146)	(75,532)	(19,981)	(1,941)	(12,689)
Income tax expense	—	125	19	—	—
Net loss	$ (105,146)	$ (75,657)	$ (20,000)	$ (1,941)	$ (12,689)
Loss per ordinary share, basic and diluted	$ (5.12)	$ (4.80)	$ (2.14)	$ (1.91)	$ (5.88)
Weighted average number of ordinary shares outstanding used in computing loss per share	20,528,727	15,754,193	9,716,790	2,305,503	2,300,959

	As of December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Balance sheet data:					
Cash and cash equivalents and marketable securities	$ 195,632	$ 101,318	$ 73,000	$ 21,362	$ 17,975
Working capital	129,152	88,778	67,437	18,904	16,894
Total assets	202,388	103,559	75,550	23,056	19,930
Total liabilities	22,086	13,465	7,035	6,749	3,109
Total shareholders' equity	$ 180,302	$ 90,094	$ 68,515	$ 16,307	$ 16,281

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 biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases. We have developed RTGel™ reverse-thermal hydrogel, a proprietary sustained release, hydrogel-based platform technology that has the potential to improve therapeutic profiles of existing drugs. Our technology is designed to enable longer exposure of the urinary tract tissue to medications, making local therapy a potentially more effective treatment option. Our lead investigational candidates, UGN-101 (mitomycin gel) for instillation, and UGN-102 (mitomycin gel) for intravesical instillation, are designed to ablate tumors by non-surgical means and to treat several forms of non-muscle invasive urothelial cancer, including low-grade upper tract urothelial carcinoma, or LG UTUC, and low-grade non-muscle invasive bladder cancer, or LG NMIBC, respectively.

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

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

In December 2019, the FDA accepted for filing and granted priority review for our New Drug Application, or NDA, for UGN-101 (mitomycin gel) for instillation as a potential treatment for patients with LG UTUC. If approved, UGN-101 would be the first non-surgical treatment option for LG UTUC. We are on track for the potential launch of UGN-101 by mid-year 2020. The FDA previously granted Orphan Drug, Fast Track, and Breakthrough Therapy Designations to UGN-101 for the treatment of LG UTUC. The NDA is supported by the positive results from the pivotal Phase 3 OLYMPUS clinical trial. Results from a final analysis of the primary endpoint showed that UGN-101 demonstrated a complete response rate of 59% in patients with LG UTUC. In addition, the durability of response was estimated to be 89% at six months and 84% at 12 months by Kaplan Meier analysis. Median time to recurrence was estimated to be 13 months. The most commonly reported treatment emergent adverse events were ureteric stenosis (43.7%), urinary tract infection (32.4%), haematuria (31.0%), flank pain (29.6%) nausea (23.9%), dysuria (21.1%), renal impairment (19.7%) and vomiting (19.7%). The majority of these adverse events were mild to moderate, with 8.5% of patients having events of ureteric stenosis reported as severe.

In addition, we are evaluating the safety and efficacy of UGN-102 (mitomycin gel) for intravesical instillation, our novel sustained-release high dose formulation of mitomycin, for the treatment of LG NMIBC. In September 2019, we reported the interim data of our Phase 2b OPTIMA II trial of investigational UGN-102 (mitomycin gel) for intravesical instillation for patients with LG Intermediate Risk NMIBC, defined as those with one or two of the following criteria: multifocal disease, large tumors and rapid rates of recurrence. The single-arm, open label study trial recently completed enrollment of 63 patients at clinical sites across the U.S. and Israel. Patients are treated with six weekly instillations of UGN-102 and undergo assessment of complete response, or CR (the primary endpoint) four to six weeks following the last instillation. In an interim cohort of 32 patients, 63% (20/32) achieved a CR. 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 LG Intermediate Risk 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 are spent on tumor resection surgeries such as transurethral resection of bladder tumor, or TURBT. 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, a toll-like receptor 7/8, or TLR 7/8, agonist which have been evaluated 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 TLR7/8, 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 could represent a valid alternative to the current standard of care for the post-TURBT adjuvant treatment of high-grade NMIBC. In the fourth quarter of 2019, we entered into a worldwide license agreement with Agenus Inc. to develop and commercialize zalifrelimab (UGN-301, anti-CTLA-4 antibody) via intravesical delivery in combination with UGN-201 (together UGN-302) for the treatment of urinary tract cancers, initially in high-grade non-muscle invasive bladder cancer (HG NMIBC). The combination treatment makes local therapy a potentially more effective treatment option while minimizing systemic exposure and potential side effects.

In October 2016, we granted an exclusive worldwide license to Allergan Pharmaceuticals International Limited, or Allergan, a wholly owned subsidiary of Allergan plc, to research, develop, manufacture, and commercialize pharmaceutical products formulated with our RTGel technology platform and clostridial toxins, including BOTOX®, a branded drug, that we believe can potentially serve as an effective treatment option for patients suffering from overactive bladder, or OAB. 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 U.S. using RTGel in combination with BOTOX. In October 2017, Allergan commenced a Phase 2 clinical trial of BOTOX/RTGel for the treatment of OAB, with the potential to evolve from multiple injections of BOTOX into the bladder to a single instillation of the novel formulation.

Our Research and Development and License Agreements

In October 2016, we entered into the Allergan Agreement 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, 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, obtaining regulatory approvals for and commercializing, on a worldwide basis, pharmaceutical products that contain RTGel and clostridial toxins (including BOTOX), alone or in combination with certain other active ingredients, collectively, the Licensed Products. Allergan is obligated to pay us a tiered royalty in the low single digits based on worldwide annual net sales of Licensed Products, subject to certain reductions for the market entry of competing products and/or loss of our patent coverage of Licensed Products. We are responsible for payments to any third party for certain RTGel-related third-party intellectual properties.

Agenus Agreement

On November 8, 2019, we entered into a license agreement with Agenus Inc. Pursuant to the agreement, Agenus granted us an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import and otherwise commercialize products incorporating a proprietary antibody of Agenus known as AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. AGEN1884 is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients and in combination with Agenus' anti-PD-1 antibody in solid tumors. Initially, we plan to develop AGEN1884 in combination with UGN-201 for the treatment of high-grade non-muscle invasive bladder cancer.

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

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

Early-Stage Feasibility Evaluation with Janssen Research & Development, LLC

On April 22, 2019, we entered into an agreement with Janssen to conduct an early-stage feasibility evaluation in a therapeutic area of mutual interest. Both parties will each conduct certain activities under the terms of the agreement, and we will incur the costs of our own efforts related to the feasibility evaluation.

For additional information regarding our research and development and license agreements, see Note 8 to our financial statements appearing elsewhere in this Annual Report.

Follow-on Public Offering

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 $161.4 million, after deducting the underwriting discounts and commissions and payment of offering expenses.

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 years ended December 31, 2019 and December 31, 2018, we recognized revenues of $18,000 and $1.1 million from RTGel sales under the Allergan Agreement, respectively. 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

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, nonclinical studies and clinical trials;
- expenses incurred to acquire, develop and manufacture nonclinical study and clinical trial materials;
- expenses incurred to purchase active pharmaceutical ingredient, or API, and other related manufacturing costs; and
- facility and equipment costs, including depreciation expense, maintenance and allocated direct and indirect overhead costs.

We expense all research and development costs as incurred. Since our employees and internal resources may be engaged in projects for multiple programs at any time, our focus is on total research and development expenditures, and we do not allocate our internal research and development expenses by project.

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

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

We have received grants under the Israeli Law for the Encouragement of Industrial Research, Development and Technological Innovation, 5754-1984, 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, 2019, we had received grants in the aggregate amount of $2.1 million.

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 had 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. In January 2020, the IIA approved our request to unwind our obligation to the IIA as a transfer of knowledge. See Note 15 to the Consolidated Financial Statements included in this report for additional information.

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

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

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

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- 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 the NDA for UGN-101is pending review by the FDA and UGN-102 is 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.

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

The license agreement provides us with an exclusive world-wide, royalty bearing, and sub-licensable license under Agenus’s intellectual property rights to exploit licensed products incorporating AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. It also provides us with pre-clinical and clinical supply of AGEN1884. No inventory was purchased on the effective date of the License Agreement and subsequent purchases of pre-clinical and clinical supplies are at arm’s length and are priced at cost plus 30% mark-up. Our acquired right to Agenus’s intellectual property represents a single identifiable asset sourced from the agreement. Therefore, all the fair value associated with the agreement is concentrated in one identifiable asset and is not considered a business in accordance with ASC 805-10-55-5A. Therefore, we have accounted for the right to Agenus’s intellectual property acquired under the license agreement as an asset acquisition of in-process research and development. See Note 8 to the Consolidated Financial Statements for further information.

General and Administrative Expenses

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

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

Interest and Other (Income) Expenses, Net

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

Income Taxes

We have yet to generate taxable income in Israel. We have historically incurred operating losses resulting in carryforward tax losses totaling approximately $151.9 million as of December 31, 2019. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carryforward 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 carryforward tax losses. We have provided a full valuation allowance with respect to the deferred tax assets related to these carryforward losses.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table sets forth our results of operations for the years ended December 31, 2019 and 2018.

	Year Ended December 31,		
	2019	2018	Change
	(in thousands)		
Revenues	$ 18	$ 1,128	$ (1,110)
Cost of revenue	—	1,803	(1,803)
Gross profit (loss)	18	(675)	693
Operating expenses:			
Research and development	49,297	36,934	12,363
General and administrative	60,199	39,571	20,628
Total operating expenses	109,496	76,505	32,991
Operating loss	(109,478)	(77,180)	(32,298)
Interest and other income, net	(4,332)	(1,648)	(2,684)
Loss before income taxes	(105,146)	(75,532)	(29,614)
Income tax expense	—	125	(125)
Net loss	$ (105,146)	$ (75,657)	$ (29,489)

Revenues

Revenues were $18,000 and $1.1 million for the years ended December 31, 2019 and 2018, respectively. The decrease of $1.1 million was primarily due to the decreased revenue recognized under the Allergan Agreement.

Research and Development Expenses

Research and development expenses increased by $12.4 million to $49.3 million in the year ended December 31, 2019 from $36.9 million in the year ended December 31, 2018. Excluding the $10 million milestone payment related to our license agreement with Agenus Inc, research and development expenses increased by $2.4 million. An increase of $2.5 million is mainly comprised of $0.9 million in increased clinical activity of the UGN-102 Phase 2b clinical trial, a $1.1 million increase in headcount and related costs to support clinical trial activities and a $0.5 million increase in nonclinical activity as we advance our pipeline. An additional increase of $3.5 million was attributable to the purchase of API and other manufacturing related activities as we prepare for our UGN-101 product commercial launch, partly offset by a decrease of $3.7 million in share-based compensation. Total non-cash research and development share-based compensation expense was $8.3 million and $12.0 million for the years ended December 31, 2019 and 2018, respectively.

General and Administrative Expenses

General and administrative expenses were $60.2 million and $39.6 million for the years ended December 31, 2019 and 2018, respectively. The increase in general and administrative expenses of $20.6 million resulted primarily from an $8.1 million increase in headcount and related costs as part of the buildout of the company in anticipation of commercialization of our first product. The remaining increase resulted primarily from a $3.1 million increase in share-based compensation expense due to new grants, an $8.5 million increase in commercial services and a $0.6 million increase in consultant and directors' fees. Total non-cash general and administrative share-based compensation expense was $21.7 million and $18.6 million for the years ended December 31, 2019 and 2018, respectively.

Interest and Other (Income) Expenses, Net

Interest and other (income) expenses, net was income of $4.3 million and income of $1.6 million for the years ended December 31, 2019 and 2018, respectively. The increase of $2.7 million was primarily due to increased interest earned on our cash balances and investments in marketable securities.

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 (loss) 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	(77,180)	(19,950)	(57,230)
Interest and other (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

Our total revenues decreased by $7.0 million to $1.1 million in the year ended December 31, 2018 from $8.2 million in the year ended December 31, 2017. This decrease is due to the proceeds of $7.5 million received from Allergan upon the achievement of a certain milestone under the Allergan Agreement in the year ended December 31, 2017.

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.

Interest and Other (Income) Expenses, Net

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

Liquidity and Capital Resources

As of December 31, 2019, we had $195.6 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, 2019, 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 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 $161.4 million, after deducting the underwriting discounts and commissions and payment of other offering expenses.

In December 2019, we entered into a sales agreement pursuant to which we may from time to time offer and sell our ordinary shares having an aggregate offering price of up to $100.0 million. The shares are offered and will be sold pursuant to a shelf registration statement on Form S-3 which was declared effective by the SEC on January 2, 2020. No sales have occurred under this agreement as of the date of this filing.

We have incurred losses since our inception and negative cash flows from our operations, and as of December 31, 2019 we had an accumulated deficit of $228.0 million. We anticipate that we will continue to incur losses for at least the next several years. Our primary uses of capital are, and we expect will continue to be, commercialization activities, research and development expenses, including third-party clinical research and development services, laboratory and related supplies, clinical costs, including manufacturing costs, legal and other regulatory expenses and general and administrative costs.

Because the NDA for UGN-101 is pending review by the FDA and UGN-102 is 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,		
	2019	2018	2017
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (71,017)	$ (37,334)	$ (9,568)
Investing activities	(145,593)	35,287	(36,277)
Financing activities	165,250	66,421	61,585
Net change in cash and cash equivalents	$ (51,360)	$ 64,374	$ 15,740

Operating Activities

Net cash used in operating activities was $71.0 million during the year ended December 31, 2019, compared to $37.3 million used in operating activities during the year ended December 31, 2018. The $33.7 million increase was attributable primarily to the increase of $29.2 million in the net loss for the year and a net increase in operating assets and liabilities of $4.5 million.

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

Investing Activities

Net cash used in investing activities was $145.6 million during the year ended December 31, 2019, compared to net cash provided by investing activities of $35.3 million during the year ended December 31, 2018. The decrease of $180.9 million is primarily related to our investment in marketable securities.

Net cash provided by investing activities was $35.3 million during the year ended December 31, 2018, compared to net cash used in investing activities of $36.3 million during the year ended December 31, 2017. The increase of $71.6 million is primarily related to our investment in 2017 and subsequent sale in 2018 of a short-term investment.

Financing Activities

Net cash provided by financing activities was $165.3 million during the year ended December 31, 2019, compared to net cash provided by financing activities of $66.4 million during the year ended December 31, 2018. The increase is primarily related to the increased net proceeds received from our January 2019 financing as compared to our January 2018 financing.

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

Funding Requirements

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

- the outcome of the FDA's review of the NDA for UGN-101;
- the progress, timing and completion of clinical trials for UGN-102;
- nonclinical 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, BOTOX/RTGel reverse thermal hydrogel and any other product candidates.

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, 2019, 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. In January 2020, the IIA approved our request to unwind our obligation to the IIA as a transfer of knowledge. See Note 15 to the Consolidated Financial Statements included in this report for additional information.

The following summarizes our significant contractual obligations as of December 31, 2019:

	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)	$ 1,758	$ 2,718	$ 58	$ —	$ 4,534

(1) Operating lease obligations consist of payments pursuant to lease agreements for our Israeli offices and laboratory facility and our New Jersey, New York and Los Angeles 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 was extended in September 2019 for three years until September 30, 2022.

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.

In April 2018, we entered into a new lease agreement for an office in Los Angeles, CA. The lease commencement date was July 10, 2018 and terminates in March 2024.

In November 2019, we subleased our offices in Los Angeles, CA. The lease commencement date was January 1, 2020 and terminates in March 2024. The subtenants exercised their early access clause and moved into the premises the end of November 2019.

Also, in November 2019, we entered into a new lease agreement, dated effective October 31, 2019, for an office in Princeton, NJ. The lease commencement date was November 29, 2019 and the lease term is 38 months.

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 consolidated 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.

Leases

We are a lessee in several noncancelable operating leases, primarily for office space, office equipment and vehicles. We currently have no finance leases.

We account for leases in accordance with ASC Topic 842, "Leases". We determine if an arrangement is a lease at inception. Right-of-use ("ROU") assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term as of the commencement date. Operating lease ROU assets are presented as operating lease right of use assets on the consolidated balance sheets. The current portion of operating lease liabilities is included in other current liabilities and the long-term portion is presented separately as operating lease liabilities on the consolidated balance sheets.

Lease expense is recognized on a straight-line basis for operating leases. Variable lease payments associated with our leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed occurs. Variable lease payments are presented as operating expense on the consolidated statements of operations in the same line item as expense arising from fixed lease payments.

Our lease terms may include options to extend the lease. The lease extensions are included in the measurement of the right of use asset and lease liability when it is reasonably certain that it will exercise that option.

Because most of our leases do not provide an implicit rate of return, an incremental borrowing rate is used based on the information available at the commencement date in determining the present value of lease payments on an individual lease basis. Our incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms.

We have lease agreements with lease and non-lease components. We applied the modified retrospective transition method and elected the transition option to use the effective date of January 1, 2019 as the date of initial application ("Transition Date"). Consequently, the disclosures required under Topic 842 are not provided for dates and periods before January 1, 2019.

Revenues

We derive virtually all 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, or 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 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.

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.

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.

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 nonclinical studies, clinical trials, API, other 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.

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 recognized as research and development expense at the time the costs are incurred.

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

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. We account for forfeitures as they occur according to the FASB's Accounting Standards Update, or ASU, 2016-09, Improvements to Employee Share-Based Payment Accounting.

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.

As of December 31, 2018, we adopted ASU 2018-07, Compensation-Stock Compensation, which establishes that the measurement of equity-classified nonemployee awards will be fixed at the grant date. The adoption of ASU 2018-07 did not have an impact on the consolidated statements of operations.

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, 2019, we had $49.7 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, 2019, 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, 2019, 2018 or 2017.

Foreign Currency Exchange Risk

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

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

Item 8. Financial Statements and Supplementary Data

UroGen Pharma, Ltd.

Index to financial statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of UroGen Pharma, Ltd.

Opinions 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, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 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, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

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 *Management's Annual Report on Internal Control over Financial Reporting* under Item 9A. 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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

Tel Aviv, Israel
March 2, 2020

/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,	
	2019	**2018**
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 49,688	$ 101,318
Marketable securities	97,389	—
Restricted cash	523	253
Prepaid expenses and other current assets	1,034	672
TOTAL CURRENT ASSETS	148,634	102,243
NON-CURRENT ASSETS		
Property and equipment, net	977	948
Restricted deposit	223	51
Right of use asset	3,735	—
Marketable securities	48,555	—
Other non-current assets	264	317
TOTAL ASSETS	$ 202,388	$ 103,559
Liabilities and Shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 11,186	$ 8,540
Employee related accrued expenses	6,711	4,925
Other current liabilities	1,585	—
TOTAL CURRENT LIABILITIES	19,482	13,465
NON-CURRENT LIABILITY:		
Long-term lease liability	2,604	—
TOTAL LIABILITIES	22,086	13,465
COMMITMENTS AND CONTINGENCIES (Note 14)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.01 par value; 100,000,000 shares authorized at December 31, 2019 and 2018; 21,026,184 and 16,214,883 shares issued and outstanding as of December 31, 2019 and 2018, respectively	57	44
Additional paid-in capital	407,986	212,921
Accumulated deficit	(228,017)	(122,871)
Accumulated other comprehensive income	276	—
TOTAL SHAREHOLDERS' EQUITY	180,302	90,094
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 202,388	$ 103,559

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

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

	Year Ended December 31,		
	2019	2018	2017
REVENUES	$ 18	$ 1,128	$ 8,158
COST OF REVENUES	—	1,803	600
GROSS PROFIT (LOSS)	18	(675)	7,558
OPERATING EXPENSES:			
RESEARCH AND DEVELOPMENT EXPENSES	49,297	36,934	18,697
GENERAL AND ADMINISTRATIVE EXPENSES	60,199	39,571	8,811
OPERATING LOSS	(109,478)	(77,180)	(19,950)
INTEREST AND OTHER (INCOME) EXPENSES, NET	(4,332)	(1,648)	31
LOSS BEFORE INCOME TAXES	(105,146)	(75,532)	(19,981)
INCOME TAX EXPENSE	—	125	19
NET LOSS	$ (105,146)	$ (75,657)	$ (20,000)
STATEMENTS OF COMPREHENSIVE LOSS			
NET LOSS	$ (105,146)	$ (75,657)	$ (20,000)
OTHER COMPREHENSIVE INCOME:			
UNREALIZED GAIN ON MARKETABLE SECURITIES	276	—	—
COMPREHENSIVE LOSS	$ (104,870)	$ (75,657)	$ (20,000)
LOSS PER ORDINARY SHARE BASIC AND DILUTED	$ (5.12)	$ (4.80)	$ (2.14)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE	20,528,727	15,754,193	9,716,790

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	Other Comprehensive Income	Total
	Number of Shares	Amount	Number of Shares	Amount	Amounts			
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 JANUARY 1, 2019	16,214,883	$ 44	—	$ —	$ 212,921	$ (122,871)	$ —	$ 90,094
CHANGES DURING 2019								
Exercise of options into ordinary shares	603,984	2			3,662			3,664
Share-based compensation					29,967			29,967
Issuance of ordinary shares in public offering, net of issuance expenses	4,207,317	11			161,436			161,447
Other comprehensive income							276	276
Net loss						(105,146)		(105,146)
BALANCE AS OF DECEMBER 31, 2019	21,026,184	$ 57	—	$ —	$ 407,986	$ (228,017)	$ 276	$ 180,302

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,		
	2019	**2018**	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (105,146)	$ (75,657)	$ (20,000)
Adjustment to reconcile net loss to net cash from operating activities:			
Depreciation and amortization	296	417	207
Amortization/Accretion on marketable securities	(572)	—	—
Stock-based compensation	29,967	30,642	6,300
Fair value adjustment of warrants for preferred shares	—	—	168
Realized loss on sale of short-term investment	—	100	—
Amortization of right of use asset	1,028	—	—
Change in lease liability	(910)	—	—
Changes in operating assets and liabilities:			
Decrease (increase) in inventory	—	316	(211)
Decrease in accounts receivable	—	—	83
(Increase) decrease in prepaid expenses and other current assets	(394)	318	(562)
Increase in accounts payable and accrued expenses	2,928	4,205	2,534
(Decrease) increase in deferred revenues	—	(650)	650
Increase in employee related accrued expenses	1,786	2,975	1,263
Net cash used in operating activities	(71,017)	(37,334)	(9,568)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Sale of short-term investments	—	35,901	—
Purchase of marketable securities	(197,686)	—	(36,001)
Maturities of marketable securities	52,590	—	—
Change in restricted deposit	(172)	(54)	(5)
Purchase of property and equipment	(325)	(560)	(271)
Net cash (used in) provided by investing activities	(145,593)	35,287	(36,277)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of options into ordinary shares	3,664	2,401	404
Proceeds from exercise of warrants for preferred shares	—	—	382
Issuance cost for shelf filing	(76)	—	—
Issuance of ordinary shares, net of issuance expenses	161,662	64,235	60,841
Issuance cost for secondary offering	—	(215)	(42)
Net cash provided by financing activities	165,250	66,421	61,585
INCREASE IN CASH AND CASH EQUIVALENTS	(51,360)	64,374	15,740
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE YEAR	101,571	37,197	21,457
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE YEAR	$ 50,211	$ 101,571	$ 37,197
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Non-cash issuance cost	$ 188	$ 102	$ 202
Non-cash new lease liabilities	$ 1,741	$ —	$ —
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.

UroGen Pharma Inc., a subsidiary of UroGen Pharma Ltd., was incorporated in Delaware in October 2015 and began operating in February 2016.

UroGen Pharma Ltd. and UroGen Pharma Inc. (together the "Company") is a biopharmaceutical company dedicated to building and commercializing novel solutions that treat specialty cancers and urologic diseases.

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 $228.0 million and $122.9 million as of December 31, 2019 and 2018, 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 nonclinical 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

Principles of Consolidation

The Company's consolidated financial statements include the accounts of its subsidiary, UroGen Pharma Inc. 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 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 "Interest and other (income) expenses, net."

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.

Marketable Securities

The Company classifies its marketable securities as available-for-sale in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, "Investments — Debt Securities". Available-for-sale debt securities are carried at fair value with unrealized gains and losses reported in other comprehensive income/loss within shareholders' equity. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest and other income (expense), net. The cost of securities sold is based on the specific-identification method.

The Company reviews its available-for-sale securities for other-than-temporary declines in fair value below its cost basis each quarter and whenever events or changes in circumstances indicate that the cost basis of an asset may not be recoverable. This evaluation is based on a number of factors that include the length of time and extent to which fair value has been less than the cost basis and adverse conditions related specifically to the security, and the intent to sell, or whether the Company will more likely than not be required to sell, the security before recovery of its amortized cost basis. The Company's assessment of whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security.

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.

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, 2019 and 2018, the Company had not accrued a provision for uncertain tax positions. See Note 12 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 6 for further discussion regarding property and equipment.

Leases

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

Commencing January 1, 2019, the Company accounts for leases in accordance with ASC Topic 842, “Leases”. The Company determines if an arrangement is a lease at inception. Right-of-use, or ROU, assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term as of the commencement date. Operating lease ROU assets are presented as operating lease right of use assets on the consolidated balance sheets. The current portion of operating lease liabilities is included in other current liabilities and the long-term portion is presented separately as operating lease liabilities on the consolidated balance sheets.

Lease expense is recognized on a straight-line basis for operating leases. Variable lease payments associated with the Company’s leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed occurs. Variable lease payments are presented as operating expense on the consolidated statements of operations in the same line item as expense arising from fixed lease payments.

The Company’s lease terms may include options of the Company as the lessee to extend the lease. The lease extensions are included in the measurement of the right of use asset and lease liability if it is reasonably certain that it will exercise that option.

Because the Company’s leases do not provide an implicit rate of return, an incremental borrowing rate is used based on the information available at the commencement date in determining the present value of lease payments on an individual lease basis. The Company’s incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms.

The Company has lease agreements with lease and non-lease components and has elected the practical expedient to combine lease and non-lease components for all underlying classes of assets.

We applied the modified retrospective transition method and elected the transition option to use the effective date of January 1, 2019 as the date of initial application (“Transition Date”). Consequently, the disclosures required under Topic 842 are not provided for dates and periods before January 1, 2019.

Topic 842 provides for a number of optional practical expedients in transition. The Company elected 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 did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to the Company.

Topic 842 had a material impact on our consolidated balance sheets but did not have an impact on our consolidated statements of operations. The most significant impact was the recognition of $3.7 million in ROU assets and $4.2 million in lease liabilities.

ROU assets for operating leases are periodically reviewed for impairment losses under ASC 360-10, “Property, Plant, and Equipment”, to determine whether a ROU asset is impaired, and if so, the amount of the impairment loss to recognize.

Accounts Payable and Accrued Expenses

Accrued expenses and other current liabilities consist of the following as of December 31, 2019 and 2018, respectively (in thousands):

	December 31, 2019	December 31, 2018
Accounts payable	$ 4,694	$ 4,272
Accrued clinical expenses	399	673
Accrued research and development costs	2,644	780
Accrued general and administrative expenses	2,767	1,029
Accrued other expense	682	1,786
Total accrued expenses and other current liabilities	$ 11,186	$ 8,540

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, the Company 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.

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).

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.

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

The Company is also entitled to royalties based on Allergan's revenue from its product and recognize revenue related to the sales-base royalty when the related sales occur,

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, 2019, 2018 and 2017, the Company recognized $18,000, $1.1 million and $0.7 million of revenue related to RTGel vials supplied to Allergan, respectively.

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 personnel costs (including share-based compensation related to directors, executives, finance, commercial, medical affairs, business development, investor relations and human resources functions). Other significant costs include commercial, medical affairs, external professional service costs, facility costs, accounting and audit services, legal services and other consulting fees. 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 nonclinical studies, clinical trials, professional services, active pharmaceutical ingredient, or API, and other related manufacturing costs. 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.

License fees and development milestone payments related to in-licensed products and technology are expensed as in-process research and development if it is determined at that point that they have no established alternative future use.

On November 8, 2019, the Company entered into a license agreement with Agenus Inc. pursuant to which Agenus granted to the Company an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary antibody of Agenus known as AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. AGEN1884 is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients and in combination with Agenus' anti-PD-1 antibody in solid tumors. Initially, the Company plans to develop AGEN1884 in combination with UGN-201 for the treatment of high-grade non-muscle invasive bladder cancer.

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

No inventory was purchased on the effective date and subsequent purchases of pre-clinical and clinical supplies are at arm's length and are priced at cost plus mark-up. The Company's acquired right to Agenus's intellectual property represents a single identifiable asset sourced from the license agreement. Therefore, all the fair value associated with the license agreement is concentrated in one identifiable asset and is not considered a business in accordance with ASC 805-10-55-5A. Therefore, the Company has accounted for the right to Agenus's intellectual property acquired under the license agreement as an acquisition of an asset.

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.The Company accounts 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.

As of December 31, 2018, the Company adopted ASU 2018-07, Compensation-Stock Compensation, which establishes that the measurement of equity-classified nonemployee awards will be fixed at the grant date. The adoption of ASU 2018-07 did not have an impact on the condensed consolidated statements of operations.

Interest and Other (Income) Expense, net

Interest and Other (Income) Expense, net, consisted of the following as of December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Changes in fair value of warrants for preferred shares	$ —	$ —	$ 168
Interest income on cash, cash equivalents and marketable securities	(4,616)	(1,872)	(125)
Realized loss on sale of short-term investment	—	100	—
Other expense (income)	284	124	(12)
Total interest and other (income) expenses	$ (4,332)	$ (1,648)	$ 31

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,		
	2019	2018	2017
Basic and diluted:			
Loss attributable to equity holders of the Company	$ 105,146	$ 75,657	$ 20,000
Dividend accumulated for preferred shares during the period	$ —	$ —	$ 825
Loss attributable to equity holders of the Company, after deducting dividend accumulated for preferred shares	$ 105,146	$ 75,657	$ 20,825
Weighted-average number of ordinary shares	20,528,727	15,754,193	9,716,790
Loss per ordinary share	$ 5.12	$ 4.80	$ 2.14

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. ASU 2016-13 requires an entity to measure and recognize expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, the standard requires allowances to be recorded through net income instead of directly reducing the amortized cost of the investment under the current other-than-temporary impairment model. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We do not expect the adoption of this standard to have a significant impact on our financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, FASB issued ASU No. 2016-02, “Leases”, or 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, or 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 are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. The lease liability is measured at the present value of the unpaid lease payments and the ROU assets are 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 Company applied the modified retrospective transition method and elected the transition option to use the effective date of January 1, 2019 as the date of initial application, or Transition Date. Consequently, financial information was not updated, and the disclosures required under the Topic 842 were not provided for dates and periods before January 1, 2019.

NOTE 4-FAIR VALUE MEASUREMENTS

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

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

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

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

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

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

Assets and liabilities measured at fair value on a recurring basis based on Level 1, Level 2, and Level 3 fair value measurement criteria as of December 31, 2019 are as follows (in thousands):

		Fair Value Measurements Using		
	Balance as of December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities:				
US government	$ 66,094	$ 66,094	$ —	$ —
Corporate bonds	68,084	—	68,084	—
Commercial paper	7,658	—	7,658	—
Money market funds(1)	16,998	16,998	—	—
Certification of deposit	4,108	—	4,108	—
	$ 162,942	$ 83,092	$ 79,850	$ —

(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, 2018 are as follows (in thousands):

		Fair Value Measurements Using		
	Balance as of December 31, 2018	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.

The Company's investments in money market funds are valued based on publicly available quoted market prices for identical securities as of December 31, 2019 and 2018.

NOTE 5-MARKETABLE SECURITIES

The following table summarizes the Company's marketable securities as of December 31, 2019 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities:				
US government	$ 65,947	$ 147	$ —	$ 66,094
Corporate bonds	67,957	131	(4)	68,084
Commercial paper	7,658	—	—	7,658
Money market funds(1)	16,998	—	—	16,998
Certificates of deposit	4,106	2	—	4,108
	$ 162,666	$ 280	$ (4)	$ 162,942

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

The Company classifies its marketable securities as available-for-sale, and they consist of all debt securities. As of December 31, 2019, they were in a net unrealized gain position of $0.3 million. Unrealized gains and losses on available-for-sale debt securities are included as a component of comprehensive loss.

As of December 31, 2019, the aggregate fair value of marketable securities held by the Company in an unrealized loss position was $17.9 million, which consisted of 17 securities. No securities have been in an unrealized loss position for more than 12 months.

As of December 31, 2019 and 2018, the Company considered the decreases in market value on its marketable securities to be temporary in nature and did not consider any of the Company's investments to be other-than-temporarily impaired.

The Company's marketable securities as of December 31, 2019 mature at various dates through November 2021. The fair values of marketable securities by contractual maturity consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Maturities within one year	$ 114,386	$ 89,965
Maturities after one year through three years	48,556	—
	$ 162,942	$ 89,965

NOTE 6-PROPERTY AND EQUIPMENT

Property and equipment, consists of the following as of December 31, 2019 and 2018 (in thousands):

	December 31,	
	2019	2018
Laboratory equipment	$ 259	$ 241
Computer equipment and software	416	271
Furniture	544	395
Leasehold improvements	530	561
Manufacturing equipment	226	227
	1,975	1,695
Less: accumulated depreciation and amortization	(998)	(747)
Property and equipment, net	$ 977	$ 948

Depreciation and amortization expense was $0.3 million $0.4 million and $0.2 million for the years ended December 31, 2019, 2018 and 2017, respectively.

NOTE 7-LEASES

In April 2016, UroGen Pharma Ltd. 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 September 2019, with an option to extend the lease for an additional period of three years. In 2019, the option was exercised, and the lease period was extended until September 2022.

UroGen Pharma Inc. entered into a lease agreement for its office for a period of seven years commencing on May 1, 2016. As part of the agreement it provided the lessor with a letter of credit which renews on an annual basis. On December 1, 2018 it 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 the Company as of December 31, 2018.

In September 2017, UroGen Pharma Inc. 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 $0.8 million.

In April 2018, UroGen Pharma Inc. 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 $1.2 million.

In November 2019, UroGen Pharma Inc. subleased its offices in Los Angeles, CA. The lease commencement date was January 1, 2020 and terminates in March 2024. The subtenants exercised their early access clause and moved into the premises the end of November 2019. The expected rental income over the lease term is approximately $1.2 million. The Company accounts for the sublease as on operating lease in accordance with ASC 842-10-25-2 and ASC 842-10-25-3. The main lease was considered for impairment and the amount was determined to be immaterial.

Also, in November 2019, UroGen Pharma Inc. entered into a new lease agreement, dated effective October 31, 2019, for an office in Princeton, NJ. The lease commencement date was November 29, 2019 and the lease term is 38 months. The minimum lease obligation is approximately $1.7 million.

In addition, the Company has other operating office equipment and vehicle leases. The Company's operating leases may require minimum rent payments, contingent rent payments adjusted periodically for inflation, or rent payments equal to the greater of a minimum rent or contingent rent. The Company's leases do not contain any residual value guarantees or material restrictive covenants. The Company's leases expire at various dates from 2021 through 2024, with varying renewal and termination options.

The components of lease cost for the year ended December 31, 2019 were as follows (in thousands):

	Year Ended December 31, 2019
Operating lease cost	$ 1,243
Sublease income	(19)
Variable lease cost	105
	$ 1,329

The amounts recognized upon adoption and as of December 31, 2019 were as follows (in thousands):

	January 1, 2019	December 31, 2019
Right of use asset	$ 3,022	$ 3,735
Long-term lease liability	2,429	2,604
Other current liabilities	929	1,585

As of December 31, 2019, no impairment losses have been recognized to date.

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

	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	1,192
Right-of-use assets obtained in exchange for new operating lease liabilities	1,741
Weighted-average remaining lease term of operating leases	2.91 years
Weighted-average discount rate of operating leases	5.54%

As of December 31, 2019, maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
2020	$ 1,758
2021	1,269
2022	1,101
2023	348
2024 and thereafter	58
Total future minimum lease payments	$ 4,534
Less: Interest	345
Present value of lease liabilities	$ 4,189

As of December 31, 2018, maturities of lease liabilities were as follows (in thousands):

	Operating Leases
Years ending December 31,	
2019	$ 1,136
2020	1,251
2021	676
2022	567
2023	301
2024 and thereafter	58
Total future minimum lease payments	$ 3,989

Rent expense charged to operations was $1.2 million, $1.2 million, and $0.6 million for the years ended December 31, 2019, 2018 and 2017, respectively.

NOTE 8- LICENSE AND COLLABORATION AGREEMENTS

Allergan 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 if there is a material supply failure from the Company. Prior to completion of the first Phase 2 clinical trial, Allergan has the right to request that the Company transfers to Allergan 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.

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 the Company 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.

Agenus Agreement

On November 8, 2019, the Company entered into a license agreement with Agenus Inc, pursuant to which Agenus granted to the Company an exclusive, worldwide (not including Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions), royalty-bearing, sublicensable license under Agenus's intellectual property rights to develop, make, use, sell, import, and otherwise commercialize products incorporating a proprietary antibody of Agenus known as AGEN1884 for the treatment of cancers of the urinary tract via intravesical delivery. AGEN1884 is an anti-CTLA-4 antagonist that is currently being evaluated by Agenus as a monotherapy in PD-1 refractory patients and in combination with Agenus' anti-PD-1 antibody in solid tumors. Initially, the Company plans to develop AGEN1884 in combination with UGN-201 for the treatment of high-grade non-muscle invasive bladder cancer.

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

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

The Company recorded the $10.0 million milestone in acquired in-process research and development expenses for the year ended December 31, 2019.

Early-Stage Feasibility Evaluation with Janssen Research & Development, LLC

On April 22, 2019, the Company entered into an agreement with Janssen to conduct an early-stage feasibility evaluation in a therapeutic area of mutual interest. The Company and Janssen will each conduct certain activities under the terms of the agreement, and the Company will incur the costs of its own efforts related to the feasibility evaluation.

NOTE 9-EMPLOYEE RIGHTS UPON RETIREMENT

In Israel, 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 10-SHAREHOLDERS' EQUITY

Ordinary Shares

The Company had 100.0 million ordinary shares authorized for issuance as of December 31, 2019 and 2018, respectively. The Company had 21.0 million and 16.2 million ordinary shares issued and outstanding as of December 31, 2019 and 2018, 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.

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.

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.

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

In December 2019, the Company entered into a sales agreement pursuant to which the Company may from time to time offer and sell the Company's ordinary shares having an aggregate offering price of up to $100.0 million. The shares are offered and will be sold pursuant to the Company's shelf registration statement on Form S-3 which was declared effective by the SEC on January 2, 2020. No sales have occurred under this agreement as of the date of this filing.

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.

NOTE 11-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.

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.

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.

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.

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

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

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

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

Options granted:

Set forth below are grants made by the Company as of December 31, 2019. The majority of options vest over three years and expire on the tenth anniversary of the date of grant.

a) During 2019, the Company granted 955,732 options with exercise prices ranging from $33.21 to $47.57 per share.

b) During 2018, the Company granted 1,195,000 options with exercise prices ranging from $38.64 to $59.23 per share.

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

The fair value of options granted during 2019, 2018 and 2017 was $27.6 million, $40.3 million and $10.9 million, respectively.

The total unrecognized compensation cost of options as of December 31, 2019 is $30.8 million, which is expected to be recognized over a weighted average period of 1.72 years.

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

	2019	2018	2017
Value of ordinary shares	$33.21-47.57	$38.64-59.23	$1.58-39.26
Dividend yield	0%	0%	0%
Expected volatility	74.09%-80.52%	72.00%-82.04%	68.45%-76.32%
Risk-free interest rate	1.36%-2.62%	1.72%-3.07%	1.38%-2.47%
Expected term	5.8-10 years	0.2-10 years	3.9-10 years

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

The following table summarizes the number of employee and non-employee options outstanding under the Plan for the years ended December 31, 2019, 2018 and 2017, and related information:

	Number of options		Weighted Average price per share
Outstanding as of January 1, 2017	2,389,899		$ 4.69
Granted	589,600	*	$ 23.95
Canceled/Forfeited	(45,186)		$ 5.41
Exercised	(690,281)		$ 4.12
Outstanding as of December 31, 2017	2,244,032		$ 9.91
Granted	1,195,000		$ 47.19
Canceled/Forfeited	(167,149)		$ 35.37
Exercised	(748,902)		$ 8.99
Outstanding as of December 31, 2018	2,522,981		$ 26.16
Granted	955,732		$ 41.96
Canceled/Forfeited	(183,725)		$ 41.85
Exercised	(423,653)		$ 9.10
Outstanding as of December 31, 2019	2,871,335		$ 32.93

* Includes 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 was $14.2 million, $31.6 million, and $21.4 for the years ended December 31, 2019, 2018, and 2017, respectively.

The following table summarizes the outstanding and exercisable options as of December 31, 2019:

	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	725,394	2.80	725,394	2.80
$10.01 - 20.00	75,000	7.39	63,333	7.40
$20.01 - 30.00	100,000	7.82	66,668	7.82
$30.01 - 40.00	433,500	7.78	208,331	6.33
$40.01 - 50.00	1,340,441	8.49	366,273	7.44
$50.01 - 59.23	197,000	7.94	145,000	7.80
	2,871,335		1,574,999	

The aggregate intrinsic value of the total vested and exercisable options as of December 31, 2019 is $22.0 million.

The following table summarizes information about RSU activity as of December 31, 2019:

	Outstanding Restricted Stock Units
Outstanding as of January 1, 2017	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
Granted	455,465
Vested and released	(183,975)
Forfeited	(15,762)
Outstanding as of December 31, 2019	519,427

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

The fair value of RSUs granted during 2019, 2018 and 2017 was $19.9 million, $5.7 million, and $3.3, respectively. The total unrecognized compensation cost of RSUs as of December 31, 2019 is $16.1 million with a weighted average recognition period of 2.04 years.

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

	Year ended December 31,		
	2019	2018	2017
Research and development expenses	$ 8,291	$ 12,038	$ 3,923
General and administrative expenses	21,676	18,604	2,377
	$ 29,967	$ 30,642	$ 6,300

NOTE 12-INCOME TAXES

The Company is taxed under Israeli tax laws:

Corporate tax rate

Presented hereunder are the Israeli tax rates relevant to the Company:

2017 – 24%

2018 and thereafter– 23%

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 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,		
	2019	2018	2017
In respect of:			
Net operating loss carryforward	$ 33,817	$ 16,943	$ 5,844
Deferred rent	—	61	46
Research and development expenses	4,591	3,891	2,887
Stock-based compensation	6,543	4,769	897
Issuance costs	2,063	1,367	1,261
In-process research and development	2,749	629	761
Right of use asset	(800)	—	—
Lease Liability	896	—	—
Accrued expenses	762	598	5
Depreciation of fixed assets	(90)	(93)	—
Other	62	84	24
Less—valuation allowance	(50,593)	(28,249)	(11,725)
Net deferred tax assets	$ —	$ —	$ —

The change in valuation allowance for the years ended December 31, 2019, 2018 and 2017 were as follows:

	2019	2018	2017
Balance at the beginning of the year	$ (28,249)	$ (11,725)	$ (4,158)
Changes during the year	(22,344)	(16,524)	(7,567)
Balance at the end of the year	$ (50,593)	$ (28,249)	$ (11,725)

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 U.S. operations, as of December 31, 2019, UroGen Pharma Inc. had federal tax net operating losses of $2.6 million and state tax net operating losses of $0.6 million in several jurisdictions available to carryforward 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 our use of federal net operating loss carryforwards if significant changes occur in the constructive stock ownership of UroGen Pharma Inc. In the event it has had an “ownership change” within the meaning of Section 382 of the Code, utilization of its net operating loss carryforwards could be restricted under Section 382 of the Code and similar state provisions. Such limitations could result in the expiration of the net operating carryforwards incurred before 2018 before their utilization. In addition, under the Tax Act, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited.

Losses for tax purposes carried forward to future years

As of December 31, 2019, and December 31, 2018, the Company had approximately $151.9 million and $72.1 million of net carryforward tax losses, respectively, available to reduce future taxable income without limitation of use.

Tax assessments

UroGen Pharma Ltd, has received final tax assessments up to and including its 2013 tax year.

NOTE 13-RELATED PARTIES

UroGen Pharma Inc. entered into a lease agreement, dated as of November 2015 and commencing as of May 2016, for office space in New York. It shared the office space equitably with Kite Pharma, Inc., a Delaware corporation, which was a cosignatory to such lease agreement. Arie Belldegrun, M.D., the Company'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, it terminated its lease for offices at 689 Fifth Avenue in New York, and on December 1, 2018, UroGen Pharma Inc. 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.

UroGen Pharma Inc. 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.

There were no related party transactions for the year ended December 31, 2019.

NOTE 14-COMMITMENTS AND CONTINGENCIES

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

The Company has received grants from the IIA for research and development funding. Up until 2007, the IIA participation in the funding of the Company's operations was as part of the 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, 2019, 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, 2019). 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. In January 2020, the IIA approved the Company's request to unwind its obligation to the IIA as a transfer of knowledge (see Note 15).

NOTE 15-SUBSEQUENT EVENTS

On January 2, 2020, the Company's shelf registration statement on Form S-3 was declared effective by the SEC. As a result, the Company is permitted pursuant to its December 2019 sales agreement with Cowen and Company, LLC to offer and sell ordinary shares of stock having an aggregate offering price of up to $100.0 million pursuant to such agreement.

On January 12, 2020, the IIA Office of Chief Scientist approved the company's request to unwind its obligation to the IIA regarding grants that were loaned to the company between January 2004 and September 2016. The Company has previously reported that the repayment of these grants could be up to three-times of the original grants and other amounts. Under the approval from the IIA, the Company will be required to:

1. Make a one-time payment in 2020, for up to three-times the grants provided (linked to Plan No. 33889) plus annual interest, net of a deduction for the royalties already paid in accordance with Appendix B of the Section 18(F) to Instructions for Benefit Track No. 1 - R&D Fund ("Benefit Track").
2. Make a commitment to continue employment of at least 75% of its base R&D jobs in Israel (at the time of settlement) for a period of at least 3 years, in accordance with Appendix B of the Benefit Track.

The total payment under the IIA approval, net of the royalties already paid, amounts to $6.6 million plus any additional accrued interest since January 2020. The Company will pay this amount in the first quarter of 2020.

Subject to payment to the IIA to unwind the Company's obligation, the company will have full freedom to transfer IIA-funded technology or manufacture products developed with IIA-funded technology outside of the State of Israel. Other than the commitment to continue employment, all other obligations with the IIA will also cease to exist as per the current agreement.

NOTE 16-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 2019 and 2018 are as follows (in thousands, except per share data):

	2019				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Total revenues	$ —	$ 18	$ —	$ —	$ 18
Total operating expenses	$ 22,433	$ 23,771	$ 23,453	$ 39,839	$ 109,496
Loss from operations	$ (22,433)	$ (23,753)	$ (23,453)	$ (39,839)	$ (109,478)
Net loss attributable to common shareholders	$ (21,444)	$ (22,477)	$ (22,252)	$ (38,973)	$ (105,146)
Net loss per share attributable to common shareholders - basic and diluted	$ (1.11)	$ (1.08)	$ (1.06)	$ (1.86)	$ (5.12)

	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)

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, 2019. 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, 2019, 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, 2019.

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 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, 2019, 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 2020 Annual Meeting of Shareholders to be filed with the SEC by April 29, 2020, or 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., 400 Alexander Park Dr., Princeton, NJ 08540.

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, 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
2.1	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), filed with the SEC on April 7, 2017).
3.1	Articles of Association of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Report on Form 6-K (File No. 001-38079), filed with the SEC on May 18, 2017).
4.1	Reference is made to Exhibit 3.1.
4.2	Description of the Registrant's Ordinary Shares.
4.3	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), filed with the SEC on April 7, 2017).
10.1*	Form of Officer Indemnity and Exculpation Agreement (incorporated by reference to Exhibit 99.2 to the Registrant's Report Form 6-K (File No. 001-38079), filed with the SEC on July 13, 2018).
10.2*	Amended and Restated 2010 Israeli Share Option Plan (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 20-F (File No. 001-38079), filed with the SEC on March 15, 2018).
10.3*	2017 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K (File No. 001-38079), filed with the SEC on February 28, 2019).
10.4*	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), filed with the SEC on April 7, 2017).
10.5	UroGen Pharma Ltd. 2019 Inducement Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38079), filed with the SEC on May 28, 2019).
10.6	Form of Stock Option Grant Notice and Stock Option Agreement under the UroGen Pharma Ltd. 2019 Inducement Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-38079), filed with the SEC on May 28, 2019).
10.7	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the UroGen Pharma Ltd. 2019 Inducement Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-38079), filed with the SEC on May 28, 2019).
10.8*	Employment Agreement by and between the Registrant and Elizabeth Barrett, dated as of January 3, 2019 (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K (File No. 001-38079), filed with the SEC on February 28, 2019).
10.9*	Employment Agreement by and between the Registrant and Peter Pfreundschuh, dated as of July 31, 2018 (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K (File No. 001-38079), filed with the SEC on February 28, 2019).

10.10*	Employment Agreement by and between the Registrant and Stephen Mullennix, dated as of January 17, 2018 (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K (File No. 001-38079), filed with the SEC on February 28, 2019).
10.11*	Employment Agreement by and between the Registrant and Mark Schoenberg, dated as of December 5, 2017 (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K (File No. 001-38079), filed with the SEC on February 28, 2019).
10.12*	Separation and Release Agreement between the Registrant and Ron Bentsur, dated as of January 3, 2019 (incorporated by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K (File No. 001-38079), filed with the SEC on February 28, 2019).
10.13†	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), filed with the SEC on April 7, 2017).
10.14††	License Agreement, dated November 8, 2019, by and between the Registrant and Agenus Inc.
10.15	Lease Agreement, dated November 4, 2019, by and between the Registrant and Witman Properties, L.L.C. and Alexander Road at Davanne, L.L.C.
21.1	Subsidiary of the Registrant.
23.1	Consent of Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm.
24.1	Power of Attorney (see signature page hereto).
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, 2019, formatted in Inline 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.
104	The cover page to this Annual Report on Form 10-K has been formatted in Inline XBRL

* 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.
†† Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Item 16. Form 10-K Summary

None.

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.

March 2, 2020

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)*	March 2, 2020
/s/ Peter Pfreundschuh Peter Pfreundschuh	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 2, 2020
/s/ Arie Belldegrun Arie Belldegrun, M.D.	Chairman	March 2, 2020
/s/ Cynthia Butitta Cynthia Butitta	Director	March 2, 2020
/s/ Fred E. Cohen Fred E. Cohen	Director	March 2, 2020
/s/ Kathryn Falberg Kathryn Falberg	Director	March 2, 2020
/s/ Stuart Holden Stuart Holden, M.D.	Director	March 2, 2020
/s/ Ran Nussbaum Ran Nussbaum	Director	March 2, 2020
/s/ Shawn C. Tomasello Shawn C. Tomasello	Director	March 2, 2020

Exhibit 4.2

DESCRIPTION OF ORDINARY SHARES

The following descriptions of our ordinary shares and provisions of our amended and restated articles of association are summaries and do not purport to be complete. For a complete description of the matters set forth in this "Description of Ordinary Shares," you should refer to our amended and restated articles of incorporation which is included as an exhibit to our Annual Report on Form 10-K, and to the applicable provisions of Israeli law.

General

Our authorized share capital consists of 100,000,000 ordinary shares, par value NIS 0.01 per share.

Our ordinary shares are not redeemable and do not have any preemptive rights.

All ordinary shares have identical voting and other rights in all respects.

Registration Number and Purpose of the Company

Our registration number with the Israeli Registrar of Companies is 513537621. Our purpose as set forth in our amended and restated articles of association is to engage in any lawful activity.

Transfer of Shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our amended and restated articles of association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our amended and restated articles of association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a meeting of shareholders have the power to elect all of our directors.

Under our amended and restated articles of association, our board of directors must consist of at least five and not more than nine directors. Our board of directors consists of eight directors.

Pursuant to our amended and restated articles of association, each of our directors is appointed by a simple majority vote of holders of our ordinary shares, participating and voting at an annual general meeting of our shareholders. Each director serves until the next annual general meeting following his or her election and his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal by a vote of the majority of the aggregate voting power of the Company at a general meeting of our shareholders or until his or her office expires by operation of law. In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on the board of directors, including filling empty board seats up to the maximum number of directors permitted under our articles of association, to serve until the next annual general meeting of shareholders. Our amended and restated articles of association do not have a retirement age requirement for our directors.

Dividend and Liquidation Rights

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. Under the Israeli Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the Company's articles of association provide otherwise. Our amended and restated articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Pursuant to the Israeli Companies Law, the distribution amount is limited to the greater of retained earnings or earnings generated over the previous two years, according to our then last reviewed or audited financial statements, provided that the end of the period to which the financial statements relate is not more than six months prior to the date of the distribution. If we do not meet such criteria, then we may distribute dividends only with court approval. In each case, we are only permitted to distribute a dividend if our board of directors and the court, if applicable, determines that there is no reasonable concern that payment of the dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of countries that are, or have been, in a state of war with Israel.

Shareholder Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to in our amended and restated articles of association as extraordinary meetings. Our board of directors may call extraordinary meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Israeli Companies Law provides that our board of directors is required to convene an extraordinary meeting upon the written request of (i) any two or more of our directors or one-quarter or more of the members of our board of directors, or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% of our outstanding voting power, or (b) 5% or more of our outstanding voting power.

Subject to the provisions of the Israeli Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and 40 days prior to the date of the meeting. Furthermore, the Israeli Companies Law requires that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;
- appointment or termination of our auditors;
- appointment of external directors (if applicable);
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- a merger; and
- the exercise of our board of director's powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

The Israeli Companies Law requires that a notice of any annual general meeting or extraordinary meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, notice must be provided at least 35 days prior to the meeting.

Under the Israeli Companies Law, shareholders of a public company are not permitted to take action by way of written consent in lieu of a meeting.

Under Israeli Companies Law, whenever we cannot convene or conduct a general meeting in the manner prescribed under the law or our articles of association, the court may, upon our, shareholders' or directors' request, order that we convene and conduct a general meeting in the manner the court deems appropriate.

Voting Rights

Quorum Requirements

Pursuant to our amended and restated articles of association, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. Pursuant to our amended and restated articles of association, the quorum required for our general meetings of shareholders consists of at least two shareholders present in person, by proxy or by other voting instrument in accordance with the Israeli Companies Law who hold or represent between them at least 33 1/3% of the total outstanding voting rights. A meeting adjourned for lack of a quorum is generally adjourned to the same day in the following week at the same time and place or to a later time or date if so specified in the notice of the meeting. At the reconvened meeting, any two or more shareholders present in person or by proxy shall constitute a lawful quorum.

Vote Requirements

Our amended and restated articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Israeli Companies Law or by our amended and restated articles of association.

We have adopted an amended and restated compensation policy regarding the terms of engagement of office holders, which our shareholders approved on June 3, 2019. The compensation policy is valid for a period of five years. Renewal or amendment of the compensation policy is subject to shareholder approval. Even if our shareholders do not approve the compensation policy, our board of directors may resolve to approve the compensation policy if and to the extent the board determines, in its judgment following internal discussions, that approval of the compensation policy is in the best interests of the Company.

Renewing or amending the compensation policy requires the recommendation to our board of directors by the compensation, nominating and corporate governance committee Thereafter our board of directors, after considering the recommendations of the compensation, nominating and corporate governance committee, need to approve the compensation policy, and will further need to be approved by our shareholders, which we refer to as a Special Majority Approval for Compensation. A Special Majority Approval for Compensation requires shareholder approval by a majority vote of the shares present and voting at a meeting of shareholders called for such purpose, provided that either: (i) such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such compensation arrangement, excluding abstentions; or (ii) the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in the compensation arrangement and who vote against the arrangement does not exceed 2% of the Company's aggregate voting rights.

The Israeli Companies Law requires that an office holder promptly disclose to our board of directors any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with the Company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. A personal interest includes an interest of any person in an action or transaction of a company, including a personal interest of such person's relative or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or chief executive officer or in which he or she has the right to appoint at least one director or the chief executive officer, but excluding a personal interest stemming from one's ownership of shares in the Company.

A personal interest also includes the personal interest of a person for whom the office holder holds a voting proxy or the personal interest of the office holder with respect to his or her vote on behalf of a person for whom he or she holds a proxy even if such person has no personal interest in the matter. An office holder is not, however, required to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction. Under the Israeli Companies Law, an "extraordinary transaction" is defined as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on a company's profitability, assets or liabilities.

If it is determined that an office holder has a personal interest in a transaction, which is not an extraordinary transaction, approval by the board of directors is required for the transaction, unless the Company's articles of association provide for a different method of approval. Further, so long as an office holder has disclosed his or her personal interest in a transaction, the board of directors may approve an action by the office holder that would otherwise be deemed a breach of his or her duty of loyalty. However, a company may not approve a transaction or action that is not in the Company's interest or that is not performed by the office holder in good faith.

An extraordinary transaction in which an office holder has a personal interest requires approval first by the Company's audit committee and subsequently by the board of directors.

The compensation of, or an undertaking to indemnify or insure, an office holder who is not a director generally requires approval first by the Company's compensation committee, then by the Company's board of directors. If such compensation arrangement or an undertaking to indemnify or insure is inconsistent with the Company's stated compensation policy, or if the office holder is the chief executive officer (apart from a number of specific exceptions), then such arrangement is further subject to a Special Majority Approval for Compensation. If the shareholders of a company do not approve the compensation terms of office holders at a meeting of the shareholders, other than directors, the compensation committee and board of directors may override the shareholders' decision, subject to certain conditions. Arrangements regarding the compensation, indemnification or insurance of a director require the approval of the compensation committee, board of directors and shareholders by simple majority, in that order, and under certain circumstances, a Special Majority Approval for Compensation.

Generally, a person who has a personal interest in a matter which is considered at a meeting of the board of directors or the audit committee may not be present at such a meeting or vote on that matter unless the chairman of the audit committee or board of directors (as applicable) determines that he or she should be present in order to present the transaction that is subject to approval. If a majority of the members of the audit committee or the board of directors (as applicable) has a personal interest in the approval of a transaction, then all directors may participate in discussions of the audit committee or the board of directors (as applicable) on such transaction and the voting on approval thereof, but shareholder approval is also required for such transaction.

Under our amended and restated articles of association, (i) the removal of a director from office requires the adoption of a resolution at a general meeting of shareholders by a majority of the aggregate voting rights of the Company, and (ii) the alteration of the rights, privileges, preferences or obligations of any class of our shares requires a simple majority of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting.

Further exceptions to the simple majority vote requirement are a resolution for the voluntary winding up, or an approval of a scheme of arrangement or reorganization, of the Company pursuant to Section 350 of the Israeli Companies Law, that governs the settlement of debts and reorganization of a company, which requires the approval of holders of 75% of the voting rights represented at the meeting and voting on the resolution.

We do not have any controlling shareholder. Under the Israeli Companies Law, each of (i) the approval of an extraordinary transaction with a controlling shareholder, and (ii) the terms of employment or other engagement of the controlling shareholder of the Company or such controlling shareholder's relative (even if such terms are not extraordinary) requires the approval of the audit committee, the board of directors and the shareholders of the Company, in that order, is required for (i) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (ii) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the Company, (iii) the terms of engagement and compensation of a controlling shareholder or his or her relative who is not an office holder or (iv) the employment of a controlling shareholder or his or her relative by the Company, other than as an office holder. In addition, the shareholder approval requires one of the following, which we refer to as a Special Majority:

- at least a majority of the shares held by all shareholders who do not have a personal interest in the transaction and who are present and voting at the meeting approves the transaction, excluding abstentions; or
- the shares voted against the transaction by shareholders who have no personal interest in the transaction and who are present and voting at the meeting do not exceed 2% of the aggregate voting rights in the Company.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years and under certain conditions, five years from a company's initial public offering, approval is required at the end of such period unless, with respect to certain transactions, the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Arrangements regarding the compensation, indemnification or insurance of a controlling shareholder in his or her capacity as an office holder require the approval of the compensation committee, board of directors and shareholders by a Special Majority.

Pursuant to regulations promulgated under the Israeli Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors or other office holders, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval under certain conditions

Access to Corporate Records

Under the Israeli Companies Law, shareholders are provided access to: minutes of our general meetings; our shareholders register and principal shareholders register, articles of association and annual audited financial statements; and any document that we are required by law to file publicly with the Israeli Companies Registrar or the Israel Securities Authority. In addition, shareholders may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Israeli Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interest or protect a trade secret or patent.

Modification of Class Rights

Under the Israeli Companies Law and our amended and restated articles of association, the rights attached to any class of shares, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association.

Registration Rights

We have entered into the Registration Rights Agreement with certain of our shareholders dated September 2014. As of December 31, 2019, holders of approximately 3.6 million of our ordinary shares have the right to require us to register these shares under the Securities Act under specified circumstances and have incidental registration rights as described below. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act.

Demand Registration Rights

If at any time we receive a request from holders of at least 30% of the registrable securities then outstanding that we file a Form S-1 registration statement with respect to registrable securities then outstanding having an anticipated aggregate offering price of at least $5.0 million, then we shall (a) within 10 days after the date such request is given, give demand notice to all holders other than the initiating holders; and (b) as soon as practicable, and in any event within 60 days after the date such request is given by the initiating holders, file a Form S-1 registration statement under the Securities Act covering all registrable securities that the initiating holders requested to be registered and any additional registrable securities requested to be included in such registration by any other holders, as specified by notice given by each such holder to us within 20 days of the date the demand notice is given.

We will not be obligated to file a registration statement at such time if in the good faith judgment of our board of directors, such registration would be materially detrimental to us and our shareholders, because such action would (a) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving us; (b) require premature disclosure of material information that we have a bona fide business purpose for preserving as confidential; or (c) render us unable to comply with requirements under the Securities Act or Exchange Act. In such event we may defer the requested filing for a period of not more than 60 days. We may not invoke this right more than once in any 12-month period and, during such 60 day period, we shall not register any securities for our own account or that of any other shareholder other than in an "Excluded Registration": (i) a registration relating to the sale of securities to our or a subsidiary's employees pursuant to a stock option, stock purchase, or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the registrable securities; or (iv) a registration in which the only ordinary shares being registered are ordinary shares issuable upon conversion of debt securities that are also being registered.

In addition we shall not be obligated to effect, or to take any action to effect, any demand registration (a) during the period that is 60 days before our good faith estimate of the date of filing of, and ending on a date that is 180 days after the effective date of, a Company-initiated registration, provided that we are actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (b) after we have effected two demand registrations; or (c) if the initiating holders propose to dispose of shares of registrable securities that may be immediately registered on Form S-3.

Form S-3 Registration Rights

If at any time when we are eligible to use a Form S-3 registration statement, we receive a request from holders of the registrable securities then outstanding that we file a Form S-3 registration statement with respect to outstanding registrable securities of such holders having an anticipated aggregate offering price of at least $3.0 million, then we shall (a) within 10 days after the date such request is given, give a demand notice to all holders other than the initiating holders; and (b) as soon as practicable, and in any event within 45 days after the date such request is given by the initiating holders, file a Form S-3 registration statement under the Securities Act covering all registrable securities requested to be included in such registration by any other holders, as specified by notice given by each such holder to us within 20 days of the date the demand notice is given.

We shall not be obligated to effect, or to take any action to effect, any Form S-3 registration (a) during the period that is 30 days before our good faith estimate of the date of filing of, and ending on a date that is 90 days after the effective date of, our initiated registration, provided that we are actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (b) if we have effected two Form S-3 demand registrations within the 12-month period immediately preceding the date of such request. A Form S-3 registration shall not be counted as "effected" until such time as the applicable registration statement has been declared effective by the SEC, unless the initiating holders withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand registration statement, in which case such withdrawn registration statement shall be counted as "effected."

Piggyback Registration Rights

In addition, if we propose to register (including, for this purpose, a registration effected by us for shareholders other than the holders) any of our securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), we shall, at such time, promptly give each holder notice of such registration. Upon the request of each holder given within 20 days after such notice is given by us, we shall, subject to underwriter requirements, cause to be registered all of the registrable securities that each such holder has requested to be included in such registration. We shall have the right to terminate or withdraw any registration initiated by us before the effectiveness of such registration, whether or not any holder has elected to include registrable securities in such registration. The expenses of such withdrawn registration shall be borne by us. Any piggyback registration rights with respect to this offering have been waived.

Other Provisions

We will pay all registration expenses (other than underwriting discounts and selling commissions) and the reasonable fees and expenses of a single counsel for the selling shareholders, related to any demand or piggyback registration. The demand, Form S-3 and piggyback registration rights described above will expire with respect to each holder of registrable securities upon such time as Rule 144 or another similar exemption under the Securities Act is available for the sale of all of such holder's shares without limitation during a three-month period without registration.

Termination of Registration Rights

No holder shall be entitled to exercise any registration rights after, and all such rights shall terminate upon the earlier to occur of (a) (i) any dissolution or liquidation of us; (ii) the proper commencement, by or against us, of any bankruptcy or insolvency proceeding under any bankruptcy or insolvency or similar law, whether voluntary or involuntary and (iii) the appointment of a receiver or liquidator to all or substantially all of our assets, and (b) the fifth anniversary of the completion of our initial public offering.

In addition, the registration rights shall terminate as to any shares of registrable securities when such shares have been (i) registered under the Securities Act pursuant to an effective registration statement filed thereunder and disposed of in accordance with the registration statement covering them, or (ii) publicly sold pursuant to Rule 144.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Israeli Companies Law to make a tender offer to all of the Company's shareholders for the purchase of all of the issued and outstanding shares of the Company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the Company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the Company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (i) the shareholders who did not respond to or accept the tender offer hold at least 5% of the issued and outstanding share capital of the Company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (ii) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the Company (or of the applicable class), the acquirer may not acquire shares from shareholders who accepted the tender offer that will increase its holdings to more than 90% of the Company's issued and outstanding share capital or of the applicable class.

Special Tender Offer

The Israeli Companies Law provides that, subject to certain exceptions, an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the Company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the Company. Similarly, the Israeli Companies Law provides that, subject to certain exceptions, an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the Company, if there is no other shareholder of the Company who holds more than 45% of the voting rights in the Company.

A special tender offer must be extended to all shareholders of a company. A special tender offer may be consummated only if (i) the offeror acquired shares representing at least 5% of the voting power in the Company and (ii) the number of shares tendered by shareholders who accept the offer exceeds the number of shares held by shareholders who object to the offer (excluding the offeror, controlling shareholders, holders of 25% or more of the voting rights in the Company or any person having a personal interest in the acceptance of the tender offer or any of their relatives or any entity controlled by them). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer. Shares purchased in contradiction to the tender offer rules under the Israeli Companies Law, will have no rights and will become dormant shares.

Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, by a majority vote of each party's shareholders. In the case of the target company, approval of the merger further requires a majority vote of each class of its shares.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of shares represented at the meeting of shareholders that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same Special Majority approval that governs all extraordinary transactions with controlling shareholders.

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the petition of holders of at least 25% of the voting rights of a company. For such petition to be granted, the court must find that the merger is fair and reasonable, taking into account the respective values assigned to each of the parties to the merger and the consideration offered to the shareholders of the target company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger is filed with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

Anti-Takeover Measures under Israeli Law

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. As of the date of this prospectus, no preferred shares will be authorized under our amended and restated articles of association. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our amended and restated articles of association, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares and voting at a general meeting. The convening of the meeting, the shareholders entitled to participate, and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Israeli Companies Law as described above in "—Voting Rights."

Borrowing Powers

Pursuant to the Israeli Companies Law and our amended and restated articles of association, our board of directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

Changes in Capital

Our amended and restated articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Israeli Companies Law and must be approved by a resolution duly passed by our shareholders at a general meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court.

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is Computershare Trust Company, N.A. Its address is 250 Royall Street, Canton, MA 02021. Its telephone number is +1 (201) 680-4503.

Listing

Our ordinary shares are listed on the Nasdaq Global Market under the symbol "URGN."

EXHIBIT 10.14

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY […*…], HAS BEEN OMITTED BECAUSE UROGEN PHARMA LTD. HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO UROGEN PHARMA LTD. IF PUBLICLY DISCLOSED.**

LICENSE AGREEMENT

AGEN1884

This License Agreement (this "Agreement") dated as of November 8, 2019 (the "Effective Date") is by and between UroGen Pharma Ltd., a company organized and existing under the laws of the State of Israel having an address at 9 HaTaasia St., Ra'anana 4365007, Israel ("UroGen"), and Agenus Inc., a Delaware corporation with offices at 3 Forbes Road, Lexington, Massachusetts 02421 USA ("Agenus"). UroGen and Agenus may each be referred to herein individually as a "Party" or, collectively, as the "Parties".

WHEREAS, UroGen is engaged in the development of drug products formulated to be used for local delivery including but not limited to by way of UroGen's proprietary sustained release gel formulation known as RTGel™ or other proprietary or licensed technologies;

WHEREAS, UroGen desires to access the proprietary Agenus Antibody known as AGEN1884 targeting CTLA-4 to be used in combination with UroGen technologies, and to obtain a license under the Agenus IP to Develop, Manufacture and Commercialize a Licensed Product(s) for use in the Field in the Territory; and

WHEREAS, Agenus is willing to supply the Agenus Antibody in bulk drug substance or in current Agenus formulated form during development period, as the parties shall agree, to UroGen to be used in Licensed Products, and to grant the requested license under the Agenus IP on the terms and conditions set out in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, terms, and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound hereby, agree as follows:

Article 1. DEFINITIONS

1.1 Defined Terms. Capitalized terms used throughout this Agreement shall have the following definitions:

(a) "Accounting Standards" with respect to a Party means that such Party shall maintain records and books of accounts in accordance with US generally accepted accounting principles, and consistently maintained

(b) "Additional Active" means any […***…] or […***…] that are not the Agenus Antibody.

(c) "Affiliate" means, as to a Person, any Person which, directly or indirectly, controls, is controlled by, or is under common control with such Person. For the purposes of this definition, "control" refers to any of the following: (a) direct or indirect ownership of more than fifty percent (50%) of the voting securities entitled to vote for the election of directors in the case of a corporation, or of more than fifty percent (50%) of the equity interest with the power to direct management in the case of any other type of legal entity; (b) status as a general partner in

any partnership; or (c) any other arrangement where an entity possesses, directly or indirectly, the power to direct the management or policies of another entity, whether through ownership of voting securities, by contract or otherwise.

(d) "Agenus Antibody" means the current injectable formulation being Developed by Agenus as of the Effective Date that contains the antibody binding specifically to CTLA-4 known as AGEN1884, identified by Chemical Abstract Service Registry Number 2148321-69-9.

(e) "Agenus IP" means the Licensed Patent Rights and the Licensed Know-How.

(f) "Applicable Law" means federal, state, local, national and supra-national laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law, including any rules, regulations, guidelines, or other requirements of a Regulatory Authority, that may be in effect from time to time during the Term and applicable to a particular activity.

(g) "Biosimilar Product" means, with respect to a Licensed Product, a biological medicinal product for human use which: (a) is highly similar to such Licensed Product; (b) has no clinically meaningful differences with regard to such Licensed Product in terms of safety, purity, or potency, as determined by Applicable Law or any applicable Regulatory Authority; (c) is approved for use in the United States under 42 U.S.C § 262(k) as a biosimilar biological product (as defined in 42 U.S.C. § 262(i)(1), (2)) or under any other jurisdiction pursuant to an equivalent regime in such jurisdiction, and (d) for which the Licensed Product is the reference product (as defined in 42 U.S.C. § 262(i)(4) or equivalent code reference in the applicable jurisdiction and regulatory regime).

(h) "Business Day" means a day other than a Saturday or Sunday or federal or state holiday in Boston, Massachusetts.

(i) "Certificate of Analysis" means the document delivered with each shipment of Agenus Antibody that includes (a) the name of the product, (b) the Lot number, (c) the date of Manufacture, (d) the expiration date, and (e) a statement as to the Agenus Antibody's compliance with Specifications.

(j) "cGCP" means the standards of current good clinical practice as are required by governmental agencies in countries in which the Licensed Products are intended to be sold under this Agreement, including as set forth in the United States Federal Food, Drug and Cosmetic Act and applicable regulations promulgated thereunder and applicable regulations or guidelines from ICH, as amended from time to time.

(k) "cGMP" means the current Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Directive 91/356/EEC, ICH Guidelines Q7A and United States Good Manufacturing Practices for Finished Pharmaceuticals pursuant to 21 C.F.R. 210 et seq., as amended from time to time.

(l) "Change in Control" means, with respect to a Party: (a) any transaction or series of related transactions pursuant to which a Third Party that does not, itself or together with its Affiliates, prior thereto beneficially own at least fifty percent (50%) of the voting power of the outstanding securities of such Party acquires or otherwise becomes the beneficial owner of securities of such Party representing at least fifty percent (50%) of the voting power of the then outstanding securities of such Party with respect to the election of directors; or (b) a merger (including a reverse triangular merger), reorganization, consolidation, share exchange, or similar transaction including the sale of all or substantially all of the assets of the company, in each case involving such Party in which the holders of voting securities of such Party outstanding immediately prior thereto and their Affiliates cease to hold voting securities that represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation, share exchange, or similar transaction.

(m) "Clinical Trial" means a study in humans of a Licensed Product to be carried out by UroGen in accordance with the terms of this Agreement.

(n) "Commercialization" means any and all activities directed to the branding, marketing, promotion, distribution, pricing, reimbursement, offering for sale, and sale of a pharmaceutical or biologic product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such pharmaceutical or biologic product regarding the foregoing, including seeking any required reimbursement approval, but excluding activities primarily directed to Manufacturing or Development. "Commercialize," "Commercializing," and "Commercialized" will be construed accordingly.

(o) "Commercially Reasonable Efforts" of a Party means, with respect to an obligation or objective, the reasonable, diligent, good faith efforts of such Party (including the efforts of its Affiliates and sublicensees), of the type to accomplish such objective as a similarly situated (with respect to size, stage of development and assets) biopharmaceutical company would normally use to accomplish a similar objective for a compound or product at a similar stage in its development or product life and of similar market potential taking into consideration safety and efficacy, cost to Develop, the competitiveness of alternative products, the proprietary position, the likelihood of Regulatory Approval, profitability, and all other relevant factors. Subject to and consistent with the foregoing, Commercially Reasonable Efforts shall include that the applicable Party (i) regularly assigns responsibility for obligations to employee(s) who monitor progress of such obligations; (ii) sets goals with respect to such obligations and objectives; and (iii) makes decisions and allocates resources designed to advance progress with respect to and achieve such obligations and objectives

(p) "Confidential Information" means, subject to Section 11.1(b), any technical, scientific or business information of one Party or its Affiliates disclosed or made available to the other Party or its Affiliates in connection with this Agreement or generated pursuant to the activities contemplated hereunder, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in oral, written, electronic or other form, or otherwise obtained through observation of a Party.

(q) "Control" or "Controlled" means, with respect to any Know-How or Patent Rights or intellectual property rights therein, the possession by a Party or any of its Affiliates, whether by ownership or license (other than by a license granted under this Agreement), of the ability to grant to the other Party access, a license and/or a sublicense in, to or under such Know-How, Patent Right or intellectual property right as provided herein without requiring the consent of a Third Party or violating the terms of any agreement or other arrangement with any Third Party or creating a payment obligation upon such Party under any agreement entered into after the Effective Date, in each case, (a) as of the Effective Date, or (b) if any of the same are acquired or created after the Effective Date, at the date it is acquired or created by the relevant Party. Notwithstanding anything in this Agreement to the contrary, a Party shall be deemed to not Control any Patent Rights, Know-How or intellectual property rights that are owned or controlled by a Third Party described in the definition of "Change in Control", or such Third Party's Affiliates, (i) prior to the closing of such Change in Control, or (ii) after such Change in Control to the extent that such Patent Rights, Know-How or intellectual property rights are conceived, discovered, developed, made or reduced to practice by such Third Party or its Affiliates (other than such Party) after such Change in Control without using such Party's technology.

(r) "Cover" means, with reference to a Valid Claim and a product, that the making, using, offering to sell, selling, importing, or exporting of such product would infringe such Valid Claim (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue) in the country in which such activity occurs without a license thereto (or Control thereof).

(s) "CTLA-4" means cytotoxic T-lymphocyte-associated protein 4.

(t) "Development" or "Develop" means all internal and external research, development, and regulatory activities related to Licensed Products, including (i) pre-clinical studies and Clinical Trials and (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials or to obtain, support, or maintain Regulatory Approval of a pharmaceutical or biologic product, but excluding activities primarily directed to Manufacturing. "Develop," "Developing," and "Developed" will be construed accordingly.

(u) "Efficacy Trial" means any […***…] of a […***…] with a […***…], […***…] of […***…], […***…], […***…], or any other […***…] or outcome measure designed to evaluate the clinical activity of an […***…].

(v) "FDA" means the United States Food and Drug Administration or any successor agency thereto.

(w) "Field" means intravesical delivery for treatment of cancers of the urinary tract. The […***…] that […***…]

(x) "First Commercial Sale" means, on a country-by-country basis, the first sale of a Licensed Product in such country for use or consumption by the general public (following receipt of all Regulatory Approvals that are required in order to sell such Licensed Product in such country) and for which any of UroGen or its Affiliates or sublicensees has invoiced sales of such Licensed Product in such country; provided, however, that the following shall not constitute a First Commercial Sale: (a) any sale to an Affiliate or sublicensee, unless such Affiliate or sublicensee is the last Person in the distribution chain of the Licensed Product; (b) any use of such Licensed Product in clinical trials or non-clinical development activities; or (c) any disposal or transfer of such Licensed Product for a bona fide charitable purpose, compassionate use, or samples.

(y) "HCR Security Agreement" means that certain Security Agreement dated as of January 19, 2018 by and between Agenus Inc. and HealthCare Royalty Partners III, L.P.

(z) "IB" means the investigator's brochure for the Licensed Product or Agenus Antibody, as applicable, as defined in 21 C.F.R. § 312.23(a)(5).

(aa) "ICH" means International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

(bb) "IND" means an investigational new drug application filed with the US Food and Drug Administration pursuant to 21 C.F.R. §312 (as amended from time to time) for authorization to commence Clinical Trials of a Licensed Product, and the equivalent regulatory filing in countries outside of the United States.

(cc) "Initiation" means, with respect to a Clinical Trial, the administration of the first dose of a Licensed Product to the first patient (or volunteer, as relevant) participating in such Clinical Trial.

(dd) "Inventions" means all inventions, discoveries, improvements, Results and other technology (whether or not patentable), and any intellectual property rights therein, including Patent Rights, that are discovered, made, conceived or reduced to practice in performance of this Agreement.

(ee) "Know-How" means any and all technical information that is not, as of the date of disclosure, in the public domain or otherwise excluded pursuant to Section 11.1(b), including information comprising or relating to data, materials, results, inventions, improvements, protocols, formulas, processes, methods, compositions, articles of manufacture, formulations, discoveries, findings, know-how and trade secrets of any kind, including scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, sequence information, vectors and host cells that include DNA, in each case (whether or not patented or patentable) in written, electronic or any other form now known or hereafter developed.

(ff) "[…***…] Agreement" means that certain […***…] Agreement, entered into […***…], by and between […***…], […***…], the […***…], on behalf of itself and […***…].

(gg) "Licensed Know-How" means all Know-How Controlled by Agenus as of the Effective Date pertaining to the Licensed Patent Rights and necessary or reasonably useful in the Development, Manufacture or Commercialization of the Licensed Product.

(hh) "Licensed Patent Rights" means all rights in the Territory under (i) the Patent Rights listed on Exhibit A, (ii) all Licensed Improvement Patent Rights, (iii) all Patent Rights that issue from the foregoing, and (iv) all continuations, continuations-in-part, divisionals, extensions, substitutions, reissues, re-examinations and renewals of any of the Patent Rights listed in (i)-(iii).

(ii) "Licensed Product" means (i) any product containing the Agenus Antibody formulated for intravesical delivery in the Field and (ii) any process that incorporates or uses the foregoing. Licensed Product excludes Additional Actives owned or Controlled by Agenus. Subject to the immediately preceding sentence, Licensed Product may include Additional Actives.

(jj) "Lot" means the finished and vialed Agenus Antibody produced in a single production run resulting from the use of a batch of bulk Agenus Antibody or a portion thereof.

(kk) "MAA" means a Marketing Authorization Application, BLA, or similar application, as applicable, and all amendments and supplements thereto, submitted to the FDA, EMA, or any equivalent filing in a country or regulatory jurisdiction other than the US or EU with the applicable Regulatory Authority, to obtain marketing approval for a Licensed Product(s), in a country or in a group of countries.

(ll) "Manufacture" or "Manufacturing" means, as applicable, all activities and operations associated with the production, manufacture, supply, receipt, processing, filling, finishing, inspections, testing, packaging, labeling, shipping, warehousing, storage and handling of a Licensed Product or Agenus Antibody as applicable, including: cell line development; process and formulation development; process validation; stability and release testing; manufacturing scale-up; pre-clinical, clinical and commercial manufacture and supply; qualification and validation of Third Party contract manufacturers, scale up, process and equipment validation, and initial manufacturing licenses, approvals and inspections; analytical development and product characterization; quality assurance and quality control development; testing and release; packaging development and final packaging and labeling; shipping configurations and shipping studies; and overseeing the conduct of any of the foregoing. When used as a verb, "Manufacture" means to engage in Manufacturing.

(mm) "Net Sales" means, with respect to a given period, the gross amount invoiced for sales of Licensed Products during such period, in arm's length sales by UroGen or its Affiliates or licensees or sublicensees to Third Parties less, in each case solely to the extent relating to such Licensed Products and solely to the extent actually incurred, allowed, paid, accrued or specifically allocated to the gross amount invoiced, and determined in accordance with the Accounting Standards customarily utilized by the applicable Person in its business:

(i) normal and customary […***…], […***…] and […***…] actually given, […***…] actually taken, […***…], […***…] or […***…] for […***…] Licensed Product, […***…] or […***…] of such Licensed Product;

(ii) […***…], […***…], […***…], […***…], […***…], […***…] and […***…] (or the equivalent thereof) actually given for Licensed Products granted to […***…] or other […***…], […***…] or any other providers of […***…], […***…] (including […***…]) or other […***…], […***…] or […***…] or other similar […***…], or to […***…], […***…], […***…] and other […***…], including their […***…], or to […***…], […***…] or other trade customers;

(iii) reasonable and customary […***…], […***…] and other […***…] expenses, each directly related to the sale of Licensed Products (if actually borne without […***…] from any […***…]);

(iv) […***…], […***…] or […***…], […***…] and […***…], and all other […***…] charges related to the sale of Licensed Products, in each case to the extent that each such item is actually borne by […***…] or its […***…] or […***…] without […***…] from any […***…] (but excluding […***…] properly […***…] or […***…] against the […***…] by […***…] or its […***…] or […***…] from such sale);

(v) actual […***…] (but not […***…]% of Net Sales); provided, however, that the amount of […***…] pursuant to this clause and actually […***…] in a subsequent […***…] shall be included in Net Sales for such subsequent […***…];

(vi) adjustments for […***…], […***…], […***…], […***…] or […***…] of […***…]; and

(vii) […***…] in connection with […***…] or […***…] of the […***…] of […***…], as amended), […***…] of the […***…] of […***…], as amended) or similar […***…] in the United States and comparable […***…] in countries outside of the United States.

Net Sales shall be calculated in accordance with […***…]. In the case of any […***…] or other […***…] for […***…], such as […***…] or […***…], of a product, or part thereof, other than in an […***…] exclusively for […***…], Net Sales shall be calculated as above on the value of the […***…] received or the […***…] (if […***…]) of such product in the country of sale or […***…], as determined in accordance with […***…].

(nn) "Patent Rights" means all the rights and interests in and to all patents and patent applications, underlying inventions, and patent term extensions or restorations, in any jurisdiction in the applicable Territory, including certificates of invention, applications for certificates of invention and priority rights, provisional patent applications, divisionals, continuations, substitutions, continuations-in-part, and all patents granted thereon; and all re-examinations, re-issues, additions, renewals, extensions, confirmations or registrations based on any such patent or patent application; and any extensions or restorations by existing or future extension or restoration mechanisms, including patent term extensions and supplementary protection certificates.

(oo) "Person" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity.

(pp) "Prosecution" or "Prosecute" means, with respect to a particular Patent Right, all activities associated with the preparation, filing, prosecution and maintenance of such Patent Right, as well as re-examinations, reissues, applications for patent term adjustments and extensions, supplementary protection certificates and the like with respect to that Patent Right, together with the conduct of interference, opposition, invalidation, reexamination, reissue proceeding, post-grant review, *inter partes* review, derivation proceeding or other similar administrative proceeding or administrative appeal thereof, with respect to that Patent Right.

(qq) "Publication" means any publication in a scientific journal, any abstract to be presented to any scientific audience not subject to confidentiality obligations, any presentation at any scientific conference, including slides, posters and texts of oral or other public presentations presented to an audience not subject to confidentiality obligations, any other scientific presentation, disclosure of a clinical trial on clinicaltrials.gov or similar clinical trial registries, and any other oral, written or electronic disclosure directed to a scientific audience not subject to confidentiality obligations, in each case which pertains to the Licensed Product.

(rr) "Quality Agreement" means the quality agreement to be executed by the Parties after the Effective Date with respect to cGMP Manufacturing of the Agenus Antibody, as may be revised by mutual agreement of the Parties from time to time.

(ss) "Qualified Subjects" means patients that meet the enrollment criteria for the Clinical Trial as set forth in the applicable protocol.

(tt) "Registrational Trial" means any Clinical Trial of a Licensed Product that (i) would satisfy the requirements of 21 C.F.R. 314.126 or corresponding foreign regulations or (ii) that is intended to provide significant evidence data to support the filing of an MAA for such Licensed Product.

(uu) "Registrational Trial Recognition Date" means, with respect to a Clinical Trial that does not constitute a Registrational Trial at the time of its Initiation, the date on which the applicable Regulatory Authority recognizes (as evidenced by written correspondence or meeting minutes of such Regulatory Authority) that such Clinical Trial would support the filing of an MAA for a Licensed Product.

(vv) "Regulatory Approval" means, with respect to a product, any and all approvals by a Regulatory Authority (including supplements, amendments), permits, licenses, registrations and authorizations necessary for the manufacture, distribution, use, promotion, marketing, transport, offer for sale, sale or other commercialization of such product or components thereof in a regulatory jurisdiction, leading up to and including marketing authorization, including MAA approval; but excluding pricing or reimbursement approvals.

(ww) "Regulatory Authority" or "Regulatory Authorities" means, with respect to a country, the regulatory authority or regulatory authorities of such country with authority over the testing, manufacture, use, storage, importation, promotion, marketing, pricing or sale of a product in such country, including the FDA and the European Medicines Agency.

(xx) "Regulatory Submission" means documents and data submitted to a Regulatory Authority to gain Regulatory Approval.

(yy) "Specifications" means the product specifications for the Agenus Antibody as set forth in the master batch record.

(zz) "Subcontractor" means a Third Party contractor engaged by a Party to perform certain obligations or exercise certain rights of such Party under this Agreement on a fee-for-service basis, excluding all Sublicensees.

(aaa) "Sublicensee" means any Third Party to which a license to Exploit a Licensed Product has been granted by UroGen (directly or through multiple tiers), or who otherwise receives a sublicense of rights granted to UroGen hereunder.

(bbb) "Sublicense Income" means the fair market cash value of any and all consideration received by UroGen from a Sublicensee under or otherwise in connection with any transaction or related transactions involving a sublicense of rights hereunder, including without limitation license issue fees, option fees and other licensing fees, milestone payments, royalties, equity securities or other payments of any kind whatsoever, or any other consideration, irrespective of the form of payment. Notwithstanding the immediately preceding sentence, specifically excluded from Sublicense Income is (i) any […***…] to […***…] or […***…] a […***…] or […***…] pursuant to a bona fide […***…] or […***…] agreement with such Sublicensee; or (ii) a […***…] of […***…] in […***…] by said Sublicensee at […***…] (provided that any […***…] shall constitute Sublicense Income) or (iii) amounts […***…] under a […***…] to […***…] shall not be […***…] from Sublicense Income.

(ccc) "Territory" means all of the countries and territories of the world, but excluding Argentina, Brazil, Chile, Colombia, Peru, Venezuela and their respective territories and possessions. In the event that any of the excluded territories in the immediately preceding sentence is no longer subject to […***…] rights under contractual agreements, UroGen shall […***…] shall exist for each excluded territory for […***…] from Agenus' written notice to UroGen that such territory has become […***…] from such […***…] rights.

(ddd) "Third Party" means any Person other than a Party or an Affiliate.

(eee) "Valid Claim" means (a) a claim of an issued patent that has not expired or been abandoned, or been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e., only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue); or (b) a claim of a pending patent application that was filed in good faith and has not been (i) abandoned, finally rejected or expired without the possibility of appeal or refiling, or (ii) pending for more than […***…] years since such claim was first presented in unamended form.

1.2 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

Term	Section
Abandoned Development	12.2(c)
Agenus Improvements	10.1
Agenus Improvement Patent Rights	10.1
Agenus Indemnified Parties	14.1
Agenus Results	6.4
Claims	14.1
Commercial Supply Agreement	3.2
Delivery	3.4
Development Plan	6.1
Disclosing Party	11.1(a)
Early Stage Development	6.1
Exchange Rate	9.6(e)
Exhibit D Documents	2.1
Exploit	5.1(a)
Force Majeure event	15.5
Forecast	6.1
Global Branding Strategy	8.2

Indemnified Party	14.3
Initial Commercialization Plan	8.1
Licensed Improvement Patent Rights	10.1
Limited Approval	6.1
[…***…]	1.1(ff)
Losses	14.1
MAE	2.2(a)
Milestone Event	9.2
Minimum Sublicensee Payment	9.5
[…***…]	1.1(ff)
Other Improvement Patent Rights	10.1
Payment Statement	9.6(b)
Proceed with Development	9.2
Product Trademarks	8.2
Promotional Materials	8.3
Recipient	11.1(a)
Royalty	9.3
SDEA	7.5
Sell-Off Period	12.3(e)
Term	12.1
Upfront Payment	9.1
UroGen Improvements	10.1
UroGen Improvement Patent Rights	10.1
UroGen Indemnified Parties	14.2

Article 2. COORDINATION AND DECISION MAKING

2.1 Coordination. Within 30 days of the Effective Date, Agenus shall provide electronic copies of the documents described in Exhibit D (the "Exhibit D Documents") then in existence. Each Party shall appoint one (1) representative to act as a collaboration manager (each, a "Manager") to coordinate activities of the Parties under this Agreement. The Parties shall meet at least once every six (6) months to engage in in dialogue on mutually agreed subjects, pursuant to an agenda to be circulated by the Managers at least ten (10) days prior to each such meeting. Coordination meetings shall be at such times and places as the Parties mutually agree, and may be conducted in person or telephonically. Agenda topics may include UroGen's progress under the Development Plan, communications with Regulatory Authorities regarding the Licensed Products, discussion of Results, adverse events and other material matters relating to Clinical Trials, Publication opportunities and coordination of Commercialization efforts and Agenus' progress on monotherapy development activities performed solely by or on behalf of Agenus. In advance of each such meeting, UroGen shall deliver an updated Development Plan to the Agenus Manager together with a written report regarding Development, Manufacturing and Commercialization activities in respect of Licensed Products since on the last such meeting. and Agenus shall deliver any updates on Agenus' progress on monotherapy development activities performed solely by or on behalf of Agenus and updates to Exhibit D Documents or any Exhibit D Documents not previously provided.

2.2 Decision-Making. To the extent that the Parties disagree on matters relating to the […***…] of […***…] in the […***…] in the […***…] pursuant to this Agreement:

(a) Agenus shall have final decision-making authority with respect to all matters that could reasonably be expected to have a material adverse impact on the […***…] of the Agenus Antibody (an "MAE"). This shall include decision-making authority with respect to any study UroGen wishes to conduct of the Agenus Antibody in connection with a […***…], subject to any instructions UroGen is mandated by the FDA to follow as part of its review or approval of a […***…]. By way of example and not limitation, an MAE […***…] a matter that […***…] be […***…] to impact the […***…] of the Agenus Antibody, but […***…] a matter relating to the […***…], […***…] or […***…] of […***…] if the outcome of the decision […***…] be […***…] to have a material adverse impact on […***…] of the Agenus Antibody.

(b) Subject to Section 2.2(a), UroGen shall have final decision-making authority with respect to all matters directly relating to the […***…] or any […***…] by UroGen.

(c) For all other matters, the matter shall be referred to the Chief Executive Officers of each Party, or such other officer designated by the Chief Executive Officer (each a "Senior Executive") for their consideration. The Senior Executives will discuss […***…] and use […***…] to resolve the matter referred to them. If the Senior Executives cannot reach a mutually acceptable decision within […***…] after the issue was referred to them, then such matter may be brought in any court of competent jurisdiction subject to Section 15.1.

Article 3. SUPPLY OF AGENUS ANTIBODY

3.1 Clinical Supply. Agenus shall use Commercially Reasonable Efforts to supply to UroGen the gram quantities of Agenus Antibody required by UroGen at […***…] of Agenus' fully burdened costs as set forth in a schedule delivered to UroGen in the form of Exhibit B (the "Cost Schedule"), plus all logistics, shipping, and any VAT or other applicable transfer taxes. Any changes to the costs set forth in the Cost Schedule shall be identified in an updated Cost Schedule delivered to UroGen annually, provided that any increase exceeding […***…] in aggregate shall be disclosed to UroGen prior to implementation of such change. Agenus may Manufacture and supply Agenus Antibody for such purpose either itself or through the use of an Affiliate or Agenus Subcontractor. All supplies of the Agenus Antibody to UroGen shall be used solely in preclinical studies or Clinical Trials in accordance with the Development Plan, as applicable, and shall not be incorporated into any Licensed Product that is sold or offered for sale.

3.2 Commercial Supply. On […***…] written request at any time after […***…] of all […***…] set forth in Section […***…], the Parties shall use […***…] to enter into a commercial supply agreement (the "Commercial Supply Agreement") pursuant to which […***…] will agree to […***…] to […***…] with […***…] of […***…] for […***…] in the […***…] , […***…] or […***…] of an […***…] or […***…]. The Commercial Supply Agreement shall provide for […***…] at […***…] of […***…], as set forth in a […***…] on a […***…] to […***…], […***…] all […***…], […***…], and any […***…] or other applicable […***…], provided that any […***…] in […***…] shall be […***…] to […***…] prior to […***…] of […***…]. In addition, the parties […***…] that the […***…] may reflect […***…] in […***…] as a result of […***…]. The Parties shall endeavor to […***…] for a Commercial Supply Agreement […***…] than […***…] after […***…] of the […***…] of the […***…], provided that in the event that the Parties […***…] to […***…] on the terms for said Commercial Supply Agreement, […***…] will assist […***…] in […***…] a […***…] of the […***…] at […***…]. In such a case, […***…].

3.3 Forecasting for Commercial Supply. […***…] to […***…] into the […***…], […***…] shall use […***…] to […***…] (see definition in Section […***…]) the […***…] of […***…] that it […***…] to […***…] for the […***…] of […***…]. […***…] will work with […***…] to […***…] the best […***…] and […***…] to […***…] the […***…] of […***…] that it […***…] to […***…] on an […***…] after the […***…], and such […***…] will be […***…] into the […***…].

3.4 Delivery. Each preclinical or clinical order of Agenus Antibody shall be shipped EXW (Incoterms 2010) Agenus' designated Manufacturing facility, using a common carrier selected by Agenus and reasonably acceptable to UroGen. Title and risk of loss for any order shall pass to UroGen upon the common carrier taking possession of the shipment ("Delivery"). UroGen shall be responsible for customs and other regulatory clearance of any Agenus Antibody, payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the import or export of the Agenus Antibody, and record-keeping in connection with such import or export.

3.5 Permits and Approvals. During the Term, Agenus and its Third Party

Manufacturing contractors will be responsible for maintaining any licenses, permits and approvals necessary for the Manufacture of the Agenus Antibody in accordance with the provisions of this Agreement and UroGen will be responsible for maintaining any other licenses, permits and approvals necessary for the Manufacture of the Licensed Product(s) in accordance with the provisions of this Agreement. Each Party will promptly notify the other Party if such Party receives notice that any such license, permit, or approval is or may be revoked or suspended.

Article 4. ACCEPTANCE AND REJECTION.

4.1 Delivery. Agenus warrants that at the time of Delivery, any Agenus Antibody delivered for use in pre-clinical and Clinical Trials under this Agreement (a) shall have been Manufactured in facilities compliant with cGMP to the extent required under Applicable Laws for clinical grade investigational product, (b) shall be consistent with the Certificate of Analysis delivered with such Agenus Antibody, and (c) shall be delivered free and clear of all liens and encumbrances. In connection with each Delivery of Agenus Antibody, Agenus shall provide a true copy of the Certificate of Analysis generated on release of the applicable Lot.

4.2 Dispute Resolution. UroGen shall accept shipments of Agenus Antibody in accordance with the processes set forth in the Quality Agreement. UroGen shall promptly, before taking any steps toward Development or Manufacture of Licensed Products, and in any event within […***…] days after receipt, notify Agenus of any defective or incomplete shipment of Agenus Antibody. Agenus and UroGen will attempt to resolve any dispute first through good faith discussions. If such dispute cannot be resolved within […***…] days and such dispute involves non-conformity with Specifications, then UroGen may submit a sample of the disputed Agenus Antibody associated with each Lot in dispute to an independent testing laboratory agreeable to both Parties for analysis, under quality assurance approved procedures, of the conformity of such sample with the Specifications. The costs associated with such analysis by such independent testing laboratory will be shared equally by the Parties.

4.3 Remedies. UroGen acknowledges and agrees that, unless otherwise set forth in the Commercial Supply Agreement, its sole remedy with respect to damaged or destroyed quantities of Agenus Antibody or the failure of any Agenus Antibody delivered pursuant to Section 3.1 to conform with Specifications is replacement of the applicable quantity of Agenus Antibody. UroGen hereby waives all other remedies at law or in equity regarding the foregoing claims. Agenus shall not be liable for any failure to conform to Specifications if notice of such non-conformity is not provided to Agenus within […***…] days after Delivery. […***…] for […***…] of […***…] pursuant to Section […***…] shall be […***…] of […***…] of any

[…***…] to […***…] with […***…].

Article 5. LICENSES

5.1 License Grant.

(a) License to UroGen. Subject to the terms and conditions of this Agreement and any […***…] of […***…] and […***…], under the […***…] (as described in Section 5.3), and expressly conditioned on UroGen's timely payment of the Upfront Payment, Agenus hereby grants to UroGen during the Term a nontransferable (except as permitted in Section 15.2), sublicensable (subject to Section 5.4), exclusive right and license under the Agenus IP (i) to develop, make, have made and use, and (ii) to offer to sell, sell and/or import (collectively (i) and (ii), "Exploit") Licensed Products in the Field in the Territory. UroGen and its sublicensees shall be solely responsible for all costs and expenses in connection with such Exploitation. The foregoing license does not include, and expressly prohibits, Development, Manufacture or Commercialization of (a) any Additional Active owned or Controlled by Agenus, unless mutually agreed upon in writing, or any method or use thereof owned or Controlled by Agenus or (b) the Agenus Antibody, except as incorporated into a Licensed Product. For clarity, UroGen's Development rights include the right to formulate the Agenus Antibody supplied by Agenus into Licensed Products, but not to otherwise engage in any Development or Manufacturing activities with respect to the Agenus Antibody or any products other than Licensed Products containing the Agenus Antibody. All Agenus Antibody shall be supplied to UroGen by Agenus pursuant to Article 3. Notwithstanding the foregoing, in the event UroGen requests […***…] of the […***…] of the Agenus Antibody to […***…] the Development, Manufacture or Commercialization of a Licensed Product, Agenus will (i) first, subject to any confidentiality obligations to Third Parties, use […***…] to provide UroGen all information that is reasonably requested by UroGen with regard to the […***…] of the Agenus Antibody and that is necessary for the Licensed Product, as well as provide reasonable assistance to the UroGen team with any questions it may have in order for UroGen to make such […***…] to the […***…] of the Agenus Antibody in its […***…] or […***…], or (ii) second, subject to its own […***…] that may exist at the time of such request, use […***…] to conduct such […***…] on a […***…] for […***…] and on […***…] and […***…] to be agreed upon between the Parties. For clarity, […***…] hereunder will […***…] in any way should UroGen determine that a Licensed Product shall also include […***…] not […***…] or […***…] by Agenus.

(b) License to Agenus. Subject to the terms and conditions of this Agreement, UroGen hereby grants to Agenus an […***…], […***…] (except as permitted in Section 15.2), […***…] (solely in connection with Agenus […***…]), […***…] and license under the […***…] that involve either (i) a […***…] of the Agenus Antibody […***…] or (ii) the Agenus Antibody to […***…] the […***…]. The foregoing license expressly […***…] of any […***…] or […***…] by […***…], or any method or use thereof […***…] or […***…] by […***…].

5.2 No Implied Licenses or Rights. Except as expressly licensed in Section 5.1, all rights in and to the Patent Rights or Know-How of each Party and its Affiliates are hereby retained by such Party and its Affiliates. For the purposes of clarity, and notwithstanding any

other provision of this Agreement, the licenses granted in Section 5.1(a) give UroGen no rights to Exploit the Agenus IP or any Licensed Product outside of the Field or the Territory, and the license granted in Section 5.1(b) gives Agenus no rights to Exploit UroGen Improvement Patent Rights in the Field, nor any rights to Exploit UroGen Patent Rights or Know-How other than the UroGen Improvement Patent Rights. Notwithstanding the exclusive licenses granted to Licensee pursuant to Section 5.1(a), Agenus retains the right to practice under the Agenus IP: (i) to exercise its rights and to perform (and to sublicense Third Parties to perform) its obligations under this Agreement and (ii) for all purposes other than the Exploitation of Licensed Products in the Field in the Territory.

5.3 […***…] Agreement. Without limiting the representations and warranties made herein by Agenus with regard to its rights to exploit the Agenus Antibody, UroGen acknowledges and agrees that certain of the […***…] has been […***…] to […***…] pursuant to the […***…] Agreement and is subject to the terms and conditions thereof including but not limited to: (a) the […***…] and […***…] with respect to […***…] of […***…] as provided in Sections […***…] and […***…] of the […***…] Agreement, (b) […***…] under Section […***…] of the […***…] Agreement, and (iii) obligations of […***…] as provided in Section […***…] of the […***…] Agreement. In the event of any conflict or inconsistency between any applicable provision of this Agreement and such provisions of the LICR Agreement, such provisions of the […***…] Agreement shall prevail with respect to the relevant […***…] to […***…] by […***…] pursuant to the […***…] Agreement. Nothing in the immediately preceding sentence shall serve to waive any representation made by Agenus to UroGen herein with regard to UroGen's […***…] to […***…] the Agenus Antibody, nor UroGen's right to enforce such representations and seek applicable remedies for material breaches thereof. For purposes of clarity, all obligations of […***…], […***…] or […***…], that do not attach to […***…] of Agenus under the […***…] Agreement shall be the sole responsibility of Agenus.

5.4 Sublicensing.

(a) Sublicense Grant. Subject to the terms and conditions of this Agreement, Agenus hereby grants to UroGen the right to sublicense all or any of UroGen's licensed rights to and under the Agenus IP to one or more Third Parties subject to Agenus' prior written approval of the identity of each proposed Sublicensee, not to be unreasonably withheld or delayed.

(b) Scope of Sublicense. No sublicense may exceed the scope of rights granted to UroGen hereunder. UroGen shall require all sublicenses to be in writing and to: (a) include an agreement by the Sublicensee to be bound by the terms and conditions of this Agreement including an audit right by Agenus of the same scope as provided in Section 9.7, (b) acknowledge Agenus' right to enforce its rights in the Agenus IP as set forth herein; (c) provide that the term of the sublicense thereunder may not extend beyond the Term; and (d) indicate that Agenus is a third party beneficiary and entitled to enforce the terms and conditions of the sublicense in the event UroGen fails to do so. UroGen shall enforce all sublicenses at its cost and shall be responsible for the acts and omissions of its Sublicensees.

(c) Licensee Liability. Notwithstanding any sublicense agreement, UroGen shall remain primarily liable to Agenus for all of UroGen's duties and obligations contained in

this Agreement, including the payment of all Royalties due pursuant to Section 9.3. Any act or omission of a Sublicensee that would be a breach of this Agreement and not timely cured (to the extent curable) if committed or omitted by UroGen will be a breach by UroGen if not timely cured (to the extent curable). Each sublicense agreement must contain a right of termination by UroGen for the Sublicensee's: (a) breach of any payment or reporting obligations affecting Agenus; (b) participation in a Licensed Patent Right Challenge; (c) violation of any US export control Laws in connection with the sale or distribution of any Licensed Product; or (d) breach of any other terms or conditions of the sublicense agreement which breach would constitute a breach of this Agreement if UroGen failed to comply therewith. In the event of a Sublicensee breach of these obligations, and if after a reasonable cure period provided in the sublicense agreement, not to exceed […***…] Days without Agenus' written consent, the Sublicensee fails to cure the Sublicensee breach, UroGen fails to cure such breach, or the breach is otherwise not capable of being cured, then UroGen shall terminate the sublicense agreement by written notice to the Sublicensee within five (5) Business Days thereafter and concurrently provide a copy of such notice to Agenus. In the event the Sublicensee breach does not cause Agenus to be in breach of its upstream obligations, then such termination of the sublicense by UroGen will cure the breach by UroGen. In the event the Sublicensee breach causes Agenus to be in breach of its upstream obligations, such termination will only cure the breach by UroGen if (i) the breach is capable of being cured and (ii) the termination also cures any corresponding breach by Agenus of its upstream obligations.

(d) Copy of Sublicense Agreement. UroGen shall deliver to Agenus a true, complete and correct copy of each sublicense agreement entered into by UroGen, and any modification or termination thereof, within […***…] days following the applicable execution, modification, or termination of the sublicense agreement, provided that UroGen may redact any confidential or proprietary information contained therein that is not necessary for Agenus to determine UroGen's compliance with this Agreement.

Article 6. DEVELOPMENT

6.1 Development Plan. Within […***…] days of the delivery of the Exhibit D Documents pursuant to the first sentence of Section 2.1, UroGen shall deliver a copy of its proposed written plan describing in reasonable detail the proposed program of its initial Development for the first therapeutic indication of the Licensed Product(s). The initial Development Plan will focus on anticipated […***…] and […***…] ("Early Stage Development") with an overview of UroGen's […***…] and […***…] for Licensed Products ("Development Plan") for Agenus' review. During Early Stage Development UroGen plans to screen Agenus Antibody for incorporation into or admixture with UroGen's proprietary sustained release gel formulation(s) known as RTGel™ or other proprietary or licensed technologies. Once a determination has been made by UroGen regarding whether Agenus Antibody is the lead candidate for use in development of the Licensed Product the next Development Plan update shall include the strategy for the initial Clinical Trials and the regulatory plan to support such Clinical Trials for such Licensed Product, as well as a rolling forecast of the quantity of Agenus Antibody that UroGen expects to need for preclinical studies and Clinical Trials (the "Forecast") of the Licensed Product. The Forecast shall cover the remainder of the calendar year in which the Development Plan was approved and the […***…] years thereafter. The Forecast shall be divided into […***…] and shall include a delivery

schedule for the first […***…] . Such Forecast shall become effective, along with the associated delivery schedule, following written approval by Agenus of the Forecast or update thereto. Agenus shall have a […***…] to […***…] (or […***…] for) each Development Plan only in connection with (a) matters that present a […***…] of […***…] to the Agenus Antibody or (b) matters that have a […***…] on Agenus' ability to […***…] the Agenus Antibody set forth in the […***…] (collectively, Agenus' "[…***…]"). The initial Development Plan shall be updated at least […***…] by UroGen and submitted to Agenus for review and […***…] not later than […***…] of each […***…] during the Term. Each updated Development Plan shall include any proposed modifications to the previously approved Forecast, an overall plan for all major Development tasks remaining to be accomplished prior to Regulatory Approval to the extent such tasks are known or can reasonably be ascertained, as well as a reasonably detailed clinical plan for each proposed Clinical Trial. The Parties acknowledge and anticipate that the Development Plan will be […***…] and […***…] for near term activities, and will initially be […***…] and […***…] for activities further out in the future. Notwithstanding any of the above with regard to […***…] and […***…], Agenus' […***…] rights shall not be unreasonably withheld or delayed.

6.2 Responsibility. UroGen shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Approvals for at least one Licensed Product in the Field and in the Territory in accordance with the Development Plan.

6.3 Compliance. In performing any Development activities for the Licensed Product, each Party hereto shall comply, and shall ensure any Persons performing work on behalf of UroGen comply, with all Applicable Law, including cGCP, the Health Insurance Portability and Accountability Act of 1996, Federal Food, Drug and Cosmetic Act, the Public Health Service Act, the Health Information Technology for Economic and Clinical Health Act, P.L. No. 111-005, Part I, Title XIII, Subpart D, 13401 through 13409, the Sunshine Act and federal anti-kickback statute (42 U.S.C. 1320a-7(h) and the related safe harbor regulations, and the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. 1395 (nn)) and all applicable anti-bribery laws, and in each case, any ex-US equivalent.

6.4 Data Sharing. The Parties will exchange information reasonably relevant for regulatory filings for the Licensed Product or otherwise relating to the safety or efficacy of Licensed Products through the coordination meetings described in Section 2.1. In addition, UroGen will provide Agenus […***…] written updates regarding Development activities of the License Products, together with […***…] of all relevant […***…] (but excluding the […***…] and […***…] details of […***…] created under this Agreement) and […***…] data (the "Results") including as reasonably requested for Agenus to meet all applicable regulatory reporting requirements. UroGen will maintain all Results in validated computer systems that are compliant with 21 C.F.R. §11. All Results delivered to Agenus shall first be de-identified for patient protected information (unless otherwise agreed by the Parties in writing) whether the Clinical Trial is conducted by UroGen, its Affiliate or a Third Party. In the event of a […***…] , UroGen shall provide access to all other data related to the Clinical Trial in accordance with procedures set forth in Section 7.2, including […***…], […***…], […***…] and any […***…] thereof relevant to any […***…]. UroGen shall ensure that any agreement it or its Affiliates enters into with any Third Party regarding the Licensed Product or its components shall include data sharing obligations for such Third Party as necessary to permit

UroGen to comply with the obligations set forth in this Section 6.4 but subject to any confidential requirements of existing confidentiality agreements or, if required, the execution of new confidentiality agreements in order to share relevant data. In addition, Agenus will provide UroGen […***…] regarding […***…] performed solely by or on behalf of Agenus related to […***…] of the Agenus Antibody, together with copies of all relevant […***…] and […***…]. Agenus will provide UroGen with copies of Exhibit D Documents not previously provided on a regular basis. Agenus and UroGen agree to update the documents to be provided pursuant to Exhibit D on an as-needed basis, such agreement not to be unreasonably withheld, to include any additional documents that may be reasonably necessary for UroGen to meet all applicable regulatory reporting requirements or mutually agreed agenda items for the coordination meetings pursuant to Section 2.1. The Parties may agree to share other such information based on mutual agreement. Agenus will maintain all […***…] in validated computer systems that are compliant with […***…]. All […***…] delivered to UroGen shall first be […***…] for […***…] (unless otherwise agreed by the Parties in writing) whether the […***…] is conducted by […***…], its […***…] or a […***…]. In the event of a […***…], […***…] shall provide access to all other data related to the […***…] in accordance with procedures set forth in Section 7.2, including […***…], […***…], […***…] and any […***…] thereof relevant to any […***…]. The Parties agree that, from […***…], they will use […***…] to work with each other upon request to […***…] with those […***…], […***…], or other […***…] that have the right to […***…], […***…] or […***…] the Agenus Antibody in their respective […***…] or in their […***…] and […***…] for the purpose of […***…] that may be useful to all parties concerned.

Article 7. REGULATORY MATTERS

7.1 Responsibility. UroGen shall be solely responsible for, at UroGen's cost and expense, preparing, filing and maintaining, and shall own, the Regulatory Approvals, IB, IND and other regulatory filings for the Licensed Product in the Field and in the Territory. UroGen shall keep the Agenus Manager informed of scheduled meetings, teleconferences and other interactions with regulators relevant to the Licensed Product.

7.2 Data Retention and Documentation. Each Party, at its own costs, shall be responsible for archiving all relevant and required original documentation in its possession or control related to the Clinical Trials and Manufacturing under this Agreement, including batch records, raw data and results in relation to the use in Clinical Trials, Manufacturing and control of each Agenus Antibody or Licensed Product. The Parties shall keep all original lab notebooks for the longer of ten (10) years or as required by Applicable Law and shall keep all such notebooks up to date in accordance with each Party's standard practices. Further details shall be delineated in the Quality Agreement.

7.3 Audits.

(a) By UroGen. No more than once per twelve (12) month period or more frequently as reasonably required to address any quality issues, and upon not less than thirty (30) days' prior written notice, Agenus will, and will use Commercially Reasonable Efforts to ensure that its Third Party manufacturers will, accommodate UroGen's reasonable request to inspect the parts of the facilities where the Manufacture of the Agenus Antibody is carried out in order to

assess compliance with cGMP, and audit the Agenus books and records directly related to the Manufacture of such Agenus Antibody. Such audits and inspections shall take place during normal business hours and not exceed two (2) Business Days. Such audits and inspections shall be conducted in a manner that minimizes interruption of Manufacturing activities. Persons inspecting or auditing the facilities, books or records shall be required to enter into separate confidentiality agreements, if not expressly covered by this Agreement and shall abide by the safety protocols and standard operating procedures of the audited facility while on site.

(b) By Agenus. No more than once per twelve (12) month period or more frequently as reasonably required to address any quality issues, and upon not less than thirty (30) days' prior written notice, UroGen will: (a) accommodate Agenus' reasonable request to inspect the parts of the facilities where the Licensed Product is Manufactured and audit the UroGen books and records directly related to the Manufacture of the Licensed Product. UroGen will also permit Agenus, and shall require its Affiliates and Persons performing work on any Clinical Trials to permit Agenus, to inspect any study sites and to audit the books and records of such Persons to determine compliance with Section 6.3. Such audits and inspections shall take place during normal business hours and not exceed two (2) Business Days. Such audits and inspections shall be conducted in a manner that minimizes interruption of UroGen's or the study site's operations. Persons inspecting or auditing the facilities, books or records shall be required to enter into separate confidentiality agreements, if not expressly covered by this Agreement, and shall abide by the safety protocols and standard operating procedures of the audited facility while on site.

7.4 Inspections of Manufacturing Facilities by Regulatory Authorities.

(a) Agenus Antibody Manufacturing. In connection with any audit by a Regulatory Authority relating to the Clinical Trial or the Licensed Product, Agenus will reasonably accommodate requests to, and will use Commercially Reasonable Efforts to ensure that its Third Party manufacturers will, allow representatives of any Regulatory Authority to inspect the relevant parts of facilities where the Manufacture of the Agenus Antibody is carried out and to inspect batch records and related documentation to verify compliance with cGMP and Applicable Law, and will promptly notify UroGen of the scheduling of any such inspection directly relating to the Manufacture of Agenus Antibody being supplied under this Agreement, as well as any deficiencies identified and remediation plans with respect thereto. Persons inspecting or auditing such facilities, books or records shall be required to enter into separate confidentiality agreements and to abide by the safety protocols and standard operating procedures of the audited facility while on site.

(b) Licensed Product Manufacturing. In connection with any audit by a Regulatory Authority relating to the Clinical Trial or the Licensed Product, UroGen (or its Third Party manufacturer) will reasonably accommodate requests to allow representatives of any Regulatory Authority to inspect the relevant parts of facilities where the Manufacture of the Licensed Product is carried out and to inspect batch records and related documentation to verify compliance with cGMP and Applicable Law, and will promptly notify Agenus of any deficiencies identified and remediation plans with respect thereto. To the extent allowable under Applicable Law, Persons inspecting or auditing such facilities, books or records shall be required to enter into separate confidentiality agreements and to abide by the safety protocols and

standard operating procedures of the audited facility while on site.

7.5 Adverse Events Reporting. UroGen shall be responsible for reporting all safety related events for the Licensed Product to appropriate Regulatory Authorities according to the Applicable Law and provide all necessary safety reporting information to ensure Agenus meets all applicable regulatory reporting obligations. Agenus shall be responsible for reporting all safety related events, including annual reporting obligations, for the Agenus Antibody to the appropriate Regulatory Authorities according to Applicable Law. UroGen and Agenus shall keep each other reasonably informed of any adverse reactions, or other material safety findings related to the Licensed Product or Agenus Antibody. The Parties shall coordinate adverse event reporting in accordance with a Safety Data Exchange Agreement to be entered into by the Parties after the Effective Date, as it may be amended by the Parties from time to time ("SDEA").

7.6 Rights of Reference.

(a) For UroGen. Agenus hereby grants, and will cause its Affiliates and Third Party licensees and sublicensees to grant, to UroGen and its Affiliates a "Right of Reference," as that term is defined in 21 C.F.R. §314.3(b) (or any successor rule or analogous law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data included in the BMF, IB, IND and Regulatory Approval for the Agenus Antibody controlled by Agenus solely as required for filing and approval of an IND for the Licensed Product, and Agenus will provide, and will cause its Affiliates and Third Party contractors, as applicable, to provide, a signed statement or letter of authorization to this effect, if requested by UroGen, in accordance with 21 C.F.R. §314.50(g)(3) (or any successor or analogous law outside of the United States). For purposes of clarity, UroGen may use and permit reference to such data as UroGen reasonably determines to be required by the applicable Regulatory Authority in respect of the UroGen Improvements.

(b) For Agenus. UroGen hereby grants, and will cause its Affiliates and Third Party licensees and sublicensees to grant, to Agenus and its Affiliates a "Right of Reference," as that term is defined in 21 C.F.R. §314.3(b) (or any successor rule or analogous law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data included in the BMF, IB, IND, Regulatory Approval or other regulatory documentation for the Licensed Product, but excluding UroGen proprietary information which is formulation specific as developed in the Licensed Products, and UroGen will provide, and will cause its Affiliates and Third Party licensees and sublicensees to provide, a signed statement or letter of authorization to this effect, if requested by Agenus, in accordance with 21 C.F.R. §314.50(g)(3) (or any successor or analogous law outside of the United States). For purposes of clarity, Agenus may use and permit reference to such data as Agenus reasonably determines to be required by the applicable Regulatory Authority in respect of the Agenus Antibody. Agenus further agrees to discuss strategies and procedures regarding its own independent Commercialization activities with respect to the Agenus Antibody (but for clarity not the Exploitation activities of Agenus partners, sublicensees or other Third Parties regardless of whether such Exploitation activities are done in coordination with Agenus).

Article 8. COMMERCIALIZATION

8.1 General. The Parties agree to discuss strategies and procedures regarding the Commercialization of the Licensed Products in the Field and in the Territory in accordance with Section 2 provided that, subject to Section 2.2(a), UroGen shall have the sole right in its sole discretion to make any final decisions relating to the Commercialization of the Licensed Products in the Field and in the Territory. Prior to […***…] of any […***…] for a Licensed Product, UroGen shall deliver to Agenus for review a […***…] and […***…] for conducting Commercialization activities (the "[…***…]"). The […***…] shall be […***…] from […***…] as UroGen shall deem […***…]. UroGen shall use Commercially Reasonable Efforts, […***…] , to […***…] Licensed Products in the Field and in the Territory (subject to Section 6.2) in accordance with the Commercialization Plan.

8.2 Branding. UroGen shall provide all proposed […***…] and related […***…] for […***…] ("[…***…]") to Agenus for review and discussion. All uses of the […***…] to identify and/or in connection with the […***…] of […***…] shall be in accordance with applicable Regulatory Approvals and all Applicable Laws. The Parties shall cooperate to ensure that UroGen's […***…] activities with respect to […***…] are consistent with […***…] for the Agenus Antibody, which […***…] will share with UroGen at UroGen's request. UroGen shall ensure that […***…] activities pursuant to this Agreement do not result in the infringement, dilution or other violation of any Third Party trademark or other proprietary rights, are permissible under Applicable Law in the applicable jurisdiction, and would not be deemed as immoral, scandalous, misleading and/or confusing to a reasonable consumer in such jurisdiction.

8.3 Promotional Materials. UroGen shall be responsible for the creation, preparation, production, reproduction and filing with the applicable Regulatory Authorities, of relevant written sales, promotion and advertising materials relating to Licensed Products ("Promotional Materials") for use in the Field and in the Territory. All such Promotional Materials shall be compliant with Applicable Law. Upon request, UroGen shall periodically share representative Promotional Materials with Agenus. Further, upon request, Agenus will periodically share representative samples of its own written sales, promotion and advertising materials relating to its own proprietary products that incorporate the Agenus Antibody (but for clarity not the sales, promotion or advertising materials of Agenus' partners, sublicensees or other Third Parties regardless of whether such materials are produced in coordination with Agenus). The Parties agree that, from […***…], they will use […***…] efforts to work with each other upon request to […***…] with those […***…], […***…], or other […***…] that have the […***…] to […***…], […***…] or […***…] the Agenus Antibody in their respective […***…] or in their […***…] and […***…] to discuss the […***…], […***…] or […***…] of the Licensed Product or their […***…] for the purpose of […***…] that may be useful to all […***…].

8.4 Sales and Distribution. UroGen shall be solely responsible for handling all returns of Licensed Products as well as all aspects of Licensed Product order processing, invoicing and collection, distribution, inventory and receivables of Licensed Products sold.

8.5 Recalls, Market Withdrawals or Corrective Actions. In the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Licensed Product sold during the Term, or in the event UroGen or any of its Affiliates or

Sublicensees determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, UroGen shall advise Agenus thereof by telephone, facsimile or e-mail as promptly as practicable, but in any event within twenty-four (24) hours and prior to public disclosure of such recall, market withdrawal or corrective action conducted. UroGen, in consultation with Agenus, shall decide whether to conduct a recall, market withdrawal or similar action and the manner in which any such recall shall be conducted. Agenus shall make available all of its pertinent records that may be reasonably requested by UroGen in order to effect a recall. […***…] shall […***…] all […***…] and […***…] that may be incurred in connection with any Licensed Product recall or withdrawal […***…] to the […***…] the recall is […***…] to Agenus Antibody supplied pursuant to Section […***…] in accordance with the Commercial Supply Agreement.

Article 9. FINANCIAL TERMS

9.1 Upfront Payment. On the Effective Date, UroGen shall pay to Agenus a one (1)-time nonrefundable and noncreditable payment of Ten Million Dollars ($10,000,000) in immediately available funds (the "Upfront Payment") by wire transfer, in accordance with wire instructions to be provided in writing by Agenus to UroGen on or before the Effective Date. The parties understand and agree that initiation of a […***…] on the […***…] does not […***…] that […***…] shall be […***…] on […***…]; provided, however, that if Agenus does not […***…] such […***…] on the […***…], UroGen will use its […***…] to ensure that Agenus […***…] the […***…] no later than the day […***…] the […***…]. For the avoidance of doubt, […***…] will not […***…] of its obligation to pay the […***…] on the […***…] so long as […***…] the […***…] no […***…] than the day […***…] the […***…].

9.2 Milestone Payments. Upon the first occurrence of any of the following milestones events with respect to a Licensed Product, UroGen shall pay Agenus the corresponding non-refundable, non-creditable amounts:

Milestone Event	**Payment**
(i)[…***…] of the […***…] in the […***…]	$[…***…]
(ii)[…***…] following completion of […***…]	$[…***…]
(iii)[…***…]	$[…***…]
(iv)[…***…] of […***…] or […***…] for […***…] in the […***…]	$[…***…]
(v)[…***…] or […***…] in the […***…]	$[…***…]
(vi)[…***…] of […***…] for […***…] in the […***…] or any one of the following: […***…], […***…], […***…], […***…] or […***…]	$[…***…]
(vii)[…***…] in the […***…] or any one of the following: […***…], […***…], […***…], […***…] or […***…]	$[…***…]
(viii)No later than […***…] after […***…] of the […***…] in which […***…] of all […***…] exceeds […***…]	$[…***…]
(ix)No later than […***…] after […***…] of the […***…] in which […***…] of all […***…] exceeds […***…]	$[…***…]
(x)No later than […***…] after […***…] of the […***…] in which […***…] of all […***…] exceeds […***…]	$[…***…]

For the sake of clarity, notwithstanding anything to the contrary, these milestone payments are intended to be made once whether or not there is one Licensed Product or more than one Licensed Product.

UroGen shall notify Agenus in writing within […***…] calendar days following the achievement of each event above ("Milestone Event") excluding Milestone Event […***…] which will require UroGen to […***…] Agenus in […***…] within […***…]. With respect to Milestone Events […***…] and […***…], such […***…] shall include either a […***…] that UroGen will proceed with […***…] of […***…] or a […***…] of […***…] pursuant to Section […***…] of this Agreement. Absent such […***…], UroGen shall be deemed to have made a decision to proceed with […***…] and the applicable […***…] shall be […***…] with respect to Milestone Event […***…] or […***…], as applicable. Following Agenus' receipt of such notice, Agenus shall invoice UroGen for the applicable payment and UroGen shall pay the amount indicated above within […***…] Business Days after delivery of such invoice. Upon achievement of any Milestone Event, any previously listed Milestone Event for which the applicable Milestone Payment has not been paid and should have been paid shall be due together with the Milestone Payment due in connection with such achieved Milestone Event. Further, if a […***…] does not constitute a […***…] at the time of its […***…], such […***…] shall be deemed a […***…] and the Milestone Event shall be deemed achieved (to the extent not previously achieved) on the […***…] for such […***…].

9.3 Royalties. Beginning on the First Commercial Sale of any UroGen Licensed Product in a country, and ending upon expiration or termination of the Term, UroGen will pay Agenus a royalty on Net Sales of the Licensed Product by UroGen and its Affiliates in such country, calculated by multiplying the applicable royalty rate by the aggregate amount of Annual Net Sales of such Licensed Product in the Territory during the applicable calendar year (the "Royalty"):

Annual Net Sales of Licensed Product	Royalty Rate
[…***…] of […***…]	14%
[…***…] of […***…]	[…***…]
[…***…] of […***…]	20%

9.4 Royalty Reductions.

(a) Patent Expiration. The Royalty due and payable to Agenus for Net Sales of a Licensed Product in a country in the Territory pursuant to Section 9.3 shall be reduced, on a Licensed Product-by-Licensed Product and country-by-country basis, by […***…]%) of the amount otherwise due on those Net Sales of Licensed Product in such country accrued at the earlier of (i) expiration of the last-to-expire Licensed Patent Rights in such country having a Valid Claim that Covers such Licensed Product or (ii) entry of the first corresponding Biosimilar Product that achieves a market share of more than […***…] ([…***…]%) in such country in a […***…] .

(b) Royalties Payable to Third Parties. If after the Effective Date and during the Term UroGen in its good faith judgment believes that it is necessary to obtain a license from any Third Party under any Patent Controlled by such Third Party in order to Exploit the Agenus Antibody in any Licensed Product (but not to Exploit any other component or process of a Licensed Product) in any country in the Territory in the Field, then UroGen may deduct from the

Royalty payment that would otherwise have been due with respect to Net Sales of such Licensed Product in such country in a particular calendar quarter an amount equal to […***…] ([…***…]%) of the royalties paid by UroGen to such Third Party pursuant to such license on sales of such Licensed Product in such country during such calendar quarter, subject to Section 9.4(c).

(c) Royalty Floor. Notwithstanding the foregoing, during any calendar quarter in the Term for a Licensed Product in a particular country in the Territory, the operation of Sections 9.4(a) and 9.4(b) shall not reduce the final Royalty rate to less […***…] ([…***…]%).

9.5 Sublicense Income. UroGen shall pay to Agenus […***…] ([…***…]%) of Sublicense Income received. Except as otherwise agreed to by the Parties in writing, Licensed Product sales by Sublicensees shall not be subject to, and shall not be included in the calculation of, Royalties payable to Agenus pursuant to Section 9.3, and all royalties collected by UroGen from Sublicensees shall constitute Sublicense Income. Notwithstanding the foregoing, the Parties agree that aggregate Sublicense Income amounts paid to Agenus in respect of a Sublicensee during any calendar quarter may not fall below the equivalent of […***…] ([…***…]%) of Net Sales by such Sublicensee during such calendar quarter (the "Minimum Sublicensee Payment").

9.6 Payment Terms and Royalty Statements.

(a) Allocation. The Upfront Payment and all Milestone Payments hereunder shall be deemed to be allocated in the manner set forth on Schedule 9.6 hereto.

(b) Payment Statements. Starting on the date of First Commercial Sale of a Licensed Product or earlier receipt of Sublicense Income by UroGen, its Affiliates or Sublicensees, UroGen shall furnish to Agenus a quarterly written report for each calendar quarter no later than […***…] following completion of each calendar quarter showing all payments due to Agenus pursuant to Sections 9.3 and 9.5 ("Payment Statement") for the relevant Quarterly Period including:

(i) the gross amount invoiced by UroGen or any of its Affiliates to any Third Party for the sale to such Third Party of Licensed Products;

(ii) the calculation of Net Sales, including the applicable Royalty rate and the type and amount of all deductions and offsets allocated with respect to such Net Sales;

(iii) the calculation of Sublicense Income payments due, including the type and amount of all Sublicense Income and reasonably detailed information on each Sublicensee's Net Sales;

(iv) if applicable, the exchange rate, as defined in 9.6(e) used for calculating any Royalties and the Sublicense Income; and

(v) such other particulars as are reasonably necessary for an accurate accounting of the payments due pursuant to this Agreement.

(c) Invoicing.

(i) Agenus shall invoice UroGen, its Affiliates and Sublicensees for all Royalties, Sublicensing Income payments and any other sums payable under this Agreement within […***…] days following the delivery of each Payment Statement for the applicable calendar quarter.

(ii) Agenus shall invoice UroGen, its Affiliates and Sublicensees for supply of Agenus Antibody: (x) as to […***…] ([…***…]%) of the estimated cost (as calculated pursuant to Section 3.1) at least […***…] days prior to the forecasted […***…], and (y) as to the remainder of such cost upon Delivery of such supply.

(iii) UroGen, its Affiliates and Sublicensees shall pay each invoice within […***…] days after receipt. Any overdue payments to Agenus by UroGen under this Agreement will accrue interest on a daily basis at a rate of […***…] per month, compounded monthly (or the maximum legal interest rate allowed by Applicable Law, if less) from and after such date and UroGen shall be responsible for reasonable legal fees and expenses incurred by Agenus in connection with the collection thereof.

(d) Cancellation. The Forecast for supply of Agenus Antibody may be adjusted in accordance with Section 6.1, and Agenus will use good faith efforts to accommodate all UroGen reasonable requests with respect to increases in supply requirements. With respect to any approved Forecast, UroGen, its Affiliates and Sublicensees may cancel supply of an amount of Agenus Antibody set forth therein provided such supply has a forecasted delivery date that is at least […***…] full calendar quarters after the date that such cancellation is requested. Cancellation on notice shorter than […***…] days' notice from the […***…] shall result in a cancellation fee calculated by […***…] (i) the […***…] of the cancelled supply […***…] (ii) the […***…] set forth below, based on the date of notice of cancellation:

- Notice of cancellation […***…] days and […***…] days […***…]
- Notice of cancellation […***…] days and […***…] days […***…]
- Notice of cancellation […***…] days […***…]

(e) Currency. UroGen, its Affiliates and Sublicensees shall make all payments in US dollars by wire transfer of immediately available funds to a bank account to be designated in writing by Agenus. For the purpose of converting the local currency in which any royalties or other payments arise into US dollars, the rate of exchange to be applied ("Exchange Rate") shall be the rolling three (3) month average exchange rate as published by OANDA.

9.7 Audit Rights. For a period of three (3) years following each calendar year, UroGen will keep, and will cause its Affiliates and sublicensees to keep, full, true and accurate books and records limited to all particulars relevant to the calculation of Net Sales of Licensed Products and Sublicense Income payments (including the relevant statements obtained from its Affiliates and Sublicensees) in sufficient detail to enable Agenus to verify the amounts payable to it or by it under this Agreement. Agenus will have the right, not more than once during any calendar year and at its own expense, to have the books and records of UroGen and its Affiliates audited by an independent certified public accounting firm reasonably acceptable to both Parties. Audits under this Section 9.6(c) will be conducted at the principal place of business of the financial personnel with responsibility for preparing and maintaining such records, during normal business hours, upon at least thirty (30) calendar days' prior written notice, and for the

sole purpose of verifying amounts payable by or to Agenus under this Agreement. Agenus will cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with the audited Person(s). If the audit demonstrates that the UroGen has not paid all royalties owing to Agenus hereunder, UroGen will pay any such underpayment to Agenus promptly and in any event within ten (10) Business Days thereafter. Further, if the amount at issue is greater than […***…] of the amount owed to Agenus with respect to the audited period, then UroGen will reimburse Agenus for the reasonable out-of-pocket cost of the audit.

9.8 Taxes. All payments due to Agenus from UroGen pursuant to this Agreement will be paid without any deduction for any VAT, withholding or other taxes that UroGen or its Affiliates or sublicensees may be required to pay to any tax authorities. Agenus will use reasonable efforts to assist UroGen to minimize and obtain all available exemptions from such VAT, withholding or other taxes. If UroGen is required to pay or Agenus is required to report, any such VAT, withholding or other taxes, then UroGen will increase the amount of any and all payments under this Agreement upon which such VAT, withholding or other taxes are due as may be necessary so that after making any payments in respect of any such VAT, withholding or other taxes Agenus receives an amount equal to the sum that it would have received had no such VAT, withholding or other taxes been required to be paid on such amount. UroGen will promptly provide to Agenus applicable receipts evidencing payment of such VAT, withholding or other taxes and other documentation reasonably requested by Agenus.

Article 10. INTELLECTUAL PROPERTY

10.1 Ownership of Program Technology. Agenus shall own any and all Inventions made (i) solely, as between the Parties, by employees, officers, contractors, consultants or agents ("Representatives") of Agenus ("Agenus Improvements"), and any Patent Rights therein ("Agenus Improvement Patent Rights") and (ii) by Representatives of Agenus in conjunction with Representatives of UroGen ("Joint Improvements"), and any Patent Rights therein ("Joint Improvement Patent Rights"). UroGen hereby assigns and agrees to assign to Agenus all its right, title and interest in and to the Joint Improvements and the Joint Improvement Patent Rights. UroGen shall own any and all Inventions made solely, as between the parties, by Representatives of UroGen ("UroGen Improvements"), and any Patent Rights therein ("UroGen Improvement Patent Rights"). All Agenus Improvement Patent Rights and Joint Improvement Patent Rights that are necessary or reasonably useful for the Development, Manufacture or Commercialization of the Licensed Product (the "Licensed Improvement Patent Rights") shall be included in the Licensed Patent Rights licensed to UroGen hereunder.

10.2 Ownership Disputes. The Parties will attempt in good faith to resolve any disputes regarding ownership of Inventions, and all Patent Rights and any other intellectual property rights therein. In the event the Parties are unable to resolve such dispute through escalation to Senior Executives of the Party, such dispute will be resolved by litigation in a court of competent jurisdiction.

10.3 Prosecution, Enforcement and Defense of Patent Rights.

(a) Agenus shall have the first right, at its discretion, to Prosecute, enforce and defend throughout the world any Agenus Improvement Patent Rights. In any jurisdiction

where Agenus chooses not to Prosecute Agenus Improvement Patent Rights, UroGen shall have the right, subject to the terms and conditions of this Agreement and any retained rights of Agenus' upstream licensors, […***…] and […***…], under the […***…] Agreement, to cause Agenus to Prosecute such Agenus Improvement Patent Rights, provided that (i) such Prosecution would not in Agenus' reasonable determination adversely affect Agenus' Patent Rights strategy and (ii) UroGen shall reimburse Agenus for all reasonable out of pocket expenses incurred in connection with such Prosecution. UroGen in its sole discretion may provide notice that it no longer wishes to reimburse such Prosecution expenses and Agenus shall either cease to incur additional expenses in connection with such Prosecution or shall continue at Agenus' own expense.

(b) UroGen shall have the first right, at its discretion, to Prosecute throughout the world any Joint Improvement Patent Rights, provided that if Agenus reasonably determines in good faith that Prosecution of any Joint Improvement Patent Rights as proposed by UroGen would reasonably be expected to materially and adversely impact the Agenus IP, then Agenus shall have the right to cause UroGen to Prosecute or abandon such Joint Improvement Patent Rights in accordance with Agenus' Patent Rights strategy. In any jurisdiction where UroGen chooses not to Prosecute Agenus Improvement Patent Rights, Agenus shall have the right, subject to the terms and conditions of this Agreement, to cause UroGen to Prosecute such Joint Improvement Patent Rights, provided that Agenus shall reimburse UroGen for all reasonable out of pocket expenses incurred in connection with such Prosecution. Agenus in its sole discretion may provide notice that it no longer wishes to reimburse such Prosecution expenses and UroGen shall either cease to incur additional expenses in connection with such Prosecution or shall continue at UroGen's own expense. The Parties shall work together to agree upon the strategy to enforce and/or defend any Joint Improvement Patent Rights. Approval of both Parties in writing shall be required prior to the enforcement and/or defense of any Joint Improvement Patent Rights.

(c) UroGen shall have the sole right, at its discretion, to Prosecute, enforce and defend throughout the world any UroGen Improvement Patent Rights.

(d) With respect to Licensed Improvement Patent Rights, the Party responsible for Prosecution shall consult with and keep the other Party fully informed of material issues relating to the Prosecution of such Patent Rights, and shall furnish to the other Party copies of documents relevant to such Prosecution in sufficient time prior to the filing of such document to allow for review and comment by the other Party and, to the extent possible in the reasonable exercise of its discretion, the Party responsible for Prosecution shall incorporate all of such comments.

(e) Notwithstanding anything in this Agreement to the contrary, Agenus shall use Commercially Reasonable Efforts to pursue and maintain Licensed Patent Rights in the jurisdictions indicated in Exhibit C.

10.4 Cooperation. Each Party hereby agrees to provide to the other Party all reasonable assistance and cooperation reasonably necessary to enable such other Party to undertake Prosecution, enforcement and defense of Patent Rights as contemplated by this Agreement, including: (a) to cause its employees, and to use reasonable efforts to cause its

licensees, sublicensees, independent contractors, agents and consultants, to be reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives); (b) to endeavor in good faith to coordinate its efforts with the other Party to minimize or avoid interference with the Prosecution, enforcement and defense of the other Party's Patent Rights that are subject to this Agreement; (c) to provide any necessary powers of attorney and executing any other required documents or instruments required to give effect to the terms of this Agreement; and (d) to cause its employees, and to use reasonable efforts to cause its licensees, sublicensees, independent contractors, agents and consultants, to provide any and all information required for the other Party to comply with its relevant duties of disclosure as required by Applicable Law in the United States or any other jurisdiction.

10.5 Challenges to Licensed Patent Rights. Neither UroGen nor any of its Affiliates or Sublicensees shall institute or actively participate as an adverse party in, or otherwise provide material support to, any legal action or administrative proceeding in the Territory to invalidate or limit the scope of any Licensed Patent Right claim or obtain a ruling that any Licensed Patent Right claim is unenforceable or not patentable or that any Licensed Product does not infringe one or more claims of any Licensed Patent Right ("Licensed Patent Right Challenge") until the expiration of eighty (80) Business Days after UroGen serves on Agenus written notice of UroGen's or any UroGen Affiliate's or Sublicensee's intention to bring or participate in a Licensed Patent Right Challenge. UroGen shall also provide to Agenus a complete written disclosure of each and every basis then known to UroGen or any UroGen Affiliate or Sublicensee for the Licensed Patent Right Challenge and shall provide Agenus with a copy of any document or publication that UroGen or any UroGen Affiliate or Sublicensee may use in connection with the Licensed Patent Right Challenge. UroGen's failure to comply with this provision will constitute a material breach of this Agreement. If a claim of a Licensed Patent Right is adjudged to be not invalid by a governmental authority of competent jurisdiction, the Royalty rates and Sublicense Income payments due Agenus under this Agreement will be doubled with respect to Net Sales of Licensed Products occurring and sublicenses executed on or after the initiation of the Licensed Patent Right Challenge.

10.6 Responsibility. It is understood and agreed that UroGen is solely responsible for searching for, identifying, evaluating or obtaining access to, Patent Rights Controlled by Third Parties (expressly excluding the Agenus IP) that may be infringed by the Development, Manufacture or Commercialization of the Licensed Product in accordance with this Agreement. Agenus shall have no responsibility or liability to UroGen with respect to such Third Party Patent Rights. In the event that either Party receives any notice of potential infringement of any Third Party Patent Rights as a result of, or otherwise impacting, the Exploitation of the Licensed Product, it shall promptly notify the other Party.

Article 11. CONFIDENTIALITY

11.1 Confidential Information.

(a) Obligations. In connection with the performance of their respective obligations under this Agreement, each Party (the "Disclosing Party") may, itself or through its Affiliates or designees, disclose certain Confidential Information to the other Party (the "Recipient") or its Affiliates or designees. During the Term and for a period of ten (10) years

thereafter, except as provided herein, the Recipient shall maintain all Confidential Information of the Disclosing Party in strict confidence and shall not use such Confidential Information for any purpose, except that the Recipient may disclose or permit the disclosure of any such Confidential Information to its Affiliates and sublicensees, or its or their respective directors, officers, employees, consultants, advisors and agents, on a need-to-know basis, who in each case are obligated to maintain the confidential nature of such Confidential Information on terms no less stringent than those of this Article 11. In addition, the Recipient may use or disclose Confidential Information of the Disclosing Party in exercising the Recipient's rights hereunder or to fulfill its obligations and/or duties hereunder; *provided* that such disclosure is made to a Person who is obligated to confidentiality and non-use obligations no less rigorous than those of this Article 11.

(b) Exceptions. The obligations of confidentiality and non-use set forth above shall not apply to the extent that the Recipient can demonstrate that the relevant Confidential Information of the Disclosing Party: (i) was publicly known prior to the time of its disclosure under this Agreement; (ii) became publicly known after the time of its disclosure under this Agreement other than through acts or omissions of the Recipient, its Affiliates or sublicensees in violation of this Agreement; (iii) is or was disclosed to the Recipient or any of its Affiliates by a Third Party having no obligation of confidentiality with respect to such Confidential Information; (iv) is independently developed by the Recipient or any of its Affiliates without access to such Confidential Information as evidenced by written records; or (v) was known by Recipient or any of its Affiliates at the time of receipt from Disclosing Party or any of its Affiliates as documented by Recipient's or any of its Affiliate's records.

(c) Mandatory Disclosures. In addition, the Recipient or any of its Affiliates may disclose Confidential Information of the Disclosing Party to the extent necessary to comply with Applicable Law or a court or administrative order; *provided* that the Recipient provides to the Disclosing Party prior written notice of such disclosure, to the extent reasonably possible, and that the Recipient takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and, to the extent possible, to minimize the extent of such disclosure.

(d) Permitted Disclosures. In addition, a Party may disclose (and, in connection therewith, use) Confidential Information of the other Party, if such disclosure:

(i) subject to the provisions of Section 11.2(a), is made to Regulatory Authorities solely to the extent necessary to gain or maintain approval (A) to conduct Clinical Trials of the Licensed Product in accordance with the terms and conditions of this Agreement, (B) by Agenus (with such disclosure right only applicable to Agenus) to Manufacture or Commercialize the Agenus Antibody or (C) by UroGen (with such disclosure right only applicable to UroGen), to Develop, Manufacture or Commercialize the Licensed Product as provided hereunder;

(ii) is made to its Affiliates, sublicensees, agents, consultants, or other Third Parties (including service providers) in connection with a bona fide transaction for an assignment of this Agreement, a licensing transaction related to the Agenus Antibody or Licensed Product under this Agreement, a loan, financing or investment, or an acquisition, merger, consolidation or similar transaction (or for such Persons to determine their interest in

performing such activities or entering into such transactions), in each case on the condition that any Third Parties to whom such disclosures are made agree to be bound by confidentiality and non-use obligations no less rigorous than those contained in this Agreement; or

(iii) consists entirely of Confidential Information previously approved by the Disclosing Party for disclosure by the Recipient.

(e) Responsibility. Each Recipient shall be responsible for any breach of the obligations of this Section 12.1 by any Person to whom such Recipient or its Affiliate disclosed the Disclosing Party's Confidential Information.

11.2 Publicity; Terms of this Agreement.

(a) Publicity. Except as required by judicial order or Applicable Law, or as set forth below, neither Party may make any public announcement or other public disclosure or issue any press release referring to this Agreement, the transactions contemplated hereby or a Licensed Product, or relating to any Inventions or Patent Rights therein that are owned or co-owned by the other Party and that constitute Confidential Information, without the prior approval of the other Party. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least […***…] prior to the date on which such Party would like to make the public announcement. The contents of any previously approved disclosure shall not require subsequent approval provided that the duplicated language is substantially unmodified and is presented in its original context. Notwithstanding the foregoing, either Party may use the other Party's name to make factual public statements as to the existence of this Agreement and the relationship between the Parties. Except as expressly set forth herein, neither Party may use the name or trademark of the other Party or its employees in any press release, advertising or promotional materials without the prior express written permission of the other Party.

(b) Regulatory Reporting. Notwithstanding the terms of this Article 11, either Party will be permitted to disclose the existence and terms of this Agreement to the extent required or advisable, based on the advice of such Party's legal counsel, to comply with Applicable Law, including the rules and regulations promulgated by the US Securities and Exchange Commission ("SEC") or any other governmental authority. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 11.2(a), to the extent practicable given the circumstances of the disclosure, the Parties will consult with each other on the terms of this Agreement for which confidential treatment will be sought in making any such disclosure.

11.3 Publications. UroGen shall have the right to make disclosures pertaining to a the Licensed Product in Publications in accordance with the following procedure: UroGen shall provide Agenus with an advance copy of the proposed Publication, and Agenus shall then have […***…] prior to submission of any Publication in which to recommend any changes it reasonably believes are necessary to preserve any Patent Rights or Know-How belonging in whole or in part to Agenus. If Agenus informs UroGen that such Publication, in the non-publishing Party's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned by or licensed, in whole or in part, to Agenus, or on any Know-How which is Confidential Information of Agenus, UroGen shall delay or prevent such

Publication as follows: (i) with respect to an Invention, such Publication shall be delayed sufficiently long (not to exceed an additional […***…]) to permit the timely preparation and filing of a patent application; and (ii) with respect to Know-How which is Confidential Information of Agenus, such Know-How shall be deleted from the Publication.

11.4 Return of Confidential Information.

(a) Return. Upon the expiration or termination of this Agreement, upon request, the Recipient will return to the Disclosing Party or destroy all Confidential Information, materials (including the Agenus Antibody) and embodiments of Know-How received by the Recipient or any of its Affiliates from the Disclosing Party or any of its Affiliates (and all copies and reproductions thereof). In addition, the Recipient and its Affiliates will destroy: (a) any notes, reports or other documents prepared by the Recipient which contain Confidential Information of the Disclosing Party; and (b) any Confidential Information of the Disclosing Party (and all copies and reproductions thereof) which is in electronic form or cannot otherwise be returned to the Disclosing Party.

(b) Destruction. Nothing in this Section 11.4 will require the alteration, modification, deletion or destruction of archival tapes or other electronic back-up media made in the ordinary course of business; *provided* that the Recipient and its Affiliates will continue to be bound by its obligations of confidentiality and other obligations under this Article 11 with respect to any of the Disclosing Party's Confidential Information contained in such archival tapes or other electronic back-up media. Any requested destruction of the Disclosing Party's Confidential Information will be certified in writing to the Disclosing Party by an authorized officer of the Recipient supervising such destruction.

(c) Retained Copy. Notwithstanding the foregoing, (i) the Recipient and its Affiliates may retain one copy of the Disclosing Party's Confidential Information solely for the purpose of determining the Recipient's continuing obligations under this Article 11 and (ii) the Recipient and its Affiliates may retain the Disclosing Party's Confidential Information and its own notes, reports and other documents to the extent reasonably required (x) to exercise the rights of the Recipient expressly surviving expiration or termination of this Agreement; (y) to perform the obligations of the Recipient expressly surviving expiration or termination of this Agreement; or (z) for regulatory or archival purposes. Notwithstanding the return or destruction of the Disclosing Party's Confidential Information, the Recipient shall continue to be bound by its obligations of confidentiality and other obligations under this Article 11.

Article 12. TERM AND TERMINATION

12.1 Term. The term of this Agreement (the "Term") shall commence on the Effective Date and, unless extended by mutual agreement of the Parties or earlier terminated in accordance with Section 12.2, shall continue in full force and effect for each Licensed Product and country in the Territory on a Licensed Product-by-Licensed Product and country-by-country basis until the later of (a) expiration of the last to expire Valid Claim of a Licensed Patent Right that Covers a Licensed Product in such country and (b) fifteen (15) years after the First Commercial Sale of

the Licensed Product in such country.

12.2 Termination.

(a) For Material Breach. Either Party may, without prejudice to any other remedies available to it in law or equity, terminate this Agreement in the event that the other Party has materially breached a provision under this Agreement. The breaching Party will have […***…] days after written notice thereof was provided to the breaching Party by the non-reaching Party to remedy such default. Any such termination will become effective at the end of such […***…] day period unless the breaching Party has cured any such breach or default prior to the expiration of such […***…] day period or the parties have agreed otherwise.

(b) For Convenience. UroGen shall have the right to terminate this Agreement for any reason on one hundred eighty (180) days' written notice to Agenus, which termination shall be effective on the later of (i) expiration of such notice period or (ii) completion of all wind-down activities and […***…] of all […***…] to Agenus.

(c) For Abandoned Development. If at any time prior to the First Commercial Sale of any Licensed Product, (i) UroGen has substantially ceased to conduct Development of Licensed Products for nine (9) consecutive months, and (ii) such inactivity was not in response to a requirement imposed by a Regulatory Authority and was not due to a Force Majeure event, and (iii) Agenus has complied with its obligations under this Agreement during such period, then UroGen shall be deemed to have abandoned Development of Licensed Products ("Abandoned Development"). In the event of Abandoned Development, either Party may terminate this Agreement on sixty (60) days' written notice to the other Party.

12.3 Consequences of Termination. In the event that this Agreement is terminated pursuant to Section 12.2, the following provisions shall apply:

(a) Supply. Agenus shall have no further obligation to supply to UroGen, its Affiliates or their respective Sublicensees and Subcontractors with Agenus Antibody.

(b) Rights of Reference. The right of reference under Section 7.6(a) shall terminate automatically and the right of reference under Section 7.6(b) shall survive indefinitely.

(c) License Termination. Within thirty (30) days after termination or expiration of this Agreement, UroGen shall:

(i) Submit a Payment Statement to Agenus, and any payments due Agenus will become immediately payable with submission of the final Payment Statement;

(ii) Immediately cease all activities concerning, including all practice and use of, the Licensed Patent Rights and Licensed Know-How, except as expressly permitted under Section 12.3(e) and

(iii) Return to Agenus all documents and tangible materials (and any copies) containing, reflecting, incorporating, or based on Agenus' Confidential Information; permanently erase such Confidential Information from its computer systems; and certify in

writing to Agenus that it has complied with the requirements of this Section 12.3(c).

(d) Sublicenses. Upon any termination of this Agreement, any sublicense that was in effect immediately prior to such termination, and such Sublicensees' rights under such sublicenses, will survive termination, with Agenus as the Sublicensee's direct licensor; provided that such Sublicensee: (i) is not the cause of a breach that resulted in the termination of this Agreement and is not itself in breach of obligations under its sublicense or this Agreement other than such obligations as neither affect nor relate to Agenus, the Licensed Patent Rights, or the Licensed Know-How; and (ii) within sixty (60) days after termination of this Agreement provides written notice to Agenus of its election to continue its sublicense as a direct license from Agenus and of its agreement to assume all obligations (including obligations for payment) contained in its sublicense agreement as direct obligations of the Sublicensee to Agenus. Any sublicense granted by UroGen must contain provisions corresponding to those of this section regarding termination and the conditions of the continuation of any sublicense.

(e) Inventory. If termination occurs at any time after Regulatory Approval of the Licensed Product, then for a period of […***…] after the effective date of the expiration or earlier termination of this Agreement (other than termination by Agenus pursuant to Section 12.2(a) or Section 12.2(c)) (the "Sell-Off Period"), UroGen will have the right to sell or otherwise dispose of all existing Licensed Products in its possession and to complete the manufacture of and sell all Licensed Products in the course of manufacture as of the effective date of such expiration or termination. UroGen shall ensure that all sales of Licensed Products during the Sell-Off Period are in accordance with the applicable terms and conditions of this Agreement, including the Royalty and reporting obligations under Article 9.

12.4 Survival in All Cases. Termination of this Agreement will be without prejudice to or limitation on any other remedies available to nor any accrued obligations of either Party. In addition, Sections 7.6(b), Sections 9.6(c)–9.8 Article 10, Article 11, Sections 12.3–12.4, Sections 13.4–13.5, Article 14 and Sections 15.1, 15.4, 15.7 and 15.10, together with related definitions, will survive any expiration or termination of this Agreement.

Article 13. REPRESENTATIONS AND WARRANTIES

13.1 Mutual Representations and Warranties. In addition to the representations and warranties set forth elsewhere in this Agreement, each Party represents, warrants, and covenants to the other Party that:

(a) it is duly incorporated or organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

(b) the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and shall not violate (i) such Party's organizational documents, (ii) any agreement, instrument or contractual obligation to which such Party is a party or by which it is bound, (iii) any requirement of any Applicable Law, or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to

such Party;

(c) this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium or other laws relating to or affecting creditors' rights generally and by general equitable principles; and

(d) neither Party, nor any of such Party's employees, officers, independent contractors, consultants or agents who will render services relating to a Licensed Product: (i) has ever been debarred or is subject to debarment or received notice from FDA of an intent to debar or has been convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a; or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under said Section 335a. If during the Term a Party has reason to believe that it or any of its employees, officers, independent contractors, consultants or agents rendering

services relating to a Licensed Product: (x) is or will be debarred or convicted of a crime for which a person or entity could be debarred under 21 U.S.C. Section 335a; or (y) is or will be under indictment for a crime for which a person or entity could be debarred under Section 335a, then such Party shall immediately notify the other Party of same in writing; and

(e) as of the Effective Date, it is not currently bound by any agreement with any Third Party, or by any outstanding order, judgment, or decree of any court or administrative agency that restricts it from granting to such other Party the rights set forth in this Agreement.

13.2 Additional Representations of Agenus. Agenus represents and warrants and covenants to UroGen that, as of the Effective Date:

(a) Agenus shall Manufacture and supply Agenus Antibody pursuant to Section 3.1 in accordance with, and subject to the terms and conditions of, this Agreement and, as applicable, the SDEA and the Quality Agreement.

(b) Agenus has not […***…] to any […***…], and to Agenus' knowledge […***…] and […***…] have not […***…] to any […***…], any […***…] or other […***…] under the […***…] and […***…] that are in conflict with the terms and conditions of this Agreement.

(c) The Patent Rights identified on Exhibit A and the Licensed Know-How constitute all rights Controlled by Agenus as of the Effective Date that are necessary for the Exploitation of the Agenus Antibody as a monotherapy in the Field in the Territory.

(d) To the knowledge of Agenus, the use of the Agenus Antibody in Agenus' business as currently conducted does not infringe the intellectual property rights of any Third Party.

(e) *Ownership; Sufficiency*. Agenus holds the right to grant UroGen the exclusive license granted pursuant to Section 5.1(a) under the Licensed Patent Rights and has […***…] to […***…], jointly with […***…] and […***…], free and clear of any […***…], […***…], […***…], […***…] or any other […***…] in the […***…] in the […***…] of all […***…] have been […***…] and […***…]. The […***…] listed on […***…] are […***…] to the […***…] between […***…] and […***…] of […***…]. To the knowledge of Agenus, all […***…] are […***…] and […***…]. Agenus has no […***…] of […***…] that may […***…] the […***…] or […***…] of any […***…]. All […***…], […***…], […***…] and other […***…] that are or have […***…] with […***…] have been […***…] by or on […***…]. Provided that […***…] is in […***…] with this […***…], […***…] will have any […***…] to […***…] to […***…] of […***…].

(f) *Prosecution Matters*. There are no inventorship challenges, opposition or nullity proceedings or interferences declared, commenced or provoked, or to the knowledge of Agenus, threatened, with respect to any […***…]. Agenus and, to the knowledge of Agenus, entities involved in the prosecution of the […***…] (such as […***…], […***…], as well as all attorneys, inventors, agents and others involved in prosecution) are in compliance with their duty of candor and disclosure to the United States Patent and Trademark Office and any foreign patent office requiring such disclosure with respect to all patent applications filed by or on behalf of Agenus and have made no material misrepresentation in such applications. Agenus has no knowledge of any information that would preclude Agenus or any […***…] from having clear title to the […***…].

(g) *Protection Measures*. Agenus has taken reasonable measures to protect the proprietary nature of the Licensed Patent Rights and Licensed Know-How, and to maintain in confidence all trade secrets and information comprising a part thereof. To the […***…] of […***…], there has been no: (i) […***…] of any […***…] in the […***…], […***…] or […***…] of […***…], or (ii) […***…] of […***…] wherein […***…] to the […***…] has been […***…] without […***…] to a […***…].

(h) […***…]. There has been no […***…], […***…] or […***…], or, to the […***…] of […***…], […***…] of any of the […***…] ([…***…] any […***…] that a […***…] under any […***…] is or may be […***…]) in […***…] the […***…], […***…] by […***…] any […***…], […***…] or […***…] of any […***…] or […***…] rights of any […***…], and there […***…] or […***…] for […***…] or […***…] by […***…] from any […***…], […***…], […***…], […***…] or any other […***…] in […***…] with the […***…].

(i) *Infringement of Agenus' Rights*. To the knowledge of Agenus, no third party (including, without limitation, any current or former employee, founder, inventor of any of the Licensed Patent Rights, or consultant to Agenus) is infringing, violating or misappropriating any of the Licensed Patent Rights or Licensed Know-How and no third party has any right to Commercialize the Licensed Patent Rights and Licensed Know-How in the Field in the Territory or to conduct human clinical trials of any Licensed Product without the prior written consent of Agenus, its Affiliates or sublicensees, as applicable.

(j) *Employee and Inventor Assignments*. Each employee of Agenus and its Affiliates, and any Agenus inventor of the Licensed Patent Rights has executed a valid and binding written agreement expressly assigning to Agenus, or an Affiliate thereof, as appropriate, all right, title and interest in any inventions and works of authorship, whether or not patentable, invented, created, developed, conceived and/or reduced to practice during the term of such employee's employment and all Patents and Know-How rights therein. An […***…] was […***…] with regard to the […***…] and to […***…], the […***…] is […***…].

(k) […***…]. […***…] has neither […***…], […***…] nor […***…] any […***…], […***…], […***…] or […***…] from any […***…], […***…], […***…] or […***…] or […***…] or […***…] in […***…] with the […***…] or […***…] of the […***…]. To the […***…] of […***…], […***…] and […***…] have […***…], […***…] nor […***…] any […***…], […***…], […***…] or […***…] from any […***…], […***…], […***…] or […***…] or […***…] or […***…] in […***…] with the […***…] or […***…] of the […***…].

(l) […***…] that (i) the […***…] it is […***…] in this Section […***…] to […***…] are […***…] to […***…] to […***…] this […***…] and […***…] the […***…]; and (ii) […***…] is […***…] these […***…] to its […***…]. In the […***…] that a […***…] of […***…] in a […***…] and […***…] that […***…] regarding these […***…], […***…] shall be […***…] to […***…] and […***…] pursuant to Section […***…] to the […***…] of any […***…] from such […***…], along with any other […***…] or […***…] to such […***…]. For the avoidance of doubt, […***…] shall have […***…] to […***…] for any […***…] of this Section […***…] a […***…] and […***…] from a […***…] of […***…] that […***…].

13.3 Additional Representations of UroGen. UroGen represents, warrants and covenants to Agenus that:

(a) It shall not, and shall ensure that its Affiliates and Sublicensees shall not, engage in any Exploitation activities relating to the Licensed Products or the Agenus Antibody outside of the Territory or outside of the Field.

(b) It has not received any notice or threat of any claim, suit, action, or proceeding, and has no knowledge or reason to know of any information, that could: (a) invalidate or render unenforceable any claim of any Licensed Patent Right; (b) prove that the Licensed Products are not covered by any claim of any Licensed Patent Right; or (c) cause any claim of any Licensed Patent Right to fail to issue or be materially limited or restricted as compared with its currently pending scope.

(c) Neither UroGen nor its Affiliates, nor any Person working on any Clinical Trial on behalf of UroGen or its Affiliates, has been disqualified or has received notice of disqualification from receiving investigational drugs or test articles pursuant to 21 C.F.R. §§ 312.70 or 812.119, 21 C.F.R. §§ 56.120, 56.121 or 21 C.F.R. Part 58, or sanctioned by a Federal Health Care Program (as defined in 42 U.S.C. Sec. 1320 a-7b(f)), including, but not limited to the federal Medicare or a state Medicaid program, or suspended, excluded, sanctioned or otherwise declared ineligible from any federal agency or program, or has any reason to believe such disqualification, suspension, exclusion, sanction or ineligibility procedures could be

instituted. UroGen shall ensure all Persons working on any Clinical Trial will disclose such information pertaining to such disqualification, suspension, exclusion, sanction or ineligibility to UroGen. In the event that during the Term, any such Person (i) becomes so disqualified, suspended, excluded, sanctioned or ineligible, or (ii) receives notice of an action or threat of an action with respect to such disqualification suspension, exclusion, sanction or ineligibility, UroGen shall notify Agenus immediately of the same.

13.4 DISCLAIMER OF WARRANTIES. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY DISCLAIMS ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR THAT ANY AGENUS ANTIBODY OR LICENSED PRODUCT ARE FREE FROM THE RIGHTFUL CLAIM OF ANY THIRD PARTY, BY WAY OF INFRINGEMENT OR OTHERWISE. AGENUS CANNOT, AND DOES NOT, GUARANTEE THAT ANY AGENUS ANTIBODY OR LICENSED PRODUCT WILL BE SUCCESSFULLY DEVELOPED OR COMMERCIALIZED.

13.5 EXCLUSION OF CONSEQUENTIAL AND INDIRECT DAMAGES. TO THE FULLEST EXTENT PERMITTED BY LAW, NEITHER PARTY WILL BE LIABLE TO THE OTHER OR ANY OTHER PERSON FOR ANY INJURY EXCLUDING ANY INDEMNITY COVERAGE SET FORTH IN ARTICLE 14 TO OR LOSS OF GOODWILL, REPUTATION, BUSINESS, PRODUCTION, REVENUES, PROFITS, ANTICIPATED PROFITS, CONTRACTS OR OPPORTUNITIES (REGARDLESS OF HOW THESE ARE CLASSIFIED AS DAMAGES), OR FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, OR ENHANCED DAMAGES WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, PRODUCT LIABILITY OR OTHERWISE (INCLUDING THE ENTRY INTO, PERFORMANCE OR BREACH OF THIS AGREEMENT), REGARDLESS OF WHETHER SUCH LOSS OR DAMAGE WAS FORESEEABLE OR THE PARTY AGAINST WHOM SUCH LIABILITY IS CLAIMED HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.

Article 14. INDEMNIFICATION

14.1 By UroGen. UroGen agrees, at UroGen's cost and expense, to defend, indemnify and hold harmless Agenus and its Affiliates, sublicensees, and their respective directors, officers, employees, licensors and agents, and its and their respective successors, heirs and assigns (the "Agenus Indemnified Parties") from and against any and all losses, liabilities, costs, damages, fees or expenses (including reasonable legal fees, expert fees and expenses of litigation) ("Losses") arising out of any claims, demands, suits, actions, or judgments by any Third Party ("Claims") to the extent resulting from (a) any […***…] or […***…] of UroGen or a UroGen Indemnified Party in connection with UroGen's performance of its obligations or exercise of its rights under this Agreement, including without limitation any […***…], […***…], […***…], or other […***…] by Licensee or any of its Affiliates or Sublicensees or any of the foregoing Persons' respective […***…] of […***…] or any other […***…] by […***…] of […***…] or […***…]; (b) any […***…] by UroGen of any […***…], […***…], […***…] set forth in this Agreement; or (c) […***…] to […***…] with […***…] or obtain any […***…] or […***…] necessary to […***…] the […***…]; in each case, […***…] to the […***…] such

Claims result from a […***…] for which […***…] is obligated to […***…] under Section 14.2.

14.2 By Agenus. Agenus agrees, at Agenus' cost and expense, to defend, indemnify and hold harmless UroGen and its Affiliates, and their respective directors, officers, employees and agents, and its and their respective successors, heirs and assigns (the "UroGen Indemnified Parties") from and against any and all Losses (except for Losses associated with non-conforming, damaged or destroyed Agenus Antibody, the remedies of which are set forth in Article 4) arising out of any Claims to the extent resulting from (a) any […***…] or […***…] of Agenus or a Agenus Indemnified Party in connection with Agenus' […***…] of the […***…]; (b) any […***…] by Agenus of any […***…], […***…], […***…] or […***…] set forth in this Agreement; or (c) […***…] to […***…] with […***…] […***…]; in each case, except to the[…***…] extent such Claims result from a […***…] for which […***…] is obligated to […***…] under Section 14.1.

14.3 Process. In the event of any such Claim against any of the Agenus Indemnified Parties or UroGen Indemnified Parties (each, an "Indemnified Party") by any Third Party, the Indemnified Party will promptly notify the indemnifying Party in writing of the Claim; provided, however, that the failure of an Indemnified Party to give such notice shall not diminish the indemnification obligation of the indemnifying Party under this Article 14 except to the extent that the indemnifying Party's ability to defend against the same is materially prejudiced thereby. The indemnifying Party shall assume direction and control of the defense, litigation, settlement, appeal or other disposition of such Claim with counsel selected by the indemnifying Party and reasonably acceptable to the Indemnified Party. The Indemnified Party will cooperate with the indemnifying Party and may, at its option and expense, be separately represented in any such action or proceeding; provided, however, that the Indemnified Party's legal fees and expenses shall be indemnifiable Losses if the interest of the Indemnified Party and those of the indemnifying Party with respect to such Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law or ethical rules. The indemnifying Party shall not be responsible for indemnification of any Claims compromised or settled without its prior written consent. Notwithstanding the foregoing, the indemnifying Party will not settle a Third Party Claim without the prior written consent of the Indemnified Party, if such settlement would impose any monetary obligation on the Indemnified party or require the Indemnified Party to submit to an injunction or other equitable relief or if such settlement admits the fault of the Indemnified Party. Notwithstanding anything to the contrary above, in the event of any such Claim against an Indemnified Party by a governmental authority asserting criminal liability or seeking an injunction or similar against the Indemnified Party, the Indemnified Party will have the right to control the defense, litigation, settlement, appeal or other disposition of the Claim at the indemnifying Party's expense.

14.4 Insurance.

(a) UroGen Insurance. UroGen shall maintain appropriate clinical trial insurance limits of $[…***…] each occurrence and $[…***…] in the aggregate. Clinical trial insurance shall be maintained for the duration of the Clinical Trials and for at least five (5) years thereafter. No later than the First Commercial Sale of a Licensed Product, UroGen shall, at its sole cost and expense, obtain, pay for, and maintain in full force and effect commercial general

liability insurance in commercially reasonable and appropriate amounts that (a) provides product liability coverage concerning the Licensed Products and contractual liability coverage for UroGen's defense and indemnification obligations under this Agreement, and (b) in any event, provide commercial general liability limits at levels that the Parties mutually agree upon as appropriate upon commercialization of the Licensed Product. To the extent any insurance coverage required under this Section 14.4(a) is purchased on a "claims-made" basis, such insurance must cover all prior acts of UroGen during the Term, and be continuously maintained for a period of time that the Parties mutually agree upon as appropriate upon commercialization of the Licensed Product. UroGen shall have Agenus named in each policy as an additional insured. Upon request by Agenus, UroGen shall provide Agenus with certificates of insurance or other reasonable written evidence of all coverages described in this Section 14.4(a). Additionally, UroGen shall provide Agenus with written notice at least thirty (30) days prior to UroGen cancelling, not renewing, or materially changing the insurance.

(b) Agenus Insurance. Agenus shall maintain appropriate clinical trial insurance limits of $[…***…] each occurrence and $[…***…] in the aggregate in connection with the Agenus Antibody. Clinical trial insurance shall be maintained for the duration of the Clinical Trials and for at least five (5) years thereafter No later than the First Commercial Sale of a Licensed Product, Agenus shall, at its sole cost and expense, obtain, pay for, and maintain in full force and effect commercial general liability insurance in commercially reasonable and appropriate amounts that (a) provides product liability coverage concerning the Agenus Antibody in the Licensed Products and contractual liability coverage for Agenus' defense and indemnification obligations under this Agreement, and (b) in any event, provide commercial general liability limits at levels that the Parties mutually agree upon as appropriate upon commercialization of the Licensed Product. To the extent any insurance coverage required under this Section 14.4(b) is purchased on a "claims-made" basis, such insurance must cover all prior acts of Agenus during the Term, and be continuously maintained for a period of time that the Parties mutually agree upon as appropriate upon commercialization of the Licensed Product. Upon request by UroGen, Agenus shall provide UroGen with certificates of insurance or other reasonable written evidence of all coverages described in this Section 14.4(b). Additionally, Agenus shall provide UroGen with written notice at least thirty (30) days prior to Agenus cancelling, not renewing, or materially changing the insurance.

(c) Subrogation. Where permitted by Applicable Law, the insurance policies described in Sections 14.4(a) and 14.4(b) above shall contain waiver of the insurer's subrogation rights against the non-insured Party.

Article 15. MISCELLANEOUS

15.1 Governing Law. This Agreement (and any claims or disputes arising out of or related thereto or to the transactions contemplated thereby or to the inducement of any Party to enter therein, whether for breach of contract, tortious conduct, or otherwise and whether predicated on common law, statute or otherwise) will in all respects be governed by and construed in accordance with the laws of the State of New York, USA, including all matters of construction, validity and performance, in each case without reference to any conflict of law

rules that might lead to the application of the laws of any other jurisdiction.

15.2 Assignment. Neither Party may assign its rights and obligations under this Agreement without the prior written consent of the other Party, except that either Party may make such assignment without the prior written consent of the other Party to an Affiliate (so long as such Party will remain jointly and severally liable with such Affiliate with respect to all obligations so assigned) or in connection with a Change in Control, or in connection with the sale of all or substantially all of the assets to which this Agreement relates. Any purported assignment in contravention of this Section 15.2 will, at the option of the non-assigning Party, be null and void and of no effect. No assignment will release either Party from responsibility for the performance of any accrued obligation of such Party hereunder. This Agreement will be binding upon and enforceable against the successor to or any permitted assignee from either of the Parties.

15.3 Entire Agreement; Amendments. This Agreement and the Exhibits referred to in this Agreement, together with the Quality Agreement and the SDEA, constitute the entire agreement between the Parties with respect to the subject matter hereof, and supersede all previous arrangements with respect to the subject matter hereof, whether written or oral.

15.4 Notices. All communications, notices, instructions and consents provided for herein or in connection herewith will be made in writing and be sent to the address below and will be (a) given in person, (b) sent by registered or certified mail, return receipt requested, postage prepaid, or (c) sent by a reputable overnight courier service. Any such communication, notice, instruction or consent will be deemed to have been delivered: (i) on receipt if given in person; (ii) three (3) Business Days after it is sent by registered or certified airmail, return receipt requested, postage prepaid within the same country as the recipient's address or five (5) Business Days after it is sent by registered or certified airmail, return receipt requested, postage prepaid from another country; or (iii) one (1) Business Day after it is sent via a reputable overnight courier service.

Notices to UroGen will be addressed to:

Address: UroGen Inc.
499 Park Avenue, Suite 1200
New York, NY 10022
Attention: Vice President Business Development
Copy to: General Counsel
Copy to: Saul Ewing Arnstein &Lehr, LLP

1919 Pennsylvania Avenue, N.W. Suite 550, Washington, D.C. 20006-3434
Attention: Mark I. Gruhin, Esquire

Notices to Agenus will be addressed to:

Agenus Inc.
3 Forbes Road
Lexington, Massachusetts 02421-7305
Attention: Vice President Business Development

Copy to: General Counsel

provided, *however*, that if either Party will have designated a different address by notice to the other Party in accordance with this Section 15.4, then to the last address so designated.

15.5 Force Majeure. No failure or omission by either Party in the performance of any obligation of this Agreement will be deemed a breach of this Agreement or create any liability to the extent the same arises from an event, act, occurrence, condition or state of facts, in each case outside the reasonable control of such Party (which may include acts of God, acts of any government, any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof, fire, storm, flood, earthquake, accident, war, rebellion, insurrection, riot, terrorism and invasion, strike, labor disturbance, inability to obtain raw materials, acts or omissions of a Third Party); provided that (a) the Party affected by such cause (each a "Force Majeure event") promptly notifies the other Party and uses diligent efforts to cure such failure or omission as soon as is practicable after the occurrence of such Force Majeure event and (b) any timeline associated with performance of obligations hereunder shall automatically be extended by a duration equal to the delay directly caused by the applicable Force Majeure event.

15.6 Independent Contractors. It is understood and agreed that the relationship between the Parties is that of independent contractors and that nothing in this Agreement will be construed to create a joint venture or any relationship of employment, agency or partnership between the Parties to this Agreement. Neither Party is authorized to make any representations, commitments or statements of any kind on behalf of the other Party or to take any action that would bind the other Party. Furthermore, none of the transactions contemplated by this Agreement will be construed as a partnership for any tax purposes.

15.7 No Implied Waivers; Rights Cumulative. No failure on the part of a Party to exercise, and no delay by either Party in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege by such Party or be construed as a waiver of any breach of this Agreement or as an acquiescence therein by such Party, nor will any single or partial exercise of any such right, power, remedy or privilege by a Party preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

15.8 Severability. If, under Applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement, this Agreement will endure except for such invalid or unenforceable provision. The Parties will consult one another and use good faith efforts to agree upon a valid and enforceable provision that is a reasonable substitute in view of the intent of this Agreement.

15.9 Execution in Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, and all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (.pdf) sent by electronic mail will be deemed to be original

signatures.

15.10 No Third Party Beneficiaries. No Person other than UroGen and Agenus (and their respective successors and permitted assignees) and […***…], to the extent expressly set forth herein, will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

15.11 Performance by Affiliates. Agenus may exercise its rights and perform its obligations through one or more of its Affiliates in accordance with the intercompany agreements between them and otherwise in Agenus' reasonable discretion provided the Affiliates have the appropriate skill and experience to perform said obligation, provided that Agenus will remain liable hereunder for the prompt performance of all such obligations hereunder.

15.12 Conflicting Provisions. In the event of inconsistencies between this Agreement and any exhibit hereto, the terms of this Agreement will control. In the event of inconsistencies between this Agreement, the Quality Agreement and the SDEA, the following principles shall determine which conflicting provisions among the agreements shall control:

(a) the Quality Agreement shall control with respect to quality requirements regarding Manufacture, storage and handling of the Agenus Antibody;

(b) the SDEA shall control with respect to the management of activities for adverse events, serious adverse events, complaints, recalls and market withdrawals; and

(c) this Agreement shall control with respect to all other matters.

15.13 Construction. In construing this Agreement, unless expressly specified otherwise: (a) references to Articles, Sections, Schedule and Exhibits are to articles and sections of, and exhibits to, this Agreement; (b) except where the context otherwise requires, use of either gender includes any other gender, and use of the singular includes the plural and vice versa; (c) headings and titles are for convenience only and do not affect the interpretation of this Agreement; (d) any list or examples following the word "including" will be interpreted without limitation to the generality of the preceding words; (e) references to a law include any amendment or modification to such law and any rules or regulations issued thereunder, and (f) all references to "Dollars" or "$" herein will mean US Dollars;

15.14 Representation by Legal Counsel. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

[*signature page follows*]

IN WITNESS WHEREOF, the Parties have signed this License Agreement as of the date last signed below.

AGENUS:

/s/ Garo Armen

Name: Garo Armen

Title: CEO and Chairman

UROGEN:

/s/ Liz Barrett

Name: Liz Barrett

Title: Chief Executive Officer

LEASE AGREEMENT

BETWEEN

WITMAN PROPERTIES, L.L.C.,
a New Jersey limited liability company

and

ALEXANDER ROAD AT DAVANNE, L.L.C.,
a New Jersey limited liability company

as Tenants in Common,

AS LANDLORD

-AND-

UROGEN PHARMA, INC.,
a Delaware corporation

AS TENANT

PREMISES: **400 Alexander Road**
West Windsor, New Jersey

DATED: **October 31, 2019**

THIS LEASE AGREEMENT (this "**Lease**"), dated as of October 31, 2019, is made by and between **WITMAN PROPERTIES, L.L.C.**, a New Jersey limited liability company and **ALEXANDER ROAD AT DAVANNE, L.L.C.**, a New Jersey limited liability company, as Tenants in Common, having offices at c/o Woodmont Properties, 100 Passaic Avenue, Suite 240, Fairfield, New Jersey 07004 (collectively, "**Landlord**"), and **UROGEN PHARMA, INC.**, a Delaware corporation having its principal office located at 499 Park Avenue, Suite 1200, New York, NY 10022 ("**Tenant**"). Landlord and Tenant may be referred to collectively in the Lease as the **"Parties"**, or each may be referred to singularly as a **"Party"**.

PREAMBLE:

BASIC LEASE PROVISIONS AND DEFINITIONS

In addition to other terms elsewhere defined in this Lease, the following terms whenever used in this Lease shall have the meanings set forth in this section, unless such meanings are expressly modified, limited or expanded elsewhere herein.

"**Actual Delivery Date**" shall be the date upon which Landlord delivers the Premises to Tenant in Delivery Condition.

"**Additional Rent**" shall mean all sums in addition to Fixed Base Rent payable by Tenant to Landlord pursuant to the provisions of this Lease.

"**Base Building Work**" is not applicable. Tenant is talking the Demised Premises as-is and Landlord is not obligated to make any improvements, changes, installations, alterations, repairs or replacements to the Premises, Building or Property, either to put Tenant in possession of the Premises or to permit Tenant to open for business, except as expressly set forth in Section 3.01 and elsewhere in this Lease.

"**Broker**" shall mean JLL and CBRE, Inc.

"**Building**" shall mean the building more commonly known as 400 Alexander Road, West Windsor, New Jersey 08540.

"**Building Hours**" shall be Monday through Friday, 8:00 A.M. to 6:00 P.M., but excluding the following Building holidays: President's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day and the day immediately following Thanksgiving Day, Christmas Day, New Year's Day; Monday before or Friday after if Christmas Day, New Year's Day or Independence Day falls on Tuesday or Thursday; and Monday after or Friday before if Christmas Day, New Year's Day or Independence Day falls on Saturday or Sunday. Common area lighting in the Building and Land shall be maintained for such additional hours as, in Landlord's sole judgment, is necessary or desirable to insure proper operation of the Building and Land.

"**Commencement Date**" shall be the earlier of the date (i) that is twenty-one (21) days after the Actual Delivery Date (which may be extended as hereinafter set forth), or (ii) such earlier date that Tenant first conducts its business within the Demised Premises. In the event, despite diligent efforts, Tenant is unable to obtain internet/data services to the Demised Premises within twenty one (21) days after the Effective Date, upon at least two (2) days prior notice to Landlord,

the foregoing 21-day period may be extended until such time as Tenant obtains internet/data services for the Demised Premises, provided, however, such extension shall in no event exceed seven (7) days.

"**Delivery Condition**" shall mean the Premises shall be delivered in "as is" "where is" condition; Landlord shall not be required to perform any work to place Tenant in occupancy of the Premises except as specifically set forth in Section 3.01.

"**Demised Premises**" or "**Premises**" shall be deemed to be 20,913 rentable square feet; the usable square footage is deemed to be 18,301 square feet, and shall consist of usable square footage of the entire fourth (4th) floor of the Building, as depicted in Exhibit A.

"**Exhibits**" shall be the following, which are attached to this Lease and incorporated herein and made a part hereof:

Exhibit A	Demised Premises
Exhibit B	Cleaning and Maintenance Specifications
Exhibit C	Rules and Regulations
Exhibit D	Reserved
Exhibit E	Furniture
Exhibit F	Tenant's Initial Improvements
Exhibit G	Certificate of Occupancy for the Building
Exhibit H	Form of SNDA
Exhibit I	Form of Letter of Credit
Exhibit J	LEED Core & Shell Tenant Lease Requirements
Exhibit K	HVAC Zones

"**Fair Market Value**" shall be determined in accordance with Section 43.04.

"**Fixed Base Rent**" shall mean annual base rent for the Term payable as follows:

LEASE YEAR	MONTHLY	ANNUALIZED RENTAL RATE	ANNUAL RATE PER SQUARE FOOT
Year 1			
Months 1-4	$22,420.48	$269,045.75	$12.87
Months 5-12	$44,840.96	$538,091.49	$25.73
Year 2	$46,078.31	$552,939.72	$26.44
Year 3*	$46,949.69	$563,396.22	$26.94

*Lease Year 3 shall consist of fourteen (14) months.

"**Land**" shall mean Lot 4.01, Block 6.07 as shown on the Tax Map of West Windsor, New Jersey, upon which the Building and its parking areas are located.

"**Lease Year**" shall mean the period beginning on the Rent Commencement Date and ending on the day immediately preceding the first (1st) anniversary of the Rent Commencement Date, or if the Rent Commencement Date shall occur other than on the first day of the month, then the period beginning on the Rent Commencement Date and ending on the last day of the month in which the first (1st) anniversary of the Rent Commencement Date occurs, and each succeeding period of twelve (12) consecutive calendar months during the Term, provided, however, that Lease Year 3 shall consist of fourteen (14) months.

"**Permitted Transfer**" shall have the meaning set forth in Section 8.03.

"**Permitted Use**" shall be executive and general office use by Tenant and "Desk Sharing Parties" (as defined in Section 2.04) and uses incidental and ancillary thereto; and, subject to Landlord's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, for any other lawful purpose.

"**Prime Rate**" shall mean the prime rate as published in the Wall Street Journal.

"Property" shall collectively refer to the Land and the Building.

"**Rent**" shall have the meaning set forth in Section 1.04.

"**Rent Commencement Date**" shall be the Commencement Date, and it shall be the date when Tenant's obligation to pay Fixed Base Rent shall commence.

"**Security Deposit**" shall mean a letter of credit in the amount of One Hundred Thousand Dollars and XX/100 Dollars ($100,000.00).

"**Substantially Complete**", "**Substantial Completion**", or words of similar import, shall mean the substantial completion, as evidenced by the issuance of a temporary certificate of occupancy, of the Base Building Work in accordance with Article 3 or the Tenant Improvements in accordance with Article 4, as the case may be, it being agreed that the Base Building Work and/or the Tenant Improvements, as the case may be, shall be deemed substantially complete notwithstanding the fact that minor or insubstantial details of construction or demolition and/or mechanical adjustment and/or decorative items (collectively, "**Punch List Items**") remain to be performed, provided the non-completion of the Punch List Items does not materially interfere with Tenant's use of the Premises for the operation of its business.

"**Tenant Improvements**" shall have the meaning set forth in Section 4.01.

"**Tenant's Percentage**" shall mean, and is stipulated by the Parties to be, 29.32%.

"**Term**" shall mean the term of this Lease, which is three (3) years and two (2) months in duration, and which runs from the Commencement Date forward, together with the number of days, if any, which are needed to have the Lease expire on the last day of a calendar month, unless extended pursuant to any Renewal Option (as later defined) contained herein. If Tenant exercises any applicable Renewal Option pursuant to Article 43, then the Term shall automatically be extended to include the applicable Renewal Period(s).

WITNESSETH:

ARTICLE 1

DEMISED PREMISES; TERM; RENT

1.01. In consideration of the terms, conditions, and agreements set forth in this Lease, and for good and valuable consideration the sufficiency of which are hereby acknowledged, Landlord hereby agrees to lease to Tenant, and Tenant hereby hires from Landlord, the Demised Premises, for the Term, for the rents hereinafter reserved and upon and subject to the terms, conditions (including limitations, restrictions and reservations) and covenants hereinafter provided. Each Party hereby expressly covenants and agrees to observe and perform all of the conditions and covenants herein contained on its part to be observed and performed.

1.02. Landlord and Tenant have mutually agreed and stipulated that the Demised Premises leased hereunder has a rentable area of 20,913 square feet. Said Premises, together with all fixtures and equipment, including Landlord's Furniture (as defined in Article 42), which at the commencement or during the term of this Lease are thereto attached (except items not deemed to be included therein and removable by Tenant as provided in Article 13), shall constitute the "Demised Premises".

1.03. The term of this Lease, for which the Demised Premises are hereby leased, shall commence on the Commencement Date and, subject to Tenant's renewal rights as set forth herein, shall end at 5:00 P.M. on the last day of the calendar month in which occurs the date that is three (3) years and two (2) months after the Commencement Date, which ending date is hereinafter called the "**Expiration Date**", or shall end on such earlier date upon which said Term may expire or be canceled or terminated pursuant to any of the provisions of this Lease or pursuant to law. Promptly following the Commencement Date, Landlord and Tenant shall execute a confirmation, in form and substance reasonably satisfactory to both parties, confirming the Commencement Date, the Rent Commencement Date and the Expiration Date; provided, however, failure to execute and deliver such confirmation shall not affect the validity of the Commencement Date, the Rent Commencement Date or the Expiration Date as herein set forth.

1.04. The rents reserved under this Lease (collectively the "**Rent**"), for the Term thereof, shall be and consist of:

(a) Fixed Base Rent in the amounts set forth in the Preamble, which shall be payable in monthly installments, as above described, on the first day of each and every calendar month during the Term commencing on the Rent Commencement Date (except as otherwise set forth in Section 1.06); and

(b) Additional Rent consisting of all such other sums of money as shall become due from and payable by Tenant to Landlord hereunder (for default in payment of which Landlord shall have the same remedies as for a default in payment of fixed rent), all to be paid to Landlord at its office, or such other place, or to such agent at such place, as Landlord may designate by notice to Tenant, in lawful money of the United States of America.

1.05. Tenant shall pay the Fixed Base Rent and Additional Rent as herein reserved promptly as and when the same shall become due and payable, pursuant to the terms and conditions of this Lease, without further demand therefor, and without any rights of abatement, deduction, counterclaim or setoff whatsoever except as otherwise expressly set forth herein.

1.06. Notwithstanding anything herein to the contrary, Tenant shall pay upon the execution and delivery of this Lease an amount equal to the sum of (i) the Security Deposit and (ii) the first month's Fixed Base Rent. If the Rent Commencement Date is on the first day of a month, such payment of Fixed Base Rent shall be credited against the first full monthly installment of Fixed Base Rent due and payable under this Lease. If the Rent Commencement Date is not on the first day of a month, then on the Rent Commencement Date, Tenant shall pay prorated Fixed Based Rent for the period from the Rent Commencement Date through the last day of such month (both dates inclusive) and the payment of Fixed Base Rent made by Tenant upon the execution and delivery of this Lease shall be credited toward Fixed Base Rent for the next succeeding calendar month.

1.07. Any payment of Rent, including monthly Fixed Base Rent or any portion thereof, and any Additional Rent, which is not received within five (5) days after it is due (any such period to be referred to as a "Grace Period"), will be subject to a late charge equal to five percent (5%) of the unpaid amount. However, not more than once in each calendar year, if applicable, Tenant may have an additional five (5) business day period after the Grace Period (any such additional period to be referred to as a "Second Grace Period") before any late payment of Rent is subject to the late charge in the preceding sentence. The late charge, if assessed, will be compensation for Landlord's additional cost of processing late payments. In addition, any Rent which is not paid within thirty (30) days after it is due, including monthly Fixed Base Rent, will accrue interest at a rate equal to the Prime Rate as defined herein plus five percent (5%) per annum, from the date on which it was due until the date on which it is paid in full with accrued interest. If Tenant is in default of this Lease for failure to pay Rent, in addition to the late charges and interest set forth above, Tenant shall be charged with and responsible for payment of all reasonable attorney fees incurred by Landlord in connection with the collection of all sums due Landlord.

ARTICLE 2

USE

2.01. Tenant shall use and occupy the Demised Premises for the Permitted Use and for no other purpose.

2.02. Tenant shall not at any time use or occupy, or do or permit anything to be done in the Demised Premises, in violation of any law, ordinance or regulation governing the use and occupation of the Demised Premises or the Building.

2.03. In no event shall the population density in the Demised Premises exceed one (1) person for every two hundred (200) rentable square feet, or such lesser amount as may be required by the certificate of occupancy for the Building. Landlord represents that the Certificate of Occupancy annexed hereto as Exhibit G has not been amended, and Landlord agrees that it will not seek to amend or modify the Certificate of Occupancy in any way that will affect Tenant's use and occupancy of the Demised Premises.

2.04. The Demised Premises may be used by third parties associated with Tenant's business (individually a "Desk Sharing Party", and collectively, "Desk Sharing Parties") on a temporary basis, upon the following express conditions, unless otherwise agreed to in writing, by

Landlord: (i) Desk Sharing Parties, in the aggregate, may not occupy more than three thousand (3,000) usable square feet of the Demised Premises; (ii) any such Desk Sharing Party shall not have any rights under this Lease except to occupy space in the Demised Premises, nor shall such occupancy create a landlord-tenant relationship or any privity with the Landlord, and any such Desk Sharing Party shall have no right, title or interest in or to the Demised Premises; (iii) Tenant continues to actively conduct its business in the Demised Premises; (iv) there shall be no separate identification of any Desk Sharing Party on any Demised Premises or Building signage; (v) there shall be no construction or other alterations to the Demised Premises to separate space within the Demised Premises for a Desk Sharing Party (i.e. the Demised Premises shall not be reconfigured to appear to have separate premises within the Demised Premises); (vi) any such arrangement with a Desk Sharing Party will terminate automatically upon the termination of this Lease; (vii) Tenant shall receive no rent or other payment or consideration for the use or occupancy of any space in the Demised Premises by any Desk Sharing Party (other than for reasonable charges for office, clerical, secretarial, messenger and similar services), and (viii) such desk sharing arrangement is for a valid business purpose and not to circumvent the provisions of this Lease, including, without limitation, Article 8. Any Desk Sharing Party use or occupancy agreement is subject and subordinate to this Lease and all matters to which this Lease is subject and subordinate. In connection with such Desk Sharing Party, Tenant will provide Landlord with a copy of a written agreement, (if any), with such Desk Sharing Party and the names and contact information for any such Desk Sharing Party. Tenant hereby indemnifies and holds Landlord harmless hereunder from any and all liabilities, expenses or costs of any nature whatsoever to Landlord arising in any manner out of or in connection with the Desk Sharing Party's use of, or presence in, the Demised Premises.

ARTICLE 3

LANDLORD WORK

3.01. Tenant agrees that it is accepting the Premises in "as is" condition without any improvements and/or alterations by Landlord except as provided for in this Lease Tenant acknowledges and agrees that neither Landlord nor any employee, agent or representative of Landlord has made any express or implied representations or warranties with respect to the physical condition of the Premises, the fitness or quality thereof or any other matter or thing whatsoever with respect to the Premises or any portion thereof, and that Tenant is not relying upon any such representation or warranty in entering into this Lease. Unless specifically stated otherwise in this Lease, Landlord shall be deemed to have tendered possession of the Premises to Tenant upon the mutual execution and delivery of this Lease. Notwithstanding anything herein to the contrary, Landlord shall, prior to the Commencement Date: (i) furnish the furniture identified on Exhibit E, and (ii) repair roof leaks, if any.

ARTICLE 4

TENANT IMPROVEMENTS

4.01. Tenant shall perform all construction, improvements, additions, modifications, decorations and alterations that may be proposed or undertaken by or for the account of Tenant to prepare, equip, decorate and furnish the Premises for Tenant's initial and/or continued use and

occupancy ("Alterations"). All Alterations shall be in conformity with the standards of quality of construction, tenant occupancy of the Building and the overall aesthetic of the Building as determined by Landlord.

4.02. All maintenance and repair, and any Alterations, performed by, on behalf of or for the account of Tenant, shall comply with the following:

(a) Any Alterations require Landlord's prior written consent. Notwithstanding the foregoing, Landlord's consent shall not be required for any Alterations comply with all three of the following criteria: the Alterations (i) are not Major Work (as hereinafter defined), (ii) do not cost, in the aggregate, more than Twenty Five Thousand Dollars ($25,000.00), and (iii) do not require a building permit. Landlord agrees not to unreasonably withhold, condition or delay, its consent to Alterations with the exception of Alterations which are Major Work for which Landlord may withhold its consent in its sole and absolute discretion.

(b) Any Alterations or repair or maintenance performed by or on behalf of Tenant must not, individually or in the aggregate, lessen the value of the Building or Property or adversely affect the usefulness of the Building or Property as a first-class office building;

(c) All Major Work shall be performed by contractors, engineers and/or architects approved by Landlord, such approval not to be unreasonably withheld, conditioned or delayed.

(d) Tenant shall, in advance, deliver to Landlord the name and address of Tenant's contractors, subcontractors, material suppliers and laborers, and a breakdown of the aggregate total cost of the Alterations repairs or maintenance, together with a certificate of insurance for such contractors, subcontractors, material suppliers and laborers. All of Tenant's contractors, whether retained under this section or as contemplated elsewhere in the Lease, shall carry and maintain insurance in such minimum amounts and types of coverage as Landlord may reasonably require, naming Landlord and Landlord's agents as additional insureds. Tenant's contractors shall deliver current certificates of insurance to Landlord prior to performance of any work at the Premises.

(e) Tenant shall, within twenty (20) days after completion of any Alterations, repairs or maintenance, provide original, fully executed final lien waivers in a form reasonably acceptable to Landlord and suitable for recording purposes, from each contractor, subcontractor, material supplier and laborer that perform Alterations, repairs or maintenance at the Premises and whose invoices exceed Ten Thousand Dollars ($10,000.00) in the aggregate.

(f) Tenant shall perform, or cause to be performed, all Alterations, repair and maintenance with diligence, using only new, first class materials and supplies, in a good and workmanlike manner in accordance with plans approved by Landlord and in accordance with all laws, codes, statues, requirements or other directive of any governmental or quasi-governmental authority and any and all approvals, permits, licenses or consents required by any ordinance, law or public regulations or by any authority having jurisdiction. Tenant warrants that all Alterations, when completed, will comply with all applicable laws.

(g) "Major Work" means any Alteration (i) affecting, altering, interfering with or disrupting any electrical, mechanical, plumbing or other system of the Building or Property; (ii) affecting the outside appearance, the façade, the roof, the foundation, the ingress to or the egress

from the Demised Premises; or (iii) of any structural element of the Building or Premises, including load bearing walls.

(h) Landlord shall have the option of requiring Tenant remove any Alterations other than Tenant's Initial Improvements (as hereinafter defined) prior to expiration of the Term upon notice given to Tenant at least sixty (60) days prior to the expiration of the Term, provided that Landlord had previously notified Tenant that it would require such removal at the time Landlord first approved such Alterations, and further provided that under no circumstance shall Tenant be required to remove any data cabling, conduit and related equipment, whether located in the ceilings, floors and/or walls, or to remove or replace any floor or wall finishes. In the event Landlord requires Tenant to remove any or all of its Alterations, Tenant shall restore the area so affected by the removal of the Alterations and repair any damage caused by the removal.

(i) Tenant shall pay to Landlord a construction supervision and management fee (the "**Landlord's Supervision Fee**") in an amount (i) equal to the product of two percent (2%) of the aggregate costs of Tenant's Alterations; plus (ii) the out of pocket costs, if any, incurred by Landlord in connection with Tenant's Alterations. Notwithstanding the foregoing, Landlord's Supervision Fee shall not be applicable for Tenant's Initial Improvements (as hereinafter defined).

4.03. Landlord hereby acknowledges that following the Commencement Date Tenant intends to modify the entry to the Demised Premises in order to create a reception area, as generally shown on Exhibit F annexed hereto (**"Tenant's Initial Improvements"**). Subject to Tenant complying with all of the requirements of this Article 4, Landlord hereby approves Tenant's Initial Improvements.

4.04 The Building has been registered to qualify for Leadership in Energy and Environmental Design ("LEED") Core & Shell status as established by the U.S. Green Council based on the LEED Core & Shell standards in effect as of the date of such registration. Any Tenant work, including Tenant's Initial Improvements and Alterations, shall comply with the standards necessary to maintain the applicable LEED Core & Shell certification of the Building, as further set forth in Exhibit J to this Lease.

ARTICLE 5

ADDITIONAL RENT

5.01. For the purpose of Sections 5.01 through 5.03:

(a) "**Taxes**" shall mean real estate taxes, and assessments, general or special, ordinary or extraordinary, foreseen or unforeseen (including lease taxes) assessed or imposed upon the Property, plus the reasonable expenses of any contests (administrative or otherwise) of tax assessments or proceedings to reduce taxes, including attorneys' and appraisers' fees, incurred each calendar year during the Term (and any renewals or extensions thereof) including, without limit, the first calendar year during which the Term of this Lease shall have commenced. However, if at any time during the term of this Lease the method of taxation prevailing at the date of this Lease shall be altered so that in lieu of, or as an addition to, or as a substitute for any or all of the above there shall be assessed, levied or imposed (i) a tax, assessment, levy, imposition or charge

based on the income or rents received therefrom whether or not wholly or partially as a capital levy or otherwise; or (ii) a tax, assessment, levy, imposition or charge measured by or based in whole or in part upon all or any part of the Land and/or Building and imposed upon Landlord; or (iii) a license fee measured by the rents; or (iv) any other tax, assessment, levy, imposition, charge or license fee however described or imposed, then all such taxes, assessments, levies, impositions, charges or license fees or the part thereof so measured or based shall be deemed to be included in the definition of "Taxes."

(b) "**Base Taxes**" shall mean the final real estate taxes imposed upon the Land and Building for the calendar year 2019.

(c) "**Tax Year**" shall mean each calendar year for which Taxes are levied by any governmental authority.

(d) "**Operating Year**" shall mean each calendar year commencing with calendar year 2020.

(e) "**Tenant's Proportionate Share of Increase**" shall mean Tenant's Percentage multiplied by the increase in Taxes in any Operating Year in excess of the Base Taxes, subject to the "Tax Cap", as hereafter defined.

(f) "**Tenant's Projected Share of Increase**" shall mean Tenant's Proportionate Share of Increase in Taxes as reasonably estimated by Landlord for the ensuing Operating Year divided by twelve (12) and payable monthly by Tenant to Landlord as Additional Rent.

5.02. Commencing on the one (1) year anniversary of the Commencement Date, and thereafter, upon each successive Operating Year, Tenant shall pay to Landlord as Additional Rent for the then Operating Year, Tenant's Projected Share of Increase in Taxes in equal monthly installments; provided, however, that Tenant shall not be required to pay Tenant's Projected Share of Increase for any period prior to the first (1st) anniversary of the Commencement Date.

5.03. Within one hundred fifty (150) days after the expiration of each Operating Year, Landlord shall furnish to Tenant a written statement of the Taxes incurred for each such Operating Year as well as Tenant's Proportionate Share of Increase, if any. If the statement furnished by Landlord to Tenant pursuant to this Section shall indicate that Tenant's Projected Share of Increase exceeded Tenant's Proportionate Share of Increase, then Landlord shall either forthwith pay the amount of such excess directly to Tenant concurrently with the statement, or shall credit the same against Tenant's next owed monthly installment of rent within ten days thereafter. If such statement furnished by Landlord to Tenant shall indicate that the Tenant's Proportionate Share of Increase exceeded Tenant's Projected Share of Increase for the then Operating Year, Tenant shall then pay the amount of such excess to Landlord within thirty (30) days; provided, however, that Tenant shall not be required to pay Tenant's Proportionate Share of Increase for any period prior to the first (1st) anniversary of the Commencement Date. If Landlord has not provided Tenant a written statement for Tenant's Projected Share of Increase as of the commencement of any Operating Year, Tenant shall be obligated to continue to pay Additional Rent each month at the same rate as reflected in the previous Operating Year's estimate furnished by Landlord until such

time as Landlord has sent the statement for the current Operating Year, whereupon appropriate adjustments will be made.

Notwithstanding the foregoing, in the event Taxes increase by more than three percent (3%) from the Base Taxes to the first Operating Year, Tenant's Proportionate Share of Increase in Taxes shall be calculated as though the increase in Taxes for the first Operating Year is three percent (3%). Thereafter, Tenant's Proportionate Share of Increase in Taxes shall not exceed three percent (3%) per Operating Year on a cumulative basis for the Term of the Lease (the "Tax Cap").

5.04. As used in Sections 5.04 through 5.06:

(a) "**Operating Expenses**" shall mean the actual expenses and costs incurred by Landlord in connection with the operating and maintaining the Property (including without limit, all improvements thereto) during each Operating Year. Such expenses shall include by way of example and not by way of limitation: (i) salaries, wages, medical, surgical and general welfare benefits, (including group life insurance) and pension payments of employees of Landlord engaged in the operation and maintenance of the Building; (ii) social security, unemployment, and payroll taxes, workers' compensation, disability coverage, uniforms, and dry cleaning for the employees referred to in Subsection (i); (iii) the cost for the Building and common areas of all charges for oil, gas, electricity (including, but not limited to, fuel cost adjustments), steam, heat, ventilation, air-conditioning, heating, and water, including any taxes on any such utilities, but excluding from Operating Expenses the Landlord's cost, including taxes thereon, of electric energy, other than for heating and air-conditioning, furnished to the Demised Premises (which electric energy so furnished shall be paid for by Tenant pursuant to the provisions of Article 15 hereof); (iv) the cost of all premiums and charges for insurance for the Building and Land, including but not limited to: rent loss/rental income, casualty, liability, fidelity and war risk (if obtainable from the United States Government); (v) the cost of all building and cleaning supplies for the Building and common areas and charges for telephone and data service for the Building; (vi) the cost of all charges for management fees (but not to exceed 3% of Landlord's gross rents from the Building), window cleaning, security services, if any, and janitorial services, and any independent contractor performing work servicing or maintaining the Property; (vii) legal and accounting services and other professional fees and disbursements incurred in connection with the operation and management of the Land and Building (other than as related to new leases, enforcing Landlord's rights under existing leases, or sales of the Building); (viii) general maintenance of the Building and Land, including but not limited to, the cost of maintaining, repairing or replacing the landscaping, sidewalks, driveways and other improvements and facilities serving the Building; (ix) maintenance of the common areas, including sums payable to the Alexander Park Master Association, Inc., a New Jersey non-profit corporation, its successors and assigns (the "**Association**"), pursuant to that certain Master Declaration of Covenants, Conditions and Restrictions for the Alexander Park Master Association, Inc., Alexander Park Office Development recorded in Deed Book 2345 at Page 753, amended as set forth in Deed Book 2436 at Page 376, Deed Book 3438 at Page 173, and Deed Book 3450 at Page 1 (as heretofore and hereafter amended, the "**DCR**"); and (x) the cost of capital expenditures, including the purchase of any item of capital equipment or the leasing of capital equipment, which (X) have the effect of reducing the expenses which would otherwise be included in Operating Expenses (provided the amount included in Operating Expenses in any Operating Year shall not exceed an amount equal to the savings reasonably anticipated to result from the installation and operation of such improvement), and/or

(Y) are required by applicable law enacted after the date of this Lease, which costs shall be included in Operating Expenses for the Operating Year in which the costs are incurred and subsequent Operating Years amortized on a straight-line basis over the useful life of the capital item (as determined in accordance with GAAP), with an annual interest factor equal to the Prime Rate at the time of Landlord's having made such expenditure plus three percent (3%). The amount included in Operating Expenses in any Operating Year (until such improvement has been fully amortized) shall be equal to the annual amortized amount. If Landlord shall have leased any such items of capital equipment designed to result in savings or reductions in Operating Costs, then the rental and other costs paid pursuant to such leasing shall be included in Operating Costs for the Operating Year in which they shall have been incurred.

For purposes of Operating Expenses the Base Year shall be adjusted to reflect a ninety-five percent (95%) occupied Building and shall be inclusive of all Operating Expense line items reasonably anticipated in the Building during the twelve (12) month period following the Commencement Date.

(b) **Exclusions from Operating Expenses**. Notwithstanding the foregoing, the following costs and expenses shall not be included in Operating Expenses:

(1) Refinancing costs, and interest and principal payments on mortgage or any other debt;
(2) ground rental payments;
(3) Landlord's gross receipts taxes, personal corporate income taxes, inheritance and estate taxes, franchise, gift and transfer taxes, charges, fees or assessments related to or resulting from any changes of ownership of the building;
(4) the cost of capital improvements/expenditures (unless treated as provided above in Section 5.04(a));
(5) the costs of painting or decorating (other than public areas), the costs of alterations to the Premises or the premises of other tenants of the Building, or the cost of any work furnished by Landlord without charge as an inducement for a tenant to lease space (i.e., free rent, improvement allowances);
(6) a property management fee in excess of three (3%) percent of the gross rental proceeds;
(7) depreciation of the Building;
(8) expenses, including rent, associated with maintaining a leasing or marketing office;
(9) salaries and other compensation of executive officers of the Landlord or Managing Agent senior to the individual Building manager;
(10) income or franchise taxes or other such taxes imposed or measured by the income of the Landlord from the operation of the Building;
(11) the cost of constructing and/or installing any special service or facility such as an observatory, broadcasting facility, luncheon club, athletic or recreational club, cafeteria or dining facility;
(12) the costs associated with utilities, services or amenities not available to all tenants or provided to any tenant to a materially greater extent or more favorable manner than generally provided to other tenants;
(13) the costs of correcting latent defects and defects in construction or renovation of the Building or its systems;

(14) the costs (including fines and penalties) to comply with laws such as ADA and environmental laws including, without limitation, laws relating to the phase-out of so-called "Freon" as a coolant;
(15) the cost of any work performed or service provided to the extent fees or other compensation are received;
(16) payments for rental items, the cost of which would constitute a capital expenditure if such equipment were purchased (unless treated as provided above in Section 5.04(a));
(17) legal, space planning, construction and other expenses incurred in connection with tenant leases including, without limitation, negotiations with prospective tenants and enforcing provisions of this lease or other leases in the Building;
(18) costs for sculptures, paintings and other objects of art located in the interior or on the exterior of the Building or immediately adjacent thereto;
(19) any fees and expenses paid to an agent which is related to Landlord or any affiliate of Landlord to the extent such fees or expenses are in excess of the customary market amounts which would be paid in the absence of such a relationship;
(20) expenditures for repairs or maintenance which are covered by warranties, guarantees or service contracts;
(21) any expenditure for which the Landlord has been or is entitled to be reimbursed by third parties such as insurance companies or would have been compensated through proceeds of insurance had the Landlord maintained insurance customarily carried by similar lessors;
(22) the cost of any repairs, alterations, additions, changes, tools, equipment replacements and the like which under generally accepted accounting principles and practices are properly classified as capital expenditures (unless treated as provided above in Section 5.04(a));
(23) advertising, promotional and marketing expenses;
(24) real estate brokerage and leasing commissions;
(25) expenses in connection with repairs or other work occasioned by the exercise of the right of eminent domain;
(26) damages incurred due to the gross negligence of the Landlord;
(27) debt costs or the costs of financing or refinancing;
(28) the costs, fines or penalties incurred due to violations by the Landlord of any governmental rule or authority;
(29) expenses incurred by Landlord, if any, in connection with the operation, cleaning, repair, safety, management, security, maintenance or other services of any kind provided to any portions of the Building which are leased or designed to be used for retail, garage or storage purposes;
(30) any compensation paid to clerks, attendants or other persons in commercial concessions operated by Landlord;
(31) Landlord's general partnership overhead not related to management of the Building;
(32) contributions to operating expense reserves;
(33) bad debt loss, rent loss or reserves for bad debt or rent loss;
(34) “Taxes”;
(35) Costs incurred in performing work or furnishing services for any tenant (including Tenant), whether at such tenant’s or Landlord’s expense, to the extent that such work or

service is intended to benefit only one tenant or subset of tenants rather than the entire tenancy of the Building;

(36) The cost of electricity (for other than heating and air-conditioning) furnished to the Demised Premises or any other space leased or leasable to tenants as reasonably estimated by Landlord (common area utilities electricity is included in Operating Expenses);

(37) Salaries, wages, or other compensation or benefits paid to off-site employees of Landlord who are not assigned full-time to the operation, management, maintenance, or repair of the Building; provided however, Operating Expenses shall include a reasonably allocable portion of compensation paid to any employee of Landlord (or an affiliate of Landlord) at the level of building manager or below, whether onsite or offsite, who is assigned part-time to the operation, management, maintenance, or repair of the Property;

(38) Costs incurred in connection with disputes with tenants, other occupants, or prospective tenants, or costs and expenses incurred in connection with negotiations or disputes with employees, consultants, management agents, leasing agents, purchasers or mortgagees of the Building;

(39) Costs, fines, interest, penalties, legal fees or costs of litigation incurred due to the late payments of taxes, utility bills and other costs incurred as a result of Landlord's failure to make such payments when due;

(40) General overhead and general administrative expenses and accounting, record-keeping and clerical support of Landlord or the management agent, unless such services are provided by third-parties other than the Landlord, Landlord’s affiliates or the management agent.

(41) Increased insurance premiums caused by Landlord's or any other tenant's hazardous acts;

(42) Costs incurred to correct violations by Landlord of any law, rule, order or regulation which was in effect as of the date hereof;

(43) Costs arising from the presence of hazardous substances in or about or below the Land or the Building, including without limitation, hazardous substances in the groundwater or soil (unless introduced or caused by Tenant);

(44) Non-cash accounting items, such as deductions for depreciation and amortization of the Building and the Building’s equipment, interest on capital invested, bad debt losses, rent losses and reserves for such losses;

(45) Except for amenities provided to all tenants of the Building (i.e. fitness club), services provided and costs incurred in connection with the operation of retail or other ancillary operations owned, operated or subsidized by Landlord;

(46) Costs of overtime HVAC service whether provided to the Tenant or any other tenant of the Building (with the understanding that Tenant shall nevertheless be responsible for after hours HVAC as set forth in Section 16.01);

(47) Costs incurred by Landlord because a tenant violated or was alleged to have violated the terms of its lease;

(48) Costs incurred by Landlord for trustees’ fees or partnership or corporate organizational groups;

(49) Charitable or political contributions or trade association dues;

(50) Accounting and legal expenses, except if and to the extent that the same are directly related to operating the Building;

(51) Any entertainment, dining or travel expenses of Landlord for any purpose; or

(52) "In-house" legal and/or accounting fees.

(c) "**Operating Year**" shall mean each calendar year commencing with calendar year 2020.

(d) "**Base Year**" shall mean calendar year 2019.

(e) "**Tenant's Proportionate Share of Increase**" shall mean Tenant's Percentage multiplied by the increase in Operating Expenses for the Operating Year over Operating Expenses for the Base Year.

(f) "**Tenant's Projected Share of Increase**" shall mean Tenant's Proportionate Share of Increase as reasonably estimated by Landlord for the ensuing Operating Year. Tenant shall pay to Landlord in equal monthly installments together with its payment of fixed rent one-twelfth (1/12) of Tenant's Projected Share of Increase as Additional Rent.

5.05. Commencing with the first Operating Year and thereafter, Tenant shall pay to Landlord as Additional Rent for the then Operating Year, Tenant's Projected Share of Increase; provided, however, that Tenant shall not be required to pay Tenant's Projected Share of Increase for any period prior to the first (1st) anniversary of the Commencement Date.

5.06. After the expiration of the first Operating Year and after the expiration of each Operating Year thereafter, Landlord shall furnish to Tenant a reasonably detailed statement of the Operating Expenses incurred for such Operating Year which statement shall set forth Tenant's Proportionate Share of Increase, if any. If the statement furnished by Landlord to Tenant, pursuant to this Section, at the end of the then Operating Year shall indicate that Tenant's Projected Share of Increase exceeded Tenant's Proportionate Share of Increase, Landlord shall either forthwith pay the amount of excess directly to Tenant concurrently with the statement or credit same against Tenant's next monthly installment of rent within thirty (30) days. If such statement furnished by Landlord to Tenant hereunder shall indicate that the Tenant's Proportionate Share of Increase exceeded Tenant's Projected Share of Increase for the then Operating Year, Tenant shall forthwith pay the amount of such excess to Landlord within thirty (30) days. If Landlord has not provided Tenant a written statement for Tenant's Projected Share of Increase as of the commencement of any Operating Year, Tenant shall be obligated to continue to pay as Additional Rent each month at the same rate as reflected in the previous estimate furnished by Landlord until such time as Landlord has sent the statement whereupon appropriate adjustments will be made.

Notwithstanding the foregoing, Tenant's contribution towards Landlord's Controllable Operating Expenses (as that term is defined below) shall not be increased by more than five percent (5%) per calendar year on a compounding and cumulative basis for the initial Term of the Lease (the "**Operating Expense Cap**"). "Controllable Operating Expenses" shall mean all Operating Expenses with the exception of the costs and expenses related to snow and ice removal, weather related expenses, security, insurance premiums and deductibles, costs of compliance with Laws, fuel charges and all utilities. The costs and expenses related to snow and ice removal, weather related expenses, security, insurance premiums and deductibles, costs of compliance with Laws, fuel charges and all utilities shall be deemed "Non-Controllable Operating Expenses" and Non-Controllable Operating Expenses shall be excluded from any Operating Expense Cap and Tenant

shall pay its full Tenant's Proportionate Share of Increase of such Non-Controllable Operating Expenses, regardless of any Operating Expense Cap. In the event Tenant exercises a Renewal Period, Tenant's Proportionate Share of Increase for the first Lease Year of such Renewal Period shall be its full Tenant's Proportionate Share of Increase, without any Operating Expense Cap being applied, based on Operating Expenses for that first full Lease Year of the applicable Renewal Period. Thereafter, the Operating Expense Cap shall be applied as set forth herein.

5.07. Every statement given by Landlord pursuant to Sections 5.03 and 5.06 shall be conclusive and binding upon Tenant unless (i) within ninety (90) days after the receipt of such statement Tenant shall have given a notice to Landlord that Tenant disputes the correctness of the statement, specifying in reasonable detail the basis for such assertion. Pending resolution of such a dispute, and absent manifest error, Tenant shall pay the Additional Rent in accordance with the statement furnished by Landlord. Landlord agrees, upon prior written request, during normal business hours to make available for Tenant's inspection, at Landlord's offices, Landlord's books and records which are relevant to any items in dispute. If after such inspection, Tenant still disputes such statement of Taxes or Operating Expenses, either party may refer the decision of the issues raised to a reputable independent firm of certified public accountants, selected by Landlord and approved by Tenant, which approval shall not be unreasonably withheld as long as such firm is a regionally or nationally recognized firm with at least twenty (20) partners or principals who are certified public accountants, and the decision of such accounting firm shall be conclusively binding upon the Parties Tenant shall not be permitted to use any accounting firm or other company which derives or ties its compensation from the savings realized by Tenant for any audit. The fees and expenses involved in such decision shall be borne by Tenant, unless the accounting firm determines that Landlord's original calculation of the actual Taxes or Operating Expenses was in error by more than five percent (5%), in which event Landlord shall pay the reasonable fees of such accounting firm. If the inspection shows an undercharge to Tenant, Tenant shall pay the amount due to Landlord within thirty (30) days after completion of the audit. If the audit indicates an overpayment by Tenant, then Tenant shall be entitled at Landlord's sole option to either (i) to receive a refund from Landlord within thirty (30) days after finalization of such audit, or (ii) a credit in an amount equal to such excess against Rent next becoming due under this Lease. In no event shall this Lease be terminable nor shall Landlord be liable for damages based upon any disagreement regarding an adjustment of Operating Expenses, except as otherwise expressly set forth in this Section 5.07. Tenant recognizes the confidential nature of Landlord's books and records and agrees to maintain the information obtained from any examination conducted pursuant to this Section 5.07 in strict confidence.

ARTICLE 6

SUBORDINATION TO MORTGAGEES

6.01. This Lease shall be subject and subordinate at all times to the lien of any mortgage, deed of trust, ground lease, installment sale agreement and/or other instrument or encumbrance heretofore or hereafter placed upon any or all of Landlord's interest or estate in the Premises or the remainder of the Property and of all renewals, modifications, consolidations, replacements and extensions thereof (all of which are hereinafter referred to collectively as a "mortgage"), all automatically and without the necessity of any further action on the part of the Tenant to effectuate such subordination. Within twenty-five (25) days of any request by Landlord, Tenant shall, at the

request of the holder of any such mortgage, attorn to such holder, and shall execute, acknowledge and deliver, upon demand by the Landlord or such holder, such further instrument or instruments evidencing such subordination of the Tenant's right, title and interest under this Lease to the lien of any such mortgage, and such further instrument or instruments evidencing and elaborating such attornment, as shall be reasonably desired by such holder. Further, (i) Landlord, at Landlord's sole cost, shall obtain a subordination, non-disturbance agreement ("SNDA") from the current holder of any ground lease and/or mortgage on in the form attached hereto as Exhibit H; and (ii) Landlord shall use commercially reasonable efforts to obtain an SNDA from any future ground lessees or mortgagees substantially in the form attached hereto as Exhibit H.

ARTICLE 7

QUIET ENJOYMENT

7.01. Landlord covenants that if and so long as Tenant pays Fixed Base Rent and any Additional Rent as herein provided and performs Tenant's covenants hereof, Landlord shall do nothing to affect Tenant's right to peacefully and quietly have, hold and enjoy the Demised Premises for the term herein defined, subject to all provisions of this Lease and to any mortgage to which this Lease shall be subordinate.

ARTICLE 8

ASSIGNMENT, MORTGAGING, SUBLETTING

8.01. Tenant may not mortgage, pledge, hypothecate, assign, transfer, sublet or otherwise deal with this Lease or the Premises in any manner except as specifically provided for in this Article 8.

8.02. (a) Except for a Permitted Transfer (as hereinafter defined), in the event that Tenant desires to sublease the whole or any portion of the Demised Premises or assign the within Lease to any other party, the terms and conditions of such sublease or assignment shall be communicated to Landlord in writing not less than twenty (20) days prior to the effective date of any such sublease or assignment and Landlord shall thereafter have ten (10) business days to respond to Tenant's request for such sublease or assignment.

(b) Tenant may assign this Lease or sublet the whole or any portion of the Premises, subject to Landlord's prior written consent, which consent shall not be unreasonably withheld, conditioned, or delayed, on the basis of the following terms and conditions (it being agreed that if the terms of any mortgage loan documents encumbering the Property require the mortgagee of the Property to consent to any sublease or assignment, and the mortgagee of the Property fails or refuses to consent to a proposed sublease or assignment, then Landlord shall not be deemed to have acted unreasonably in withholding its consent to such sublease or assignment):

(1) The Tenant shall provide to Landlord the name and address of the assignee or subtenant.

(2) The assignee shall assume, by written instrument, all of the obligations of this Lease, and a copy of such assumption agreement shall be furnished to Landlord within ten (10) days of its execution. Any sublease shall expressly

acknowledge that said subtenant's rights against the Landlord shall be no greater than those of the Tenant.

(3) The Tenant and each assignee (including if such assignee is in place as a result of a Permitted Transfer), shall be and remain liable for the observance of all the covenants and provisions of this Lease, including, but not limited to, the payment of Fixed Base Rent and Additional Rent reserved herein, as and when required to be paid, through the entire Term of this Lease.

(4) The Tenant and any assignee shall promptly pay to Landlord one-half (1/2) of any net consideration received for any assignment or one-half (1/2) of the net sublease rent, as and when received, in excess of the Fixed Base Rent and Additional Rent required to be paid by Tenant for the period affected by said assignment or sublease for the area sublet, computed on the basis of an average square foot rent for the gross square footage Tenant has leased. As used herein, net consideration and/or net rent shall mean gross rent (Fixed Base and Additional) or gross consideration less any reasonable legal fees, brokerage commissions, and/or tenant work paid by Tenant in connection with the assignment or sublet, said legal fees, brokerage commissions or tenant work to be amortized over the term of the sublet.

(5) In any event, the acceptance by Landlord of any rent (Fixed Base and Additional) from the assignee or from any of the subtenants or the failure of Landlord to insist upon a strict performance of any of the terms, conditions and covenants herein shall not release Tenant herein, nor any assignee assuming this Lease, from any and all of the obligations herein during and for the entire Term of this Lease.

(6) Landlord shall require a One Thousand Five Hundred and 00/100 Dollar ($1,500.00) payment to cover its handling charges for each request for consent to any sublet or assignment prior to its consideration of the same.

(7) Tenant shall have no claim, and hereby waives the right to any claim, against Landlord for money damages by reason of any refusal, withholding or delaying by Landlord of any consent, and in such event, Tenant's only remedies therefor shall be an action for specific performance, injunction or declaratory judgment to enforce any such requirement.

8.03. Any sublet or assignment to (i) an entity controlling, controlled by or under common control with Tenant, or (ii) any successor of Tenant resulting from a merger, consolidation, sale of all or substantially all of the assets or equity interests of Tenant or other form of corporate reorganization (in any such case, a "**Permitted Transfer**"), shall not be subject to the provisions of Subsection 8.02(b)(4) and shall not require Landlord's prior written consent, but the provisions of Subsections 8.02(b)(2), (3), (5) and (7) shall apply to any Permitted Transfer. Notwithstanding the foregoing, in order for an assignment resulting from a sale of all or substantially all of the assets of Tenant to a third party to be deemed a Permitted Transfer, (x) the purchaser of Tenant's assets must have a net worth computed in accordance with United States generally accepted accounting principles at least equal to the net worth of Tenant on the date of

such sublet or assignment, and (y) upon request provide proof reasonably satisfactory to Landlord of such net worth prior to the effective date of any such transaction.

8.04. Except as specifically set forth above, no portion of the Demised Premises or of Tenant's interest in this Lease may be acquired by any other person or entity, whether by assignment, mortgage, sublease, transfer, operation of law or act of the Tenant, nor shall Tenant pledge its interest in this Lease or in any security deposit required hereunder.

ARTICLE 9

COMPLIANCE WITH LAWS

9.01. Tenant covenants to comply with all present and future laws, orders and regulations of the federal, state and municipal governments or any of their departments affecting Tenant's manner of use and occupancy of the Demised Premises.

9.02. Tenant may, at its expense (and if necessary, in the name of but without expense to Landlord) contest, by appropriate proceedings prosecuted diligently and in good faith, the validity, or applicability to the Demised Premises, of any law or requirement of public authority, and Landlord shall reasonably cooperate with Tenant at no cost to Landlord in such proceedings provided that:

(a) Tenant shall defend, indemnify, and hold harmless Landlord against all liability, loss or damage which Landlord shall suffer by reason of such non-compliance or contest, including reasonable attorney's fees and other expenses reasonably incurred by Landlord;

(b) Such non-compliance or contest shall not constitute or result in any violation of any superior mortgage, or, if such superior mortgage shall permit such non-compliance or contest on condition of the taking of action or furnishing of security by Landlord, such action shall be taken and such security shall be furnished at the expense of Tenant;

(c) Tenant shall keep Landlord advised as to the status of such proceedings;

(d) Tenant, by its acts or omissions, does not place Landlord or other tenants in jeopardy or subject to any form of penalty or fine; and

(e) Any such proceedings shall not affect the payment of Fixed Rent or Additional Rent or other sums payable hereunder, nor prevent Tenant from using the Demised Premises for its intended purpose.

ARTICLE 10

INSURANCE

10.01. Tenant shall obtain and keep in full force and effect at all times during the Term of this Lease, at its own cost and expense: (a) "All Risk" property insurance against fire, theft, vandalism, malicious mischief, sprinkler leakage and such additional perils as are now, or hereafter may be, included in a standard extended coverage endorsement from time to time in general use

in the State of New Jersey upon property of every description and kind owned by Tenant and or under Tenant's care, custody or control located in the Building or for which Tenant is legally liable or installed by or on behalf of Tenant, including by way of example and not by way of limitation, furniture, fixtures, installation and any other personal property in an amount equal to the full replacement costs thereof; (b) Commercial General Liability Insurance Coverage to include personal injury, bodily injury, broad form property damage, operations hazard, owner's protective coverage, and blanket contractual liability naming Landlord, and Landlord's mortgagee or trust deed holder and ground landlord (if any) as additional named insureds in an amount per occurrence of not less than One Million and 00/100 ($1,000,000) Dollars combined single limit per occurrence and Two Million and 00/100 ($2,000,000) Dollars general aggregate for bodily injury or death and property damage occurring in, upon, adjacent, or connected with the Demised Premises and any part thereof on a per location basis, as well as at least One Million and 00/100 ($1,000,000) Dollars of coverage for property insurance. Tenant shall name such other insureds associated with the Building as Landlord reasonably requests. Tenant shall pay all premiums and charges therefor and upon failure to do so Landlord may, but shall not be obligated to, make payments, and in such latter event the Tenant agrees to pay the amount thereof to Landlord on demand and said sum shall be deemed to be Additional Rent, and in each instance collectible on the first day of any month following the date of notice to Tenant in the same manner as though it were rent originally reserved hereunder, together with interest thereon at the rate of three points in excess of Prime Rate. Copies of the original insurance policies or appropriate certificates shall be deposited with Landlord together with any renewals, replacements or endorsements at all times to the end that said insurance shall be in full force and effect for the benefit of the Landlord during the Term of this Lease; (c) Worker's Compensation insurance in form and amount as required by law; (d) excess or "umbrella" liability insurance in an amount of not less than Three Million and 00/100 ($3,000,000) Dollars; and (e) any other form or forms of insurance or any increase in the limits of any of the aforesaid enumerated coverages or other forms of insurance as Landlord or the mortgagee of Landlord may reasonably require from time to time if in the reasonable opinion of Landlord or said mortgagees or said coverage and/or limits become inadequate or less than that commonly maintained by prudent tenants in similar buildings in the area by tenants making similar uses.

10.02. All insurance policies required pursuant to this Article shall be taken out with insurers rated A- XII by A.M. Best Company, who are licensed to do business in the State of New Jersey. A policy or certificate evidencing such insurance together with a paid bill shall be delivered to Landlord not less than fifteen (15) days prior to the commencement of the Term hereof. Such insurance policy or certificates will unequivocally provide an undertaking by the insurers to notify Landlord and the mortgages of Landlord in writing not less than thirty (30) days prior to any material change, reduction in coverage, cancellation or other termination thereof (except that any cancellation for non-payment shall require only ten (10) days prior written notice). Should a certificate of insurance initially be provided, a policy shall be furnished by Tenant within thirty (30) days of the Term's commencement. The aforesaid insurance shall be written with reasonable and customary deductibles.

10.03. Insofar as and to the extent that the following provision may be effective without invalidating or making it impossible to secure insurance coverage obtainable from responsible insurance companies doing business in the state in which the Property is located (even though extra premium may result therefrom), Landlord and Tenant mutually agree that Landlord and Tenant shall have no liability to one another, or to any insurer, by way of subrogation or otherwise,

on account of any loss or damage to their respective property, the Demised Premises or its contents, or the Property, regardless of whether such loss or damage is caused by the negligence of Landlord or Tenant, arising out of any of the perils or casualties insured against by the property insurance policies carried, or required to be carried, by the parties pursuant to this Lease. The insurance policies obtained by Landlord and Tenant pursuant to this Lease shall permit waivers of subrogation which the insurer may otherwise have against the non-insuring party. In the event the policy or policies do not allow waiver of subrogation prior to loss, either Landlord or Tenant shall, at the request of the other party, deliver to the requesting party a waiver of subrogation endorsement in such form and content as may reasonably be required by the requesting party or its insurer. In the event that any additional premium is payable by either party as a result of this provision, the other party shall reimburse the party paying such premium the amount of such extra premium. The releases herein contained shall not apply to any loss or damage occasioned by the willful acts of either of the parties hereto.

10.04. Each party hereby releases the other party with respect to any claim (including a claim for negligence) which it might otherwise have against the other party for loss, damage, or destruction with respect to its property (including rental value or business interruption) occurring during the term of this Lease to the extent to which it is insured under a policy or policies containing a waiver of subrogation or naming the other party as an additional insured, as provided in this Article.

10.05. Landlord covenants and agrees that throughout the Term it will insure the Building (excluding any property with respect to which Landlord is obligated to insure pursuant to Section 10.01, above) against damage by fire and standard extended coverage perils and public liability insurance in such reasonable amounts with such reasonable deductibles as required by any mortgagee or ground Landlord (if any), or if none, as would be carried by a prudent owner of a similar building in the area. In addition, Landlord shall maintain and keep in force and effect during the Term, rental income insurance insuring Landlord against abatement or loss of Fixed Base Rent and Additional Rent, in case of fire or other casualty similarly insured against, in an amount at least equal to one year's Fixed Base Rent for the Building. Landlord may, but shall not be obligated to, take out and carry any other forms of insurance as it or the mortgagee or ground lessor (if any) of Landlord may require or reasonably determine available. All insurance carried by Landlord on the Building or Land shall be included as an Operating Expense pursuant to Article 5.

10.06 To the extent available, Landlord and Tenant each agree to include an endorsement in its property insurance policies reflecting the waiver of the insurer's right of subrogation against the other party as contemplated by Section 10.03.

ARTICLE 11

RULES AND REGULATIONS

11.01. Tenant and its employees and agent shall faithfully observe and comply with the Rules and Regulations annexed hereto as Exhibit C, and such reasonable changes therein (whether by modification, elimination, or addition) as Landlord at any time or times hereafter may make and communicate in writing to Tenant; provided, however, that in case of any conflict or

inconsistency between the provisions of this Lease and any of the Rules and Regulations as originally promulgated or as changed, the provisions of this Lease shall control.

11.02. Nothing contained in this Lease shall be construed to impose upon Landlord any duty or obligation to Tenant to enforce the Rules and Regulations or the terms, covenants, or conditions in any other lease, as against any other tenant and Landlord shall not be liable to Tenant for violation of the same by any other tenant or its employees, agents or visitors. However, Landlord shall not enforce any of the Rules and Regulations in such manner as to discriminate against Tenant or anyone claiming under or through Tenant.

ARTICLE 12
Intentionally Deleted

ARTICLE 13

TENANT'S PROPERTY

13.01. All fixtures, equipment, improvements, and appurtenances attached to or built into the Demised Premises at the commencement of or during the term of this Lease, whether or not by or at the expense of Tenant, shall be and remain a part of the Demised Premises, shall be deemed the property of Landlord and shall not be removed by Tenant, except as hereinafter in this Article expressly provided.

13.02. All business and trade fixtures, machinery and equipment, communications equipment and office equipment (excluding cabling and/or conduit within walls or above dropped ceilings), whether or not attached to or built into the Demised Premises, which are installed in the Demised Premises by or for the account of Tenant, without expense to Landlord, and can be removed without permanent structural damage to the Building, and all furniture, furnishings and other articles of movable personal property owned by Tenant and located in the Demised Premises (all of which are sometimes called "**Tenant's Property**"), shall be and shall remain the property of Tenant and may be removed by it at any time during the term of this Lease; provided that if any of Tenant's Property is removed, Tenant shall repair or pay the cost of repairing any damage to the Demised Premises or to the Building resulting from such removal. Tenant's Property shall specifically exclude Landlord's Furniture and Tenant shall not be permitted to remove Landlord's Furniture from the Demised Premises except as permitted in Article 42. Any equipment or other property for which Landlord shall have granted any allowance or credit to Tenant shall not be deemed to have been installed by or for the account of Tenant, without expense to Landlord, and shall not be considered Tenant's Property.

13.03. At or before the Expiration Date, or the date of an earlier termination of this Lease, or as promptly as practicable after such an earlier termination date, Tenant at its expense, shall remove from the Demised Premises all of Tenant's Property except such items thereof as Tenant shall have expressly agreed in writing with Landlord were to remain and to become the property of Landlord, and, if requested by Landlord in accordance with Article 4 of this Lease all Alterations by or on behalf of Tenant after the Commencement Date shall be removed by Tenant and Tenant shall repair any damage to the Demised Premises or the Building resulting from such removal.

13.04. Any other items of Tenant's Property which shall remain in the Demised Premises after the Expiration Date or after a period of fifteen (15) days following an earlier termination date,

may, at the option of the Landlord, be deemed to have been abandoned, and in such case either may be retained by Landlord as its property or may be disposed of, without accountability, in such manner as Landlord may see fit, at Tenant's expense.

13.05. This Article 13 shall survive the expiration or earlier termination of this Lease.

ARTICLE 14

REPAIRS AND MAINTENANCE

14.01. Landlord shall at its expense, maintain the Property in good repair and condition as a Class A office building, including but not limited to the maintenance and repair of the roof, foundation, air conditioning, heating, plumbing and electrical systems, structural components, parking areas, walkways, and landscaping. Tenant will not in any manner deface or injure the Building, and will pay the cost of repairing any damage or injury done to the Building or any part thereof by Tenant or Tenant's agents, employees or invitees. Tenant shall take good care of the Premises and keep the Premises free from waste and nuisance of any kind. Tenant shall keep the Premises, including Landlord's Furniture and all fixtures installed by Tenant and any plate glass and special store fronts, in good condition, reasonable wear and tear and damage caused by casualty excepted, and make all necessary non-structural repairs except those caused by fire, casualty or acts of God covered by Landlord's fire insurance policy covering the Building. The performance by Tenant of its obligations to maintain and make repairs shall be conducted only by contractors and subcontractors approved in writing by Landlord (which approval shall not be unreasonably withheld, conditioned, or delayed), it being understood that Tenant shall procure and maintain and shall cause contractors and subcontractors engaged by or on behalf of Tenant to procure and maintain insurance coverage against such risks, and in such amounts as Landlord may reasonable require and with such companies as landlord may reasonably approve, in connection with any such maintenance and repair. If Tenant fails to make such repairs or take steps to have such condition corrected after the occurrence of the damage or injury, Landlord may at its option make such repair, and Tenant, shall within thirty (30) days of request therefor, pay Landlord for the cost thereof. At the end or other termination of this Lease, Tenant shall deliver up the Premises with all improvements located thereon (except as otherwise herein provided) in good repair and condition, reasonable wear and tear and damage caused by casualty excepted, and shall deliver to Landlord all keys to the Premises.

14.02. If Landlord shall fail to perform any term, condition, covenant or obligation required under this Lease and such failure either (a) has a material adverse impact on Tenant's access to or use of the Demised Premises or Landlord shall fail to perform snow removal in the public portions of the Property, and such failure continues for more than five (5) days after notice to Landlord, or (b) in the event of a failure other than what is set forth in subsection (a), such failure has continued for a period of forty five (45) days after prior written notice and opportunity to cure thereof from Tenant to Landlord; provided, however, that if the term, condition, covenant or obligation to be performed by Landlord is such that it cannot reasonably be performed within the applicable time period set forth in this Section 14.02, such default shall be deemed to have been cured if Landlord commences such performance within said 45-day period (or 5-day period, as the case may be) and thereafter diligently undertakes to complete the same, Tenant may, at its option, without waiving any claim for damages for breach of agreement, at any time thereafter

cure such default for the account of Landlord and any amount paid or any contractual liability incurred by Tenant in so doing shall be deemed paid or incurred for the account of Landlord and Landlord shall reimburse Tenant therefore within thirty (30) days of Tenant's demand.

ARTICLE 15

ELECTRICITY

15.01. To the extent available at the Property, Tenant shall obtain electric service directly from the provider and provide evidence satisfactory to Landlord that electric charges for the Demised Premises have been changed into Tenant's name for billing purposes within three (3) days after the Actual Delivery Date. Any utility service agreement with respect to the Premises is subject to Landlord's approval, which approval shall not be unreasonably withheld. If electric is submetered, Tenant shall pay to Landlord, as Additional Rent for such service, during the Term, an amount equal to the amount Landlord actually pays to the utility company to provide electricity to the Premises, including all applicable surcharges, demand charges, taxes and other sums payable in respect thereof, without any mark-up, service charge or other additional fees or profit margin imposed by Landlord and Tenant shall receive the net of any rebates or credits actually received by Landlord in respect of such electricity supplied to the Premises and paid for by Tenant, based on Tenant's demand and/or consumption of electricity as registered on a meter or sub-meter installed by Landlord for purposes of measuring such demand and consumption. Landlord, at Landlord's sole cost and expense (but subject to recoupment by Landlord pursuant to Sections 5.05 and 5.06) shall maintain such meters or sub-meters in good working order. If at any time the Demised Premises are not separately metered Tenant shall have the right to audit such readings, bills and calculations. For the avoidance of doubt, electric energy for the HVAC system and all common areas of the Building is included in Operating Expenses, and Tenant shall pay Tenant's Percentage of the same.

15.02. Landlord shall not be liable in any way to Tenant for any failure or defect in the supply or character of electric energy furnished to the Demised Premises by reason of any requirement, act, or omission of the public utility serving the Building with electricity or for any other reason. Landlord shall furnish and install all replacement lighting tubes, lamps, bulbs, and ballasts required in the Demised Premises at Tenant's expense.

15.03. Tenant's use of electric energy in the Demised Premises shall not at any time exceed the capacity of any of the electrical conductors and equipment in or otherwise serving the Demised Premises.

ARTICLE 16

HEATING, VENTILATION AND AIR-CONDITIONING

16.01. Landlord, subject to the provisions of Section 5.04, shall maintain and operate the heating, ventilating, and air-conditioning systems (hereinafter called "**the systems**") and shall furnish heat, ventilating, and air conditioning (hereinafter collectively called "**air conditioning service**") in the Demised Premises through the systems, for comfortable occupancy of the Demised Premises from 7:00 A.M. to 6:00 P.M. Monday through Friday ("**Regular Hours**") and 8:00 A.M. to 1:00 P.M. on Saturdays, except for Building Holidays. If Tenant shall require air-conditioning service at any other time (hereinafter called "**after hours**"), Landlord shall furnish such after hours

air-conditioning service upon reasonable advance notice from Tenant, and Tenant shall pay Landlord's then established charges therefor on Landlord's demand, which is currently Seventy Five Dollars ($75.00) per hour per chargeable zone (as described in Landlord's memorandum dated October 23, 2019), attached hereto as Exhibit K.

16.02. Use of the Demised Premises, or any part thereof, in a manner exceeding the design conditions for air-conditioning service to the Demised Premises or rearrangement of partitioning which interferes with normal operation of the air-conditioning in the Demised Premises, may require changes in the air-conditioning system servicing the Demised Premises. Such changes, so occasioned, shall be made by Landlord at Tenant's expense.

ARTICLE 17

LANDLORD'S OTHER SERVICES

17.01. Landlord, subject to the provisions of Section 5.04, shall provide public elevator service, passenger and service, by elevators serving the floors on which the Demised Premises are situated during Regular Hours, and shall have at least one passenger elevator subject to call at all other times.

17.02. Landlord, subject to the provisions of Section 5.04, shall cause the Demised Premises to be cleaned with regular janitorial services in accordance with the specifications set forth on attached Exhibit B. Tenant shall pay to Landlord on demand the costs incurred by Landlord for (a) extra cleaning work in the Demised Premises required because of (i) misuse or neglect on the part of Tenant or its employees or visitors; (ii) use of portions of the Demised Premises for preparation, serving or consumption of food or beverages, data processing, or reproducing operations, private lavatories or toilets or other special purpose areas requiring greater or more difficult cleaning work than office areas; (iii) unusual quantity of interior glass surfaces; (iv) non-building standard materials or finishes installed by Tenant or at its request; and (b) removal from the Demised Premises and the Building of so much of any refuse and rubbish of Tenant as shall exceed that ordinarily accumulated daily in the routine of business office occupancy. Landlord hereby confirms that the nothing currently in the Demised Premises applies to clauses (ii), (iii) and (iv) of the previous sentence. Landlord, its cleaning contractor, and their employees shall have after-hours access to the Demised Premises and the free use of light, power, and water in the Demised Premises as reasonably required for the purpose of cleaning the Demised Premises in accordance with Landlord's obligations hereunder. In the event Tenant becomes dissatisfied with the janitorial services provided by Landlord's cleaning contractor, and if the cleaning contractor does not timely address its sub-standard performance, Landlord shall, upon Tenant's reasonable request, replace the cleaning contractor as soon as is reasonably possible.

17.03. Landlord, subject to the provisions of Section 5.04, shall furnish adequate hot and cold water to each floor of the Building for drinking, lavatory, and cleaning purposes, together with soap, towels, and toilet tissue for each lavatory. If Tenant uses water for any other purpose, Landlord, at Tenant's expense, may install meters to measure Tenant's consumption of cold water and/or hot water for such other purposes and/or steam, as the case may be. In such instances Tenant shall pay for the quantities of cold water and hot water shown on such meters, at Landlord's cost thereof, on the rendition of Landlord's bills therefor.

17.04. Landlord, at its expense, and at Tenant's request, shall insert the name of the Tenant on the Building directory. All Building directory changes made at Tenant's request after the Tenant's initial listings have been placed on the Building directory shall be made by Landlord at the expense of Tenant, and Tenant agrees to promptly pay to Landlord as Additional Rent the cost of such changes within ten (10) days after Landlord has submitted an invoice therefor.

17.05. Landlord reserves the right, without any liability to Tenant, to temporarily stop service of any of the heating, ventilating, air conditioning, electric, sanitary, elevator, or other Building systems serving the Demised Premises, or the rendition of any of the other services required of Landlord under this Lease, whenever and for so long as may be necessary, by reason of accidents, emergencies, strikes, or the making of repairs or changes which Landlord is required by this Lease or by law to make or in good faith deems necessary, by reason of difficulty in securing proper supplies of fuel, steam, water, electricity, labor or supplies, or by reason of any other cause beyond Landlord's reasonable control.

17.06 If the Demised Premises or any portion thereof are rendered untenantable or inaccessible or are not able to be used by Tenant without material and significant hardship or inconvenience for a period of three (3) consecutive business days (subject to extension due to Force Majeure) as a result of a failure of the water, heating, ventilating, air conditioning, electric, sanitary, elevator, or other Building systems serving the Demised Premises, Tenant's Rent shall be proportionately abated commencing on the fourth (4th) day of such service interruption until such time as the systems have been restored and the Demised Premises or the affected portion thereof is no longer untenantable or inaccessible, provided that there shall be no abatement of Rent if such failure is caused by the acts or omission of Tenant, its agents, contractors, licensees or invitees.

17.08. Landlord shall initially make available for Tenant's use 64 parking spaces, which number shall be increased in the event that Tenant leases additional space in the Building at the rate of 3.47 parking spaces per additional 1,000 usable square feet of the Demised Premises, to be utilized in common use with other tenants of the Building in the parking area adjacent to the Building. Landlord shall, at Landlord's expense (but includable in Operating Expenses), provide all necessary snow removal.

17.09. The Building and the Demised Premises shall be cleaned in accordance with the Cleaning and Maintenance Schedule set forth on Exhibit B annexed hereto and made a part hereof.

17.10. Landlord shall have no obligation to provide personnel for Building and parking lot security (including but not limited to a staffed lobby security desk and/or a parking lot security guard or patrol car) (collectively, "**Security Personnel**"). If Landlord elects, in its sole and absolute discretion, to provide Security Personnel at any time, the reasonable costs of such Security Personnel shall be included in Operating Expenses. Landlord shall supply a card access system for both the front and back doors of the Building, and provide at the commencement of the Lease, at Landlord's expense, up to 45 access cards for all of Tenant's employees. Tenant shall pay Landlord for any subsequent and/or replacement cards at Landlord's reasonable charge therefor.

ARTICLE 18

ACCESS; CHANGES IN BUILDING FACILITIES; SIGNAGE

18.01. All walls, windows, and doors bounding the Demised Premises (including exterior Building walls, core corridor walls and doors, and any core corridor entrance), except the inside surfaces thereof, any terraces or roofs adjacent to the Demised Premises, and any space in or adjacent to the Demised Premises used for shafts, stacks, pipes, conduits, fan room, ducts, electric or other utilities, sinks or other Building facilities, and the use thereof, as well as access thereto through the Demised Premises for the purposes of operation, maintenance, decoration, and repair, are reserved to Landlord.

18.02. Tenant shall permit Landlord to install, use, and maintain pipes, ducts, and conduits within the demising walls, bearing columns, and ceilings of the Demised Premises. All of Landlord's work shall be conducted in a manner that will not unreasonably interfere with the Tenant's operations in the Premises.

18.03. Landlord or Landlord's agent shall have the right upon twenty-four (24) hour notice to request (except in emergency under clause (ii) hereof, for which no prior notice or request shall be necessary) to enter and/or pass through the Demised Premises or any part thereof, at reasonable times during reasonable hours, (i) to examine the Demised Premises and to show them to the holders of superior mortgages, prospective purchasers or mortgagees of the Building as an entirety; and (ii) for the purpose of making such repairs or changes or doing such repainting in or to the Demised Premises or its facilities, as may be provided for by this Lease or as may be mutually agreed upon by the parties or as Landlord may be required to make by law or in order to repair and maintain said structure or its fixtures or facilities. Landlord shall be allowed to take all materials into and upon the Demised Premises that may be required for such repairs, changes, repainting, or maintenance, without liability to Tenant but Landlord shall not unreasonably interfere with Tenant's use of the Demised Premises or Tenant's business operations. Landlord shall also have the right to enter on and/or pass through the Demised Premises, or any part thereof, at such times as such entry shall be required by circumstances of emergency affecting the Demised Premises or the Building. Tenant shall have the right to escort Landlord and/or its agents through the Demised Premises in the event of any such entry to the Demised Premises, provided, however, that if Tenant does not provide an escort, Landlord shall still have the right to enter the Demised Premises as provided in this Lease.

18.04. During the period of twelve (12) months prior to the Expiration Date, Landlord may exhibit the Demised Premises to prospective tenants.

18.05. Landlord reserves the right, without incurring any liability to Tenant therefor, to make such changes in or to the Building and the fixtures and equipment thereof, as well as in or to the street entrances, halls, passages, elevators, escalators, and stairways thereof, as it may deem necessary or desirable, provided, however, that such changes shall not impair Tenant's quiet enjoyment of the Demised Premises, reduce the size of the Demised Premises, or restrict Tenant's access to the Demised Premises by more than a de minimis extent.

18.06. Subject to applicable law and the terms and conditions of this Lease including Article 16 regarding after hours charges for HVAC, the Building shall be accessible by Tenant twenty-four (24) hours per day, seven (7) days per week, three hundred sixty-five (365) days per year through a card key access system.

18.07. Tenant shall be permitted to install its own signage within the Premises. Landlord shall provide, at its sole cost and expense, Building standard signage/directory in the first (1st) floor lobby and Tenant shall have the right to be listed on the standard signage/directory in the lobby.

18.08. To the extent permitted by any governmental authority having jurisdiction, Tenant shall be permitted to utilize the one existing box sign on the exterior façade of the Building (the "**Building Façade Signage**"). Landlord reserves the right to expand the dimensions of the existing Building Façade Signage so that Landlord may place additional tenants and/or building identification on the Building Façade Signage. Further, Tenant shall be permitted to have one placement on the monument signage serving the Building, of a size, design and location acceptable to Landlord (the "**Monument Signage**"). The Building Façade Signage and Monument Signage shall be subject to (i) applicable laws, codes and ordinances, (ii) the approval of the Association if and to the extent required by the DCR, and (iii) the prior written approval of Landlord (which shall not be unreasonably withheld, conditioned or delayed), and shall be at Tenant's sole cost and expense (except that Landlord shall be responsible for the costs of designing and constructing any monuments upon which a Monument Signage is placed, subject to reimbursement through Operating Expenses). Nothing contained in this Section 18.08 or elsewhere in the Lease shall prohibit Landlord from placing additional signage on or about the Building or Property or any of the facades of the Building, or modifying any existing signage, provided such signage is approved by the governmental authority having jurisdiction.

ARTICLE 19

NOTICE OF ACCIDENTS

19.01. Tenant shall give notice to Landlord, promptly after Tenant learns thereof, of (i) any theft, accident or injury occurring within the Demised Premises; (ii) all fires in the Demised Premises; (iii) all damage to or defects in the Demised Premises, including the fixtures, equipment, and appurtenances thereof, for the repair of which Landlord might be responsible; and (iv) all damage to or defects in any parts or appurtenances of the Building's sanitary, electrical, heating, ventilating, air-conditioning, elevator, and other systems located in or passing through the Demised Premises or any part thereof or any part of the Building. If Landlord fails to repair or correct any such condition which is Landlord's responsibility hereunder to correct, Tenant shall have the rights set forth in Section 14.02.

19.02. Landlord shall give notice to Tenant within a reasonable amount of time after Landlord learns thereof, to the extent such matters are reasonably anticipated to impact the health and/or safety of the Tenant or any of Tenant's employees or invitees, of (i) any burglary within the Building; (ii) any significant fires at the Building; and (iii) damage to or defects in any parts or appurtenances of the Building's sanitary, electrical, heating, ventilating, air-conditioning, elevator, and other systems located in any part of the Building. Failure of Landlord to notify Tenant of the foregoing matters shall not be deemed a default under this Lease.

ARTICLE 20

NON-LIABILITY AND INDEMNIFICATION

20.01. Neither Landlord nor any agent or employee of Landlord shall be liable to Tenant for any injury or damage to Tenant or to any other person or for any damage to, or loss (by theft or otherwise) of, any property of Tenant or of any other person, except to the extent such injury, loss or damage is due to the gross negligence or willful misconduct of Landlord.

20.02. Tenant shall indemnify, defend and save Landlord harmless against and from all liabilities, claims, suits, fines, penalties, damages, losses, fees, costs and expenses (including reasonable attorneys' fees) which may be imposed upon, incurred by or asserted against Landlord by reason of (a) any work or thing done in, on or about the Demised Premises or any part thereof by or on behalf of Tenant; (b) any use, occupation, condition, operation of the Demised Premises or any part thereof or of any parking lot, street, alley, sidewalk, curb, vault, passageway or space adjacent thereto or any occurrence on any of the same on the part of Tenant; (c) any act or omission on the part of Tenant or any subtenant or any employees, licenses or invitees; (d) any accident, injury (including death) or damage to any third party or property owned by someone other than Tenant and not under the care, custody or control of Tenant occurring in or about the Demised Premises or any part thereof or in, on or about any street, alley, sidewalk, curb, vault, passageway or space adjacent thereto, unless due to the gross negligence or willful misconduct of Landlord, its agents or employees; and/or (e) any failure on the part of Tenant to perform or comply with any of the covenants, agreements, terms or conditions contained in this lease.

20.03. Tenant shall not be held responsible for, and is hereby expressly relieved from, any and all liability by reason of any injury, loss, or damage to any person or property in or about the Property (exclusive of the Premises), whether the loss, injury or damage be to the person or property of Landlord or any other person, except to the extent such injury, loss or damage is due to the negligence or willful misconduct of Tenant, Tenant's employees, invitees, agents, contractors or affiliates. Landlord agrees to indemnify, defend and save Tenant harmless from and against all claims, actions, damages, liabilities and expenses, including but not limited to reasonable attorneys' fees and other legal expenses, on account of such injury, loss or damage to the extent arising from the gross negligence or willful misconduct of Landlord or its employees, agents, or contractors (excluding any other tenants of the Building).

The provisions of Section 20.02 and 20.03 shall survive the expiration or earlier termination of the Lease.

20.04. Except as otherwise expressly provided in this Lease, this Lease and the obligations of Tenant hereunder shall be in no way affected, impaired or excused because Landlord is unable to fulfill, or is delayed in fulfilling, any of its obligations under this Lease by reason of strike, other labor trouble, governmental pre-emption or priorities or other controls in connection with a national or other public emergency or shortages of fuel supplies or labor resulting therefrom, or other like cause beyond Landlord's reasonable control.

ARTICLE 21

DESTRUCTION OR DAMAGE

21.01. If the Building or the Demised Premises shall be partially or totally damaged or destroyed by fire or other cause, then whether or not the damage or destruction shall have resulted from the fault or neglect of Tenant, or its employees, agents or visitors (and if this Lease shall not have been terminated as in this Article hereinafter provided), Landlord shall repair the damage and restore and rebuild the Building and/or the Demised Premises, at its expense, with reasonable dispatch after notice to it of the damage or destruction; provided, however, that Landlord shall not be required to repair or replace any of the Tenant's Property.

21.02. If the Building or the Demised Premises shall be partially damaged or partially destroyed by fire or other cause then the rents payable hereunder shall be abated to the extent that the Demised Premises shall have been rendered untenantable and for the period from the date of such damage or destruction to the date the damage shall be repaired or restored; provided, however, if the damage shall be attributable to the fault or negligence of Tenant, its agents or employees, then rent shall continue but shall be reduced by any amounts received by Landlord pursuant to Landlord's coverage for business interruption and/or rent insurance attributable to the Demised Premises. If all or a substantial majority of the Demised Premises shall be totally (which shall be deemed to include substantially totally) damaged or destroyed or rendered completely (which shall be deemed to include substantially completely) untenantable on account of fire or other cause, the Rents shall abate as of the date of the damage or destruction and until Landlord shall repair, restore, and rebuild the Building and the Demised Premises; provided, however, that should Tenant reoccupy a portion of the Demised Premises during the period of restoration work is taking place and prior to the date that the same are made completely tenantable, Rents allocable to such portion shall be payable by Tenant from the date of such occupancy.

21.03. If the Building or the Demised Premises shall be totally damaged or destroyed by fire or other cause, or if the Building shall be so damaged or destroyed by fire or other cause (whether or not the Demised Premises are damaged or destroyed) as to require a reasonably estimated expenditure of more than twenty-five percent (25%) of the full insurable value of the Building immediately prior to the casualty, then in either such case, Landlord may terminate this Lease by giving Tenant notice to such effect within one hundred eighty (180) days after the date of the casualty. In case of any damage or destruction mentioned in this Article, Tenant may terminate this Lease by notice to Landlord if Landlord has not completed the making of the required repairs and restored and rebuilt the Building and the Demised Premises within twelve (12) months from the date of such damage or destruction, or within such period after such date (not exceeding six (6) months) as shall equal the aggregate period Landlord may have been delayed in doing so by adjustment of insurance, labor trouble, governmental controls, act of God, or any other cause beyond Landlord's reasonable control ("**Force Majeure**").

21.04. No damages, compensation, or claim shall be payable by Landlord for inconvenience, loss of business, or annoyance arising from any repair or restoration of any portion of the Demised Premises or of the Building pursuant to this Article. Landlord shall endeavor to restore such repair or restoration promptly and in such manner as not unreasonably to interfere

with Tenant's use and occupancy during such time that Tenant is able to use the Demised Premises during Landlord's restoration.

21.05. Notwithstanding any of the foregoing provisions of this Article, if Landlord or the holder of any superior mortgage shall be unable to collect all of the insurance proceeds (including rent insurance proceeds) applicable to damage or destruction of the Demised Premises or the Building by fire or other cause, by reason of some action or inaction on the part of Tenant or any of its employees, agents or contractors in connection with the processing of any claim, then, without prejudice to any other remedies which may be available against Tenant, there shall be no abatement of Tenant's rents.

21.06. Landlord will not carry insurance of any kind on Tenant's Property, and shall not be obligated to repair any damage thereto or replace the same.

21.07. The provisions of this Article shall be considered an express agreement governing any case of damage or destruction of the Demised Premises by fire or other casualty, and any law of the State of New Jersey providing for such a contingency in the absence of an express agreement, and any other law of like import, now or hereafter in force, shall have no application in such case.

21.08. If the Demised Premises and/or access thereto become partially or totally damaged or destroyed by any casualty not insured against, then Landlord shall have the right to terminate this Lease upon giving the Tenant thirty (30) days' notice and upon the expiration of said thirty (30) day notice period, this Lease shall terminate as if such termination date were the Expiration Date. In the event of an uninsured casualty, Landlord shall give Tenant notice within sixty (60) days after the casualty, whether or not Landlord intends to restore the Demised Premises and/or access to the Demised Premises regardless of the lack of insurance coverage. In the event Landlord (i) informs Tenant it has elected not to restore the Demised Premises and/or access thereto due to the casualty being uninsured; or (ii) if the casualty is not insured, fails to inform Tenant within sixty (60) days after the casualty that Landlord is uninsured for the casualty, Tenant shall also have the right, upon thirty (30) days' notice, to terminate the Lease, and this Lease shall terminate as if such termination date provided by Tenant were the Expiration Date.

ARTICLE 22

EMINENT DOMAIN

22.01. If the whole or a substantial part of the Building shall be lawfully taken by condemnation or in any other manner for any public or quasi-public use of purpose, this Lease and the term and estate hereby granted shall forthwith terminate as of the date of vesting of title on such taking (which date is herein after also referred to as the "date of the taking"), and the rents shall be prorated and adjusted as of such date.

22.02. If any part of the Building shall be so taken, this Lease shall be unaffected by such taking, except that Tenant may elect to terminate this Lease in the event of a partial taking, if the area of the Demised Premises shall not be reasonably sufficient for Tenant to continue feasible operation of its business.

22.03. Landlord shall be entitled to receive the entire award in any proceeding with respect to any taking provided for in this Article without deduction therefrom for any estate vested in Tenant by this Lease, and Tenant shall receive no part of such award. Tenant hereby expressly assigns to Landlord all of its right, title, and interest in or to every such award. The foregoing shall not, however, deprive, limit, nor restrict Tenant of, or from, any separate award for moving expenses, business dislocation damages or for any other award which would not reduce the award payable to Landlord. Upon the date the right to possession shall vest in the condemning authority, this Lease shall cease and terminate with Rent adjusted to such date.

ARTICLE 23

SURRENDER

23.01. On the last day of the term of this Lease, or upon any earlier termination of this Lease, or upon any re-entry by Landlord upon the Demised Premises, Tenant shall quit and surrender the Demised Premises to Landlord in good order, condition, and repair, except for ordinary wear and tear, casualty and condemnation damages, and Tenant shall remove all of Tenant's Property therefrom and perform such restoration work as is required by this Lease. Landlord's Furniture shall be surrendered together with the Demised Premises, in good order and condition, except for ordinary wear and tear. This Article 23 shall survive the expiration or earlier termination of this Lease.

ARTICLE 24

CONDITIONS OF LIMITATION

24.01. This Lease and the Term and estate hereby granted are subject to the limitation that:

(a) Whenever Tenant defaults in the payment of installment of Fixed Base Rent, or in the payment of any Additional Rent or any other charge payable by Tenant to Landlord, and such default shall continue for five (5) days after written notice thereof; or

(b) Whenever Tenant shall do or permit anything to be done, whether by action or inaction, contrary to any of Tenant's obligations hereunder, and if such situation shall continue and shall not be remedied by Tenant within thirty (30) days after Landlord shall have given to Tenant a written notice specifying the same, or, in the case of a happening or default which cannot with due diligence be cured within a period of thirty (30) days and the continuance of which for the period required for cure will not subject Landlord to risk of criminal liability or foreclosure of any superior mortgage if Tenant shall not, (i) within said thirty (30) day period advise Landlord of Tenant's intention to duly institute all steps necessary to remedy such situation; (ii) duly institute within said thirty (30) day period, and thereafter diligently prosecute to completion all steps necessary to remedy the same; and (iii) complete such remedy within such time after the date of giving of said notice to Landlord as shall reasonably be necessary; or

(c) Whenever any event shall occur or any contingency shall arise whereby this Lease or the estate hereby granted or the unexpired balance of the term hereof would, by operation of law or otherwise, devolve upon or pass to any person, firm, or corporation other than Tenant, except as expressly permitted by Article 8;

then, and in any of the foregoing cases, this Lease and the Term and estate hereby granted, whether or not the Term shall theretofore have commenced, shall, if the Landlord so elects, terminate upon ten (10) days written notice by Landlord to Tenant of Landlord's election to terminate the Lease and the term hereof shall expire and come to an end on the date fixed in such notice, with the same effect as if that day were the Expiration Date, but Tenant shall remain liable for the Fixed Base Rent and Additional Rent which subsequently accrues (and for all accrued but unpaid Fixed Base Rent and Additional Rent as of the date of the termination) and for damages as provided in Article 26.

ARTICLE 25

RE-ENTRY BY LANDLORD

25.01. If Tenant shall default in the payment of any installment of Fixed Base Rent, or of any installment of Additional Rent, on any date upon which the same ought to be paid and if such default shall continue for five (5) days after written notice thereof, or if this Lease shall expire as provided in Article 24, Landlord or Landlord's agents and employees may immediately or at any time thereafter re-enter the Demised Premises, or any part thereof, either by summary dispossess proceedings or by any suitable action or proceeding at law, or by force or otherwise, without being liable to indictment, prosecution or damages therefor, and may repossess the same, and may remove any persons therefrom, to the end that Landlord may have, hold, and enjoy the Demised Premises again as and of its first estate and interest therein. The word "re-enter", as herein used, is not restricted to its technical legal meaning. In the event of any termination of this Lease under the provisions of Article 24 or if Landlord shall re-enter the Demised Premises under the provisions of this Article or in the event of the termination of this Lease, or of re-entry, by or under any summary dispossess or other proceeding or action or any provision of law by reason of default hereunder on the part of Tenant, Tenant shall thereupon pay to Landlord the Fixed Base Rent and Additional Rent payable by Tenant to Landlord up to the time of such termination of this Lease, or of such recovery of possession of the Demised Premises by Landlord, as the case may be, and shall also pay to Landlord damages as provided in Article 26.

25.02. In the event of a breach or threatened breach by Landlord or Tenant of any of their respective obligations under this Lease, either Landlord or Tenant, as the case may be, shall also have the right of injunction. The special remedies hereunder are cumulative and are not intended to be exclusive of any other remedies or means of redress to which the parties may lawfully be entitled at any time.

25.03. If this Lease shall terminate under the provisions of Article 24, or if Landlord shall re-enter the Demised Premises under the provisions of this Article, or in the event of any termination of this Lease, or of re-entry, by or under any summary dispossess or other proceeding or action or any provision of law by reason of default hereunder on the part of Tenant, Landlord shall be entitled to retain all moneys, if any, paid by Tenant to Landlord, whether as advance rent, security, or otherwise, but such moneys shall be credited by Landlord against any fixed rent or Additional Rent due from Tenant at the time of such termination or re-entry or, at Landlord's option, against any damages payable by Tenant under Article 26 or pursuant to Law.

ARTICLE 26

DAMAGES

26.01. If this Lease is terminated under the provisions of Article 24, or if Landlord shall re-enter the Demised Premises under the provisions of Article 25, or in the event of the termination of this Lease, or of re-entry, by or under any summary dispossess or other proceeding or action of any provision of law by reason of default hereunder on the part of Tenant, Tenant shall pay to Landlord as damages, at the election of Landlord, either;

(a) A sum which at the time of such termination of this Lease or at the time of any such re-entry by Landlord, as the case may be, represents the then value of the excess, if any, of (i) the aggregate of the Fixed Base Rent and the Additional Rent payable hereunder which would have been payable by Tenant (conclusively presuming the Additional Rent to be the same as was payable for the year immediately preceding such termination) for the period commencing with such earlier termination of this Lease or the date of any such re-entry, as the case may be, and ending with the Expiration Date, had this Lease not so terminated or had Landlord not so re-entered the Demised Premises, discounted to present value at the rate of four (4%) percent over (ii) the aggregate rental value of the Demised Premises for the same period, or

(b) Sums equal to the Fixed Base Rent and the Additional Rent (as above presumed) payable hereunder which would have been payable by Tenant had this Lease not so terminated, or had Landlord not so re-entered the Demised Premises, payable upon the due dates therefor specified herein following such termination or such re-entry and until the Expiration Date, provided, however, that if Landlord shall relet the Demised Premises during said period, Landlord shall credit Tenant with the net rents received by Landlord from such reletting, such net rents to be determined by first deducting from the gross rents as and when received by Landlord from such reletting, the expenses incurred or paid by Landlord in terminating this Lease or in re-entering the Demised Premises and in securing possession thereof, as well as the expenses of reletting, including altering and preparing the Demised Premises for new tenants, brokers' commissions, and all other expenses properly chargeable against the Demised Premises and the rental therefrom; it being understood that any such reletting may be for a period shorter or longer than the remaining term of this Lease; but in no event shall Tenant be entitled to receive any excess of such net rents over the sums payable by Tenant to Landlord hereunder, nor shall Tenant be entitled in any suit for the collection of damages pursuant to this Subsection to a credit in respect of any net rents from a reletting, except to the extent that such net rents are actually received by Landlord. Damages shall also include the unamortized portion of any brokerage fees or commissions paid by Landlord. If the Demised Premises or any part thereof should be relet in combination with other space, then proper apportionment on a square foot basis shall be made of the rent received from such reletting and of the expenses of reletting.

If the Demised Premises or any part thereof to be relet by Landlord for the unexpired portion of the term of this Lease, or any part thereof, before presentation of proof of such damages to any court, commission or tribunal, the amount of rent reserved upon such reletting shall, prima facie, be the fair and reasonable rental value for the Demised Premises, or part thereof, so relet during the term of the reletting.

26.02. Suit or suits for the recovery of such damages, or any installments thereof, may be brought by Landlord from time to time at its election, and nothing contained herein shall be deemed to require Landlord to postpone suit until the date when the term of this Lease would have expired if it had not been so terminated under the provisions of Article 24, or under any provision of law, or had Landlord not re-entered the Demised Premises. Nothing herein contained shall be construed to limit or preclude recovery by Landlord against Tenant of any sums or damages to which, in addition to the damages particularly provided above, Landlord may lawfully be entitled by reason of any default hereunder on the part of Tenant. Nothing herein contained shall be construed to limit or prejudice the right of Landlord to seek and obtain as liquidated damages by reason of the termination of this Lease or re-entry on the Demised Premises for the default of Tenant under this Lease, an amount equal to the maximum allowed by any statute or rule of law in effect at the time when, and governing the proceedings in which, such damages are to be proved whether or not such amount be greater, equal to, or less than any of the sums referred to in Section 26.01.

26.03. In addition to the foregoing and without regard to whether this Lease is terminated, Tenant shall pay to Landlord upon demand, all costs and expenses incurred by Landlord, including reasonable attorney's fees, with respect to any lawsuit instituted or defended or any action taken by Landlord to enforce all or any of the provisions of this Lease.

26.04. Notwithstanding anything in this Article 26 to the contrary, if this Lease is terminated under the provisions of Article 24, or if Landlord shall re-enter the Demised Premises under the provisions of Article 25, or in the event of the termination of this Lease, or of re-entry, by or under any summary dispossess or other proceeding or action of any provision of law by reason of default hereunder on the part of Tenant, Landlord shall not have the right to seek or collect damages from Tenant for Fixed Base Rent or Additional Rent not yet due and payable (i.e., Landlord shall not have the right to accelerate such rent) unless and until any mortgagee of the Land or Building or Landlord's interest therein accelerates its loan as a result of Tenant's default beyond all applicable notice and cure periods hereunder.

ARTICLE 27

WAIVERS

27.01. Tenant, for Tenant, and on behalf of any and all persons claiming through or under Tenant, including creditors of all kinds, does hereby waive and surrender all right and privilege which they or any of them might have under or by reason of any present or future law, to redeem the Demised Premises or to have a continuance of this Lease for the term hereby demised after being dispossessed or ejected therefrom by process of law or under the terms of this Lease or after the termination of this Lease as herein provided.

27.02. In the event that Tenant is in arrears in payment of Fixed Base Rent or Additional Rent hereunder, Tenant waives Tenant's right, if any, to designate the items against which any payments made by Tenant are to be credited, and Tenant agrees that Landlord may apply any payments made by Tenant to any items it sees fit, irrespective of and notwithstanding any designation or request by Tenant as to the items against which any such payments shall be credited.

27.03. Landlord and Tenant hereby waive trial by jury in any action, proceeding or counterclaim brought by either against the other on any matter whatsoever arising out of or in any way connected with this Lease, the relationship of Landlord and Tenant, Tenant's use or occupancy of the Demised Premises, including any claim of injury or damage, or any emergency or other statutory remedy with respect thereto.

ARTICLE 28

NO OTHER WAIVERS OR MODIFICATIONS

28.01. The failure of either Party to insist in any one or more instances upon the strict performance of any one or more of the obligations of this Lease, or to exercise any election herein contained, shall not be construed as a waiver or relinquishment for the future of the performance of such one or more obligations of this Lease or of the right to exercise such election, but the same shall continue and remain in full force and effect with respect to any subsequent breach, act, or omission. No executory agreement hereafter made between Landlord and Tenant shall be effective to change, modify, waive, release, discharge, terminate or effect an abandonment of this Lease, in whole or in part, unless such executory agreement is in writing, refers expressly to this Lease and is signed by the Party against whom enforcement of the change, modification, waiver, release, discharge, or termination of effectuation of the abandonment is sought.

ARTICLE 29

CURING TENANT'S DEFAULTS

29.01. If Tenant shall default in the performance of any of Tenant's obligations under this Lease, Landlord, without thereby waiving such default, may (but shall not be obligated to) perform the same for the account and at the expense of Tenant, without notice, in a case of emergency, and in any other case, only if such default continues after the expiration of (i) ten (10) business days from the date Landlord gives Tenant notice of its intention to cure, or (ii) the applicable grace period provided in Section 24.02 or elsewhere in this Lease for cure of such default, whichever occurs later.

ARTICLE 30

BROKER

30.01. Tenant and Landlord each covenants, warrants, and represents to the other that there was no broker except the Broker instrumental in consummating this Lease and that no conversations or negotiations were had with any broker except Broker concerning the renting of the Demised Premises. Tenant agrees to hold Landlord harmless against any claims for a brokerage commission arising out of any conversations or negotiations had by Tenant with any broker except Broker. Landlord agrees to hold Tenant harmless against any claims for a brokerage commission arising out of any conversations or negotiations had by Landlord with any broker including Broker. Landlord agrees to pay Broker pursuant to a separate agreement.

ARTICLE 31

NOTICES

31.01. Any notice, statement, demand, or other communications required or permitted to be given, rendered, or made by either party to the other, pursuant to this Lease or pursuant to any applicable law or requirement of public authority, shall be in writing (whether or not so stated elsewhere in this Lease) and shall be deemed to have been properly given, rendered or made, if sent by (i) registered or certified mail, return receipt requested, or (ii) by reputable overnight courier, in either case addressed to the other Party at the address hereinabove set forth in the opening paragraph of this Lease (except that after the Commencement Date, Tenant's address shall be the Demised Premises, with a copy sent simultaneously and in like manner to Tenant at 499 Park Avenue, Suite 1200, New York, NY 10022 Attn: Legal, with an additional copy sent by email to legal@urogen.com), and shall be deemed to have been given, rendered, or made three (3) business days following the date of mailing or on the first business day after it was sent by overnight courier, as the case may be. Either Party may, by notice as aforesaid, designate a different address or addresses for notices, statements, demands, or other communications intended for it. In the event of the cessation of any mail delivery for any reason, personal delivery shall be substituted for the aforementioned method of serving notices.

ARTICLE 32

ESTOPPEL CERTIFICATE

32.01 Tenant agrees, within twenty (20) days after written request, to execute and deliver to Landlord a statement certifying that this Lease is unmodified and in full force and effect (or if there have been modifications, that the same is in full force and effect as modified and stating the modifications), certifying the dates to which the Fixed Base Rent and Additional Rent have been paid, whether any dispute exists with respect thereto and stating whether or not, to Tenant's best knowledge, Landlord is in default in performance of any of its obligations under this Lease, and, if so, specifying each such default of which Tenant may have knowledge and any other information which Landlord shall reasonably require, it being intended that any such statement delivered pursuant hereto may be relied upon by others.

ARTICLE 33

Intentionally Deleted

ARTICLE 34

REPRESENTATIONS, CONSTRUCTION, GOVERNING LAW

34.01. Landlord represents and warrants that, to the best of Landlord's actual knowledge, as of the Commencement Date, the Building complies with all applicable laws, rules, ordinances, and regulations, including without limitation all zoning, fire, life safety, building codes, environmental laws, and the Americans with Disabilities Act ("ADA") (as amended) (collectively, the "Laws"). Subject to the foregoing, Tenant expressly acknowledges and agrees that Landlord has not made and is not making, and Tenant, in executing and delivering this Lease, is not relying

upon any warranties, representations, promises or statements, except to the extent that the same are expressly set forth in this Lease. It is understood and agreed that all understandings and agreements heretofore had between the parties are merged in this Lease, which alone fully and completely express their agreements and that the same are entered into after full investigation, neither party relying upon any statement or representation not embodied in this Lease made by the other. Landlord further represents that, to Landlord's actual knowledge:

(a) there are no pending or threatened action against Landlord or the Building relating to any alleged violations of the Laws from any governmental authority or third party; and

(b) Landlord is not aware of the existence of any Hazardous Substances at, on or under the Property that require remediation under any Environmental Laws. For purposes of this subsection: "Hazardous Substances" means any pollutant, toxic substance, hazardous substance, hazardous waste or any similar term as defined in any Environmental Law; and "Environmental Laws" means any Law applicable to Landlord or the Property and relating to environmental matters or concerning pollution or protection of the environment, including Laws governing the use, storage, disposal, discharge, cleanup or reporting of Hazardous Substances.

As used in this Section and elsewhere in the Lease, to "Landlord's actual knowledge" shall mean actual, and not any implied, imputed or constructive knowledge, without any investigation by Landlord.

34.02. If any of the provisions of this Lease, or the application thereof to any person or circumstances, shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such provision or provisions to persons or circumstances other than those as to whom or which it is held invalid or unenforceable, shall not be affected thereby, and every provision of this Lease shall be valid and enforceable to the fullest extent permitted by law.

34.03. This Lease shall be governed in all respects by the laws of the State of New Jersey, without regard to any conflict of law principles that might otherwise cause the laws of a different jurisdiction to govern or apply.

34.04. In the event of any litigation, arbitration, or other legal proceedings that may arise between the Parties to enforce any of the provisions of this Lease, or any right of either Party hereunder except for litigation as described in Article 26.03, the prevailing Party shall be entitled to recover its costs, expenses, and reasonable attorneys' fees in addition to any other relief to which such Party many be entitled. An award for such costs, expenses, and reasonable attorneys' fees may be included in any judgment rendered in such litigation, arbitration, or other legal proceeding. This paragraph shall survive the termination of this Lease.

ARTICLE 35

SECURITY

35.01. Tenant shall deposit with Landlord the Security Deposit upon the execution of this Lease. The Security Deposit shall be held by Landlord as security for the faithful performance by Tenant of all the terms of this Lease by said Tenant to be observed and performed. The Security Deposit shall not and may not be mortgaged, assigned, transferred, or encumbered by Tenant,

without the written consent of Landlord, and any such act on the part of Tenant shall be without force and effect and shall not be binding upon Landlord. If any of the Fixed Base Rent or Additional Rent herein reserved or any other sum payable by Tenant to Landlord shall be overdue and unpaid beyond applicable notice and cure periods, or if Landlord makes payment on behalf of Tenant, or if Tenant shall fail beyond applicable notice and cure periods to perform any of the terms, covenants, and conditions of this Lease then Landlord may, at its option and without prejudice to any other remedy which Landlord may have on account thereof, appropriate and apply the so much of the Security Deposit as may be necessary to compensate Landlord toward the payment of Fixed Base Rent or Additional Rent and any loss or damage sustained by Landlord due to such breach on the part of Tenant, plus expenses; and Tenant shall forthwith within ten (10) business days after demand restore the Security Deposit to the original sum deposited. The issuance of a warrant and/or the re-entering of the Demised Premises by Landlord for any default on the part of Tenant or for any other reason prior to the expiration of the term shall not be deemed such a termination of this Lease as to entitle Tenant to the recovery of the Security Deposit. If Tenant complies with all of the terms, covenants, and conditions of this Lease and pays all of the Fixed Base Rent and Additional Rent and all other sums payable by Tenant to Landlord as they fall due, the Security Deposit shall be returned in full to Tenant within thirty (30) days after the expiration of the Term of this Lease and Tenant's satisfaction of all its obligations accruing prior to this Lease expiration date. In the event of bankruptcy or other creditor-debtor proceedings against Tenant, the Security Deposit and all other securities shall be deemed to be applied first to the payment of Fixed Base Rent and Additional Rent and other charges due Landlord for all periods prior to the filing of such proceedings. In the event of sale by Landlord of the Building, Landlord shall deliver the then balance of the Security Deposit to the transferee of Landlord's interest in the Demised Premises and Landlord shall thereupon be discharged from any further liability with respect to the Security Deposit and this provision shall also apply to any subsequent transferees. No holder of a superior mortgage to which this Lease is subordinate shall be responsible in connection with the Security Deposit, by way of credit or payment of any Fixed Base Rent or Additional Rent, or otherwise, unless such mortgagee actually shall have received the entire Security Deposit.

35.02. The Security shall be in the form of an irrevocable, clean "Evergreen" automatically renewable commercial letter of credit (the "**Letter of Credit**") in the form annexed hereto as Exhibit I, issued by a "Confirming Bank" which shall mean a bank which is authorized by the State of New Jersey to conduct banking business in the State of New Jersey, and is a member of the New York Clearing House Association. The Confirming Bank shall have combined capital, surplus and undivided profits of at least $500 million and a long-term rating of at least "Aa", as published by Moody's Investors Services, Inc., or its successor (collectively, the "Confirming Bank Criteria"). If at any time during the term of this Lease, the Confirming Bank does not maintain the Confirming Bank Criteria, then Landlord may so notify Tenant and, unless Tenant delivers a replacement Letter of Credit from another bank meeting the Confirming Bank Criteria within ninety (90) days after receipt of such notice, Landlord may draw the full amount of the Letter of Credit and hold the proceeds as a cash security deposit in accordance with this Article 35. The Letter of Credit shall provide that it shall be fully transferable by Landlord to any transferee of Landlord's interest in the Demised Premises with any transfer fee paid by the beneficiary, and which shall also provide for presentation and payment in the City of New York, (or if not able to be presented in the City of New York, able to be presented via facsimile or other electronic method) which shall permit Landlord (a) to draw thereon up to the full amount of the

credit evidenced thereby (but partial drawings shall be permitted) in the event of any default by Tenant beyond applicable notice and cure periods in the terms, provisions, covenants or conditions of this Lease or (b) to draw the full amount thereof to be held as cash security pursuant to Article hereof if for any reason the Letter of Credit is not renewed within thirty (30) days prior to its expiration date, in which event Landlord covenants and agrees to deposit same in an interest bearing account or certificate. Landlord shall be entitled to and shall be paid the lesser of (x) interest earned on such cash security deposit or (y) to 1% per annum of such security deposit for administration of such security account or certificate solely to the extent held as cash pursuant to the preceding sentence. The remainder of the interest on such account or certificate shall belong to Tenant, but shall be retained by Landlord as additional security in accordance with the terms of this paragraph. The Letter of Credit (and each renewal thereof) shall (i) be for a term of not less than one (1) year (except that the last Letter of Credit shall be for a term expiring sixty (60) days after the Expiration Date), (ii) expressly provide for the issuing bank to notify Landlord in writing not less than sixty (60) days prior to its expiration as to its non-renewal, and (iii) if not so renewed each year (or later period of expiration) shall be immediately available for Landlord to draw up to the full amount of such credit (to be held as cash security as aforesaid). Not less than thirty (30) days prior to the expiration date of each Letter of Credit (and every renewal thereof if not automatically renewed by its terms), Tenant shall deliver a renewal Letter or if Tenant is not renewing the then current Evergreen Letter, Tenant shall deliver to Landlord a new Letter of Credit subject to all of the conditions aforesaid, all to the intent and purposes, that a Letter of Credit in the sum of $100,000.00 shall be in effect during the entire term of this lease. In the event Tenant is issuing a new Letter of Credit, Landlord shall deliver the Letter of Credit being replaced to Tenant concurrently with receipt of the new Letter of Credit. The Letter of Credit shall specifically provide that any transfer fees shall be payable by the beneficiary. Failure by Tenant to comply with the provisions of this Article shall be deemed a material default hereunder entitling Landlord to exercise any and all remedies as provided in this Lease for default in the payment of Fixed Base Rent and, to draw on the existing Letter of Credit up to its full amount.

ARTICLE 36

PARTIES BOUND

36.01. The obligations of this Lease shall bind and benefit the successors and assigns of the Parties with the same effect as if mentioned in each instance where a Party is named or referred to, except that no violation of the provisions of Article 8 shall operate to vest any rights in any successor or assignee of Tenant and that the provisions of this Article shall not be construed as modifying the conditions of limitation contained in Article 24. However, the obligations of Landlord under this Lease shall not be binding upon Landlord herein named with respect to any period subsequent to the transfer of its interest in the Building as owner or Tenant thereof and in event of such transfer, said obligations shall thereafter be binding upon each transferee of the interest of Landlord herein named as such owner or Tenant of the Building, but only with respect to the period ending with a subsequent transfer within the meaning of this Article.

36.02. If Landlord shall be an individual, joint venture, tenancy in common, partnership, trust, unincorporated association, or other unincorporated aggregate of individuals and/or entities or a corporation, Tenant shall look only to such Landlord’s estate and property in the Property and the rents and proceeds therefrom and, where expressly so provided in this Lease, to offset against

the rents payable under this Lease for the collection of a judgment (or other judicial process) which requires the payment of money by Landlord in the event of any default by Landlord hereunder. No other property or assets of such Landlord shall be subject to levy, execution or other enforcement procedure for the satisfaction of Tenant's remedies under or with respect to this Lease, the relationship of Landlord and Tenant hereunder, or Tenant's use or occupancy of the Demised Premises. The Parties agree that except as otherwise expressly set forth herein, neither party shall be liable to the other for any special, indirect, or consequential damages arising out of Landlord's breach of this Lease.

ARTICLE 37

CONSENTS

37.01. Wherever it is specifically provided in this Lease that a Party's consent is not to be unreasonably withheld, a response to a request for such consent shall also not be unreasonably delayed or conditioned. If either Landlord or Tenant considers that the other had unreasonably withheld, delayed, or conditioned a consent, it shall so notify the other Party within ten (10) days after receipt of notice of denial of the requested consent or, in case notice of denial is not received, within ten (10) days after making its request for the consent, or in the case such requested consent is conditioned, within ten (10) days of receiving notice of such condition.

37.02. Tenant hereby waives any claim for damages against Landlord which it may have based upon any assertion that Landlord has unreasonably withheld or unreasonably delayed any such consent, and Tenant agrees that its sole remedy shall be an action or proceeding to enforce any such provision or for specific performance, injunction or declaratory judgment. The sole remedy for Landlord's unreasonably withholding, conditioning or delaying of consent shall be as provided in this Article.

ARTICLE 38

MORTGAGE FINANCING - TENANT COOPERATION

38.01. In the event that Landlord desires to seek mortgage financing secured by the Demised Premises or Landlord's interest therein, Tenant agrees to reasonably cooperate with Landlord in support of Landlord's application(s) by delivery to Landlord's mortgage broker or mortgagee, an estoppel certificate as described in Article 32 and such other information as they shall reasonably require with respect to Tenant's occupancy of the Demised Premises, provided however that Tenant shall not be obligated to provide any financial statements other than its most recently filed Form 10-K or 10-Q. Any such cooperation by Tenant pursuant to this Section shall be at no cost or expense to Tenant.

ARTICLE 39

ENVIRONMENTAL COMPLIANCE

39.01. Tenant shall, at Tenant's sole cost and expense, comply with the New Jersey Industrial Site Recovery Act and the regulations promulgated thereunder (referred to as "**ISRA**") as same relate to Tenant's occupancy of the Demised Premises, as well as all other state, federal

or local environmental law, ordinance, rule, or regulation either in existence as of the date hereof or enacted or promulgated after the date of this Lease, that concern the management, control, discharge, treatment and/or removal of hazardous discharges or otherwise affecting or affected by Tenant's use and occupancy of the Demised Premises. Tenant represents that Tenant's North American Industry Classification System ("**NAICS**") number does not subject it to ISRA.

ARTICLE 40

HOLDING OVER

40.01. Tenant will have no right to remain in possession of all or part of the Demised Premises after the expiration or earlier termination of the Term. The parties recognize and agree that the damage to Landlord resulting from any failure by Tenant to timely surrender possession of the Demised Premises as aforesaid will be extremely substantial, will exceed the amount of the monthly installments of the Fixed Base Rent and Additional Rent theretofore payable hereunder, and will be impossible to accurately measure. Tenant therefore agrees that if possession of the Premises is not surrendered to Landlord upon the expiration or termination of this Lease, in addition to any other rights or remedies Landlord may have hereunder or at law, and without in any manner limiting Landlord's right to demonstrate and collect any damages suffered by Landlord and arising from Tenant's failure to surrender the Demised Premises as provided herein, Tenant shall pay to Landlord on account of use and occupancy of the Demised Premises for each month and for each portion of any month during which Tenant holds over in the Demised Premises after the expiration or termination of this Lease, in addition to all Additional Rent otherwise required to be paid hereunder, (i) a sum equal to one hundred twenty five percent (125%) of the Fixed Base Rent which was payable under this Lease during the last month of the Term for the first three (3) months of holdover; and (ii) a sum equal to one hundred fifty percent (150%) of the Fixed Base Rent which was payable under this Lease during the last month of the Term thereafter. In addition, Tenant agrees to indemnify and save Landlord harmless from and against all claims, losses, damages, liabilities, costs and expenses (including, without limitation, reasonable attorneys' fees and disbursements) resulting from Tenant failing to so surrender the Premises within thirty (30) days after the expiration or termination of the Term, including, without limitation, any claims made by any succeeding tenant founded on such delay exceeding thirty (30) days. Nothing herein contained shall be deemed to permit Tenant to retain possession of the Demised Premises after the expiration or termination of this Lease or to limit in any manner Landlord's right to regain possession of the Demised Premises through summary proceedings, or otherwise, and no acceptance by Landlord of payments from Tenant after the expiration or termination of this Lease shall be deemed to be other than on account of the amount to be paid by Tenant in accordance with the provisions of this Article 40. The provisions of this Article 40 shall survive the expiration or termination of this Lease.

ARTICLE 41

CERTAIN DEFINITIONS AND CONSTRUCTIONS

41.01. The terms "include," "including," and "such as", as used in this Lease, shall each be construed as if followed by the phrase "without being limited to."

41.02. The various terms which are italicized and defined in other Articles of this Lease or are defined in Exhibits annexed hereto, shall have the meanings specified in such other Articles and such Exhibits for all purposes of this Lease and all agreements supplemental thereto, unless the context shall otherwise require.

41.03. The submission of this Lease for examination does not constitute a reservation of, or option for, the Demised Premises, and this Lease becomes effective as a Lease only upon execution and delivery thereof by Landlord and Tenant.

41.04. The Article headings in this Lease and the Index prefixed to this Lease are inserted only as a matter of convenience in reference and are not to be given any effect whatsoever in construing this Lease.

41.05. This Lease shall be construed without regard to any presumption or other rule requiring construction against the Party causing this Lease to be drafted.

41.06. (a)References to Landlord as having no liability to Tenant or being without liability to Tenant, shall mean the Tenant is not entitled to terminate this Lease, or to claim actual or constructive eviction, partial or total, or to receive any abatement or diminution of rent, or to be relieved in any manner of any of its other obligations hereunder, or to be compensated.

(b) The term Laws and/or requirements of public authorities and words of like import shall mean laws and ordinances of any or all of the Federal, state, city, county, and borough governments and rules, regulations, orders and/or directives of any or all departments, subdivisions, bureaus, agencies, or office thereof, or of any other governmental, public, or quasipublic authorities, having jurisdiction in the premises, and/or the direction of any public officer pursuant to law.

(c) The term requirements of insurance bodies and words of like import shall mean rules, regulations, orders, and other requirements of the New Jersey Board of Fire Underwriters and/or similar body performing the same or similar functions and having jurisdiction or cognizance of the Building and/or the Demised Premises.

(d) The term repair shall be deemed to include restoration and replacement done in workmanlike manner as may be necessary to achieve and/or maintain good working order and condition.

(e) Reference to termination of this Lease includes expiration or earlier termination of the term of this Lease or cancellation of this Lease pursuant to any of the provisions of this Lease or to law. Upon a termination of this Lease, the term and estate granted by this Lease shall end at noon of the date of termination as if such date were the date of expiration of the term of this Lease and neither Party shall have any further obligation or liability to the other after such termination (i) except as shall be expressly provided for in this Lease, or (ii) except for such obligation as by its nature or under the circumstances can only be, or by the provisions of this Lease, may be performed after such termination and, in any event, unless expressly otherwise provided in this Lease, any liability for a payment which shall have accrued to or with respect to any period ending at the time of termination shall survive the termination of this Lease.

ARTICLE 42

FURNITURE

An inventory of the furniture which is to be provided for Tenant's use within the Demised Premises is attached hereto as Exhibit E (the "**Landlord's Furniture**"). Landlord shall deliver the Demised Premises furnished with Landlord's Furniture, all such Landlord's Furniture to be in "as is" condition. Landlord makes no representations or warranties regarding the condition, fitness for a particular use or any other aspect of Landlord's Furniture and Tenant shall use the furniture at

its own risk. Notwithstanding the foregoing, Landlord represents and warrants that Landlord's Furniture is owned by Landlord, free and clear of all liens and encumbrances. Tenant shall not remove, disassemble, repurpose, dispose of or sell any Landlord's Furniture without Landlord's prior written consent. Tenant shall immediately notify Landlord of any damage sustained by any of Landlord's Furniture and provide Landlord the opportunity to inspect the damage. Tenant shall surrender Landlord's Furniture together with the Premises at the end of the Term, in good condition, wear and tear excepted.

ARTICLE 43

RENEWAL OPTIONS

43.01. Provided that at the time of the exercise of the applicable option to renew and as of the expiration of the then current Term (i) Tenant is not then in default beyond applicable notice and cure periods of the terms, covenants, and provisions of this Lease, and (ii) Tenant shall be in occupancy and possession of the Demised Premises pursuant to this Lease, Landlord hereby grants to Tenant the option (the "**Renewal Option**") to renew the term of this Lease for two (2) additional periods of three (3) years each (each, a "**Renewal Period**"). The first Renewal Period, if the Renewal Option therefor is exercised, will commence on the day after the initial Expiration Date upon the same terms and conditions as set forth in this Lease other than the Fixed Base Rent which shall be the Fair Market Value of the Demised Premises at the time of the commencement of the Renewal Period multiplied by the rentable square footage of the Demised Premises (but in no event less than the Fixed Base Rent payable hereunder by Tenant for the last 12 months of the original Term). The second Renewal Period, if the Renewal Option therefor is exercised, will commence on the day after the scheduled expiration of the first Renewal Period upon the same terms and conditions as set forth in this Lease other than the Fixed Base Rent which shall be the Fair Market Value of the Demised Premises at the time of the commencement of the second Renewal Period multiplied by the rentable square footage of the Demised Premises (but in no event less than the Fixed Base Rent payable hereunder by Tenant for the last 12 months of the first Renewal Period). The Fixed Base Rent shall automatically increase on each anniversary of the commencement of the applicable Renewal Period by an amount equal to three percent (3%) over the Fixed Base Rent for the prior Lease Year.

43.02. Tenant shall exercise the first Renewal Option by giving written notice to Landlord (a "**Renewal Notice**") not earlier than twelve (12) months and not later than nine (9) months prior to the initial Expiration Date, TIME BEING OF THE ESSENCE. Tenant shall exercise the second Renewal Option, if applicable, by giving a Renewal Notice to Landlord not earlier than twelve (12) months and not later than nine (9) months prior to the scheduled expiration date of the first Renewal Period, TIME BEING OF THE ESSENCE. If Tenant fails to give a Renewal Notice with respect to the first Renewal Option or the second Renewal Option, Tenant will be deemed to have waived such Renewal Option and the provisions of this Section shall be null and void. The Renewal Options accorded in this Article 43 are personal to Tenant and may not be assigned except to an assignee of Tenant pursuant to a Permitted Transfer.

43.03. Fair Market Value shall mean the amount, on a per square foot basis, that a willing tenant would pay and a willing landlord would accept in an arms' length transaction for office space comparable to the Demised Premises in the Plainsboro/Princeton New Jersey office market area, giving appropriate consideration to the recent renovations of the Building, tenant improvements, free rent periods, brokerage commissions, Tax and Operating Cost base years, and other applicable factors.

43.04. For purposes of determining "**Fair Market Value**" for either Renewal Period, the following procedure shall apply:

(a) Landlord shall, within fifteen (15) business days after its receipt of a Renewal Notice, provide its written determination of the Fair Market Value at the commencement of the applicable Renewal Period ("**Landlord's Determination**") to Tenant.

(b) Within fifteen (15) business days after its receipt of Landlord's Determination, Tenant may, if it does not agree with Landlord's Determination, deliver notice to Landlord setting forth Tenant's determination of the Fair Market Value at the commencement of the applicable Renewal Period ("**Tenant's Determination**"). If Tenant fails to object to Landlord's Determination and provide Tenant's Determination in writing within such fifteen (15) business day period, then Landlord's Determination shall be deemed the Fair Market Value for the commencement of the applicable Renewal Period and shall be binding upon Tenant for purposes of determining Fixed Base Rent for such Renewal Period.

(c) If, within thirty (30) days after the delivery of Tenant's Determination (the "**Negotiation Period**"), Landlord and Tenant shall mutually agree upon the determination of Fair Market Value (a "**Mutual Determination**") for the commencement of the applicable Renewal Period, then their Mutual Determination shall constitute the Fair Market Value for purposes of determining Fixed Base Rent during the applicable Renewal Period.

(d) If Landlord and Tenant shall be unable to reach a Mutual Determination during the Negotiation Period, then Tenant may revoke its Renewal Notice at its sole option by advising Landlord in writing of such, or if Tenant fails or elects not to revoke its Renewal Notice then Landlord and Tenant shall jointly appoint an independent qualified commercial real estate broker with at least fifteen (15) years of office leasing experience in the Plainsboro/Princeton New Jersey office market area (the "**Arbiter**") to determine Fair Market Value at the commencement of the applicable Renewal Period. Notwithstanding anything herein to the contrary, Tenant shall have no right to revoke its Renewal Notice after the appointment of the Arbiter.

(e) If appointed, the Arbiter's fee shall be borne equally by Landlord and Tenant. In the event that Landlord and Tenant shall be unable to jointly agree on the designation of the Arbiter within fifteen (15) business days after the end of the Negotiation Period, then the Parties agree to allow the American Arbitration Association, or any successor organization, to designate the Arbiter in accordance with its commercial rules.

(f) The Arbiter shall conduct such investigations as he or she may deem appropriate and shall, within thirty (30) days after the date of designation of the Arbiter, choose either Landlord's Determination or Tenant's Determination only, and such choice by the Arbiter shall be conclusive and binding upon Landlord and Tenant for purposes of determining Fixed Base Rent at the commencement of the applicable Renewal Period. Each Party shall pay its own counsel fees and expenses, if any, in connection with any arbitration under this Article. The Arbiter shall not have the power to add to, modify or change any of the provisions of this Lease.

ARTICLE 44

RIGHT OF FIRST OFFER

44.01 **Right of First Offer**. So long as no default exists beyond applicable notice and cure periods either at the time that Landlord is obligated to give notice according to this Section or on the date on which Landlord would otherwise deliver possession of the First Offer Space (as that term is defined in this Section), Tenant will have a continuing right of first offer (the "**Right of First Offer**") to lease space on the Third Floor of the Building (the "**First Offer Space**"). Tenant's right to the First Offer Space is subject to the rights of any tenants under any leases hereafter existing of any space in the Building ("**third party leases**"), including any options to lease, rights of expansion, rights of first refusal, or other options or rights of any tenants ("**third party rights**") under any third party leases. Landlord hereby confirms to Tenant that there are currently no existing third party rights.

44.02 **Exercise of Right of First Offer**. The Right of First Offer will be exercised in accordance with, and subject to, the following terms and conditions:

(a) Landlord shall notify Tenant in writing if it decides to lease the First Offer Space. Landlord's notice will include:

(i) the specific location of the First Offer Space and the rentable area comprising the First Offer Space;

(ii) the approximate date on which the First Offer Space will become available for occupancy by Tenant; and

(iii) the improvements, if any, as Landlord is willing to make to the First Offer Space.

(b) Within ten (10) business days after Tenant's receipt of Landlord's notice, Tenant will exercise the Right of First Offer for the entirety of the First Offer Space, or the offer will expire as set forth in Paragraph (e) of this Article. If Tenant exercises the Right of First Offer, then the leasing of the First Offer Space will be on the same terms and conditions as the Lease except:

(i) If within the first two Lease Years of the Term, the Fixed Base Rent shall be at the same per square foot rental rate as then applicable to the Demised Premises. If after the expiration of Lease Year 2, the Fixed Base Rent to be paid for all the First Offer Space will be the Fair Market Value as then determined by Landlord pursuant to Article 43. Tenant shall also pay all Additional Rent allocable to the First Offer Space.

(ii) Tenant's obligation to pay Rent for the First Offer Space will commence on the date such space is made available to Tenant, but not sooner than the date specified in Landlord's notice unless Tenant occupies the First Offer Space prior to such date, and will continue through the expiration or earlier termination of the Term of the Lease.

(iii) Landlord will deliver and Tenant will accept the First Offer Space in its then existing condition, on an "as is" basis. Tenant will not be entitled to receive any contribution or allowance from Landlord for improvement of the First Offer Space.

(c) The rentable area of the Premises will be adjusted appropriately to include the rentable area of the First Offer Space and Landlord and Tenant will execute, at the request of either, an instrument stating the rentable area of the expanded Demised Premises, as so adjusted.

(d) Tenant's right to occupy the First Offer Space will continue to and end at the same time as its right to occupy the Demised Premises.

(e) If Tenant does not exercise the Right of First Offer as to the First Offer Space strictly in accordance with this Section, time being of the essence, the Right of First Offer will cease to exist as to the First Offer Space and Landlord shall be free for a period of twelve (12) months to lease the First Offer Space on such terms as Landlord may determine and without any restrictions by reason of this Lease. In the event Landlord does not consummate a lease within such twelve (12) month period, the First Offer Space shall again be subject to Tenant’s Right of First Offer.

(f) Tenant cannot assign its Right of First Offer to any sublessee of the Premises, or to any assignee of the Lease other than an assignee pursuant to a Permitted Transfer, or to any other person; however, if the Tenant has exercised the Right of First Offer and has leased a First Offer Space, then Tenant's right to sublease the First Offer Space, or to assign its rights under the Lease to the First Offer Space, will be subject to Article 8. Tenant’s Right of First Offer will expire upon any assignment of the Lease or sublease of the Demised Premises other than, in either case, a Permitted Transfer.

(g) Upon inclusion of the First Offer Space, all references in the Lease to the "Premises" or “Demised Premises” shall be deemed to include the First Offer Space.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, Landlord and Tenant have duly executed this Lease Agreement as of the day and year first above written.

WITNESS:

LANDLORD:

WITMAN PROPERTIES, L.L.C., a New Jersey limited liability company

/s/ Witness

By: /s/Eric Witmondt
Name: Eric Witmondt
Title: Manager

ALEXANDER ROAD AT DAVANNE, L.L.C., a New Jersey limited liability company

/s/ Witness

By: /s/Michael Mandelbaum
Name: Michael Mandelbaum
Title: Manager

ATTEST:

TENANT:

UROGEN PHARMA INC., a Delaware corporation

By: /s/Stephen Mullennix
Name: Stephen Mullennix
Title: COO

EXHIBIT A

DEMISED PREMISES

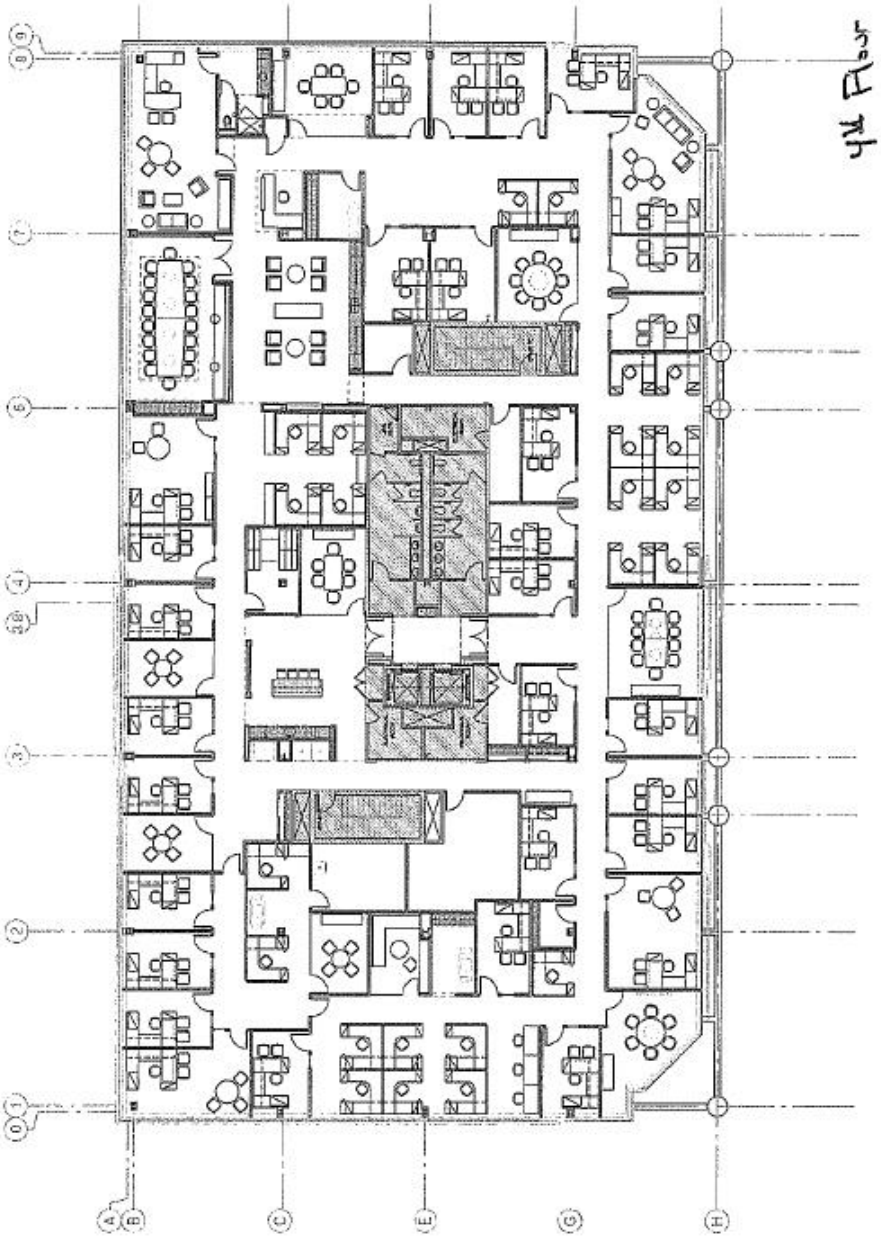


EXHIBIT B

CLEANING AND MAINTENANCE SPECIFICATIONS

Landlord will provide building standard cleaning services to the tenant area and the ground floor lobby area in accordance with the following specifications:

NIGHTLY (Monday through Friday, except Building Holidays)

1. GENERAL CLEANING

a. Empty all waste and recycling receptacles, removing waste and recycling material to designated central location for disposal.

b. Empty and damp wipe clean all ashtrays. Screen and clean all sand urns, wipe exterior of sand urns.

c. Wash and disinfect all water coolers and drinking fountains.

d. Wipe clean fingermarks, smudges, etc. from all doors, security desks, wall surfaces, furniture system trim, fixtures, cabinets, files, conference tables, chairs, partition glass, flat ledges, heating units, baseboards, blinds and window ledges.

e. Replace plastic liners in all waste-disposal cans.

f. Hand brush and/or vacuum all upholstered furniture, including furniture system fabric panels.

g. Doors: Wash and wipe clean all kick panels, push/pull areas.

h. Wash and disinfect all public telephones.

i. Wipe down mail chute and mail depository nightly.

2. FLOORS

Group A - Ceramic tile, marble, terrazzo.

Group B - Linotile, asphalt, koroseal, plastic vinyl, rubber, wood, cork, or other types of floors and base.

a. All floors in Group A to be swept and wet-mopped. Move light furniture, planters and equipment other than desks and files.

b. All floors in Group B to be dry mopped, using a “dustdown” preparation, and spots to be removed by wet process.

c. Main lobby to be machine buffed nightly.

3. VACUUMING

a. Vacuum all rugs and carpeted areas, moving light furniture and office equipment other than desks and file cabinets. Spot clean to remove soluble spots which safely respond to standard spotting procedures without risk of injury to color or fabric.

4. WASHROOMS AND TOILETS

a. Sweep, mop, rinse, and dry floors. Polish mirrors, chrome plumbing and bright-work. Clean enameled surfaces.

b. Wash and disinfect basins, urinals, and bowls using scouring powder to remove stains, making certain to clean undersides of rims of urinals and bowls.

c. Wash and disinfect both sides of all toilet seats.

d. Supply and service all toilet tissue, soap, towels, and sanitary napkins. Sanitary napkins will be supplied in coin operated dispensers.

e. All wastepaper cans and all receptacles are to be emptied and new plastic liners installed.

f. Hand dust and wash clean all partitions, tile walls, dispensers, and receptacles in lavatories and vanity area.

g. Empty and clean sanitary disposal receptacles and install new plastic liners.

5. ELEVATORS

a. Clean the floor in accordance with specifications outlined above based upon the type of flooring installed. The doors, metal wall surfaces, wood wall surfaces, ceiling and fixtures shall be dusted.

6. GLASS

a. Clean both sides of all lobby glass, building entrance doors, upper lobby glass, furniture system partition glass and interior wall glass.

7. STAIRWELLS

a. Check all stairwells and landings nightly throughout entire demised area, and keep in clean condition. All stairways and landings will be dry mopped nightly. Railings, ledges, and equipment will be dusted nightly.

WEEKLY

8. GENERAL CLEANING

a. Hand dust all office equipment, furniture, fixtures, including paneling, shelving, window sills and mullions, telephones and all flat surfaces with a treated cloth or yarn duster.

9. FLOORS

a. Floors in Group B will be wet mopped weekly.

10. WASHROOMS AND TOILETS

a. Wash down walls in washrooms and stalls, from trim to floor.

11. ELEVATORS

a. The doors, surfaces and fixtures shall be damp wiped. The floors shall be stripped, waxed and machine buffed weekly.

12. STAIRWAYS

a. These areas shall be stripped, waxed and buffed weekly. This will be governed by the amount of wear due to weather and other conditions.

13. MAIN LOBBY

a. Clean walls with damp cloth and dust weekly.

MONTHLY

14. FLOORS

a. Waxing, buffing, stripping or machine scrubbing of the floors in Group A and B.

15. HIGH DUSTING

a. Dust all closet shelving and wash all closet floors, when accessible.

QUARTERLY

16. GLASS

a. Clean inside of windows.

17. HIGH DUSTING

a. Damp dust all pictures, charts, graphs, light fixtures, etc., not reached in nightly cleaning.

b. Dust clean all vertical surfaces such as walls, partitions, doors, door bucks and other surfaces not reached in nightly cleaning.

c. Damp dust air conditioning diffusers, wall grills, door louvers, registers and Venetian blinds.

SEMI ANNUALLY

18. GLASS

a. Clean all doors and exterior side of exterior windows.

ANNUALLY

19. HIGH DUSTING

a. Dust interior and exterior of light fixtures.

MISCELLANEOUS

a. On completion of work, all slop sinks are to be thoroughly cleaned, and cleaning equipment to be stored neatly in designated locations.

b. All cleaning services except those performed by day porters, window cleaners, and matrons are to be performed nightly, five nights per week. No Saturday, Sunday or Building holiday service to be provided. In no event shall performance of any cleaning service interfere with Tenant's normal business operation.

c. The Contractor or Landlord is to furnish all necessary approved cleaning materials, implements, and machinery for the satisfactory completion of the work. This includes scaffolding, vacuum machines, scrubbing machines, etc.

d. Contractor shall furnish proof of liability and property damage insurance reasonably acceptable to Landlord, and Worker's Compensation Insurance in amounts required under the laws of New Jersey.

e. Tenant will be charged for cleaning services in excess of the specifications outlined above.

f. Tenant will be charged for the incremental cost to clean any areas of the Demised Premises used for special purposes requiring more difficult cleaning work than office areas including, but not limited to, private toilets and showers, dining areas, cafeteria, kitchen, etc.

EXHIBIT C

RULES AND REGULATIONS

1. The rights of tenants in the entrances, corridors, elevators, and escalators of the Building are limited to ingress to and egress from the tenants' demised premises for the tenants and their employees, licensees, and invitees, and no tenant shall use or permit the use of the entrances, corridors, escalators, or elevators for any other purpose. No tenant shall invite to the tenant's demised premises, or permit the visit of, persons in such numbers or under such conditions as to interfere with the use and enjoyment of any of the plazas, entrances, corridors, escalators, elevators, and other facilities of the Building by other tenants. Fire exits and stairways are for emergency use only, and they shall not be used for any other purpose by the tenants, their employees, licensees, or invitees. No tenant shall encumber or obstruct, or permit the encumbrance or obstruction of any of the sidewalks, plazas, entrances, corridors, escalators, elevators, fire exits, or stairways of the Building. Landlord reserves the right to control and operate the public portions of the Building and the public facilities, as well as facilities furnished for the common use of the tenants, in such manner as it deems best for the benefit of the tenants generally.

2. The Landlord may refuse admission to the Building outside of ordinary business hours to any person not having a pass issued by Landlord or the tenant whose demised premises are to be entered or not otherwise properly identified, and may require all persons admitted to or leaving the Building outside of ordinary business hours to register. Any person whose presence in the Building at any time shall, in the judgment of the Landlord, be prejudicial to the safety, character, reputation, and interests of the Building or of its tenants may be denied access to the Building or may be ejected therefrom. In case of invasion, riot, public excitement, or other commotion, the Landlord may prevent all access to the Building during the continuance of the same, by closing the doors or otherwise, for the safety of the tenants and protection of property of the Building. Landlord may require any person leaving the Building with any package or other object to exhibit a pass from the tenant from whose premises the packaging or object is being removed, but the establishment and enforcement of such requirement shall not impose any responsibilities on the Landlord for the protection of any tenant against the removal of property from the premises of the tenant. Landlord shall in no way be liable to any tenant for damages or loss arising from the admission, exclusion, or ejection of any person to or from the tenant's premises or the Building under the provisions of this rule. Canvassing, soliciting, or peddling in the Building is prohibited, and every tenant shall cooperate to prevent the same.

3. No tenant shall obtain or accept for use in its demised premises ice, food for on premises preparation other than warming, beverage towel, barbering, boot blackening, floor polishing, lighting maintenance, cleaning, or other similar services from any persons not authorized by Landlord in writing to furnish such services, provided that the charges for such services by persons authorized by Landlord are not excessive and where appropriate and consonant with the security and proper operation of the Building sufficient persons are so authorized for the same service to provide tenants with a reasonably competitive selection. Such services shall be furnished only at such hours, in such places within the Tenant's Demised Premises and under such reasonable regulations as may be fixed by Landlord. Tenant may have a coffee service, subject to Landlord's approval, and a kitchen for the use of its employees commensurate with normal office use.

4. The cost of repairing any damage to the public portions of the Building or the public facilities or to any facilities used in common with other tenants, caused by a tenant or the employees, licensees, or invitees of the tenant shall be paid by such tenant.

5. No lettering, sign, advertisement, notice or object shall be displayed in or on the windows or doors, or on the outside of any tenant's demised premises, or at any point inside any tenant's premises where the same might be visible outside of such demised premises, except that the name of the tenant may be displayed on the entrance door of the tenant's demised premises, and in the elevator lobbies of the floors which are occupied entirely by any tenant, subject to the approval of the Landlord as to the size, color, and style of such display. The inscription of the name of the tenant on the door of the tenant's demised premises shall be done by Landlord at the expense of the tenant.

6. No awnings or other projections over or around the windows shall be installed by any tenant, and only such window blinds as are supplied or permitted by Landlord shall be used in a tenant's demised premises. Linoleum, tile, or other floor covering shall be laid in a tenant's demised premises only in a manner approved by Landlord.

7. Landlord shall have the right to prescribe the weight and position of safes and other objects of excessive weight, and no safe or other object whose weight exceeds the lawful load for the area upon which it would stand shall be brought into or kept upon a tenant's demised premises. If, in the judgment of Landlord, it is necessary to distribute the concentrated weight of any heavy object, the work involved in such distribution shall be done at the expense of the tenant and in such manner as the Landlord shall determine. The moving of safes and other heavy objects shall take place only outside of ordinary business hours upon previous notice to the Landlord, and the persons employed to move the same in and out of the Building shall be reasonably acceptable to the Landlord and if so required by law, shall hold a Master Rigger's license. Freight, furniture, business equipment, merchandise, and bulky matter of any description shall be delivered to and removed from the demised premises only in the freight elevators and through the service entrances and corridors, and only during hours and in a manner approved by Landlord. Arrangements will be made by Landlord with any tenant for moving large quantities of furniture and equipment into or out of the Building.

8. No machines or mechanical equipment of any kind other than typewriters and other ordinary portable business machines, may be installed or operated in any tenant's demised premises without Landlord's prior written consent, and in no case (even where the same are of a type so accepted or as so consented to by Landlord) shall any machines or mechanical equipment be so placed or operated as to disturb other tenants; but machines and mechanical equipment which may be permitted to be installed and used in a tenant's demised premises shall be so equipped, installed and maintained by such tenant as to prevent any disturbing noise, vibration, or electrical or other interference from being transmitted from such premises to any other area of the Building.

9. No noise, including the playing of any musical instruments, radio or television, which, in the judgment of Landlord might disturb other tenants in the building, shall be made or permitted by any tenant, and no cooking shall be done in the tenant's demised premises, except as expressly approved by Landlord. Nothing shall be done or permitted in any tenants' demised premises, and nothing shall be brought into or kept in any tenants' demised premises, which would impair or interfere with any of the Building services or the proper and economic heating, cleaning,

or other servicing of the Building or the demised premises, or the use of enjoyment by any other tenant of any other demised premises, nor shall there be installed by any tenant any ventilating, air conditioning, electrical or other equipment of any kind which, in the judgment of Landlord, might cause any such impairment or interference. No dangerous, inflammable, combustible, or explosive object or material shall be brought into the building by any tenant or with the permission of any tenant. Any cuspidors or similar containers or receptacles used in any tenants' demised premises shall be cared for and cleaned by and at the expense of the tenant.

10. No acids, vapors, or other materials shall be discharged or permitted to be discharged into the waste lines, vents or flues of the Building which may damage them. The water and wash closets and other plumbing fixtures in or serving any tenant's premises shall not be used for any purpose other than the purposes for which they were designed or constructed, and no sweepings, rubbish, rags, acids or other foreign substances shall be deposited therein.

11. No additional locks or bolts of any kind shall be placed upon any of the doors or windows in any tenants' demised premises and no lock on any door therein shall be changed or altered in any respect. Additional keys for a tenant's demised premises and toilet rooms shall be procured only from the Landlord, which may make a reasonable charge therefor. Upon the termination of a tenant's lease, all keys of the tenant's demised premises and toilet rooms shall be delivered to the Landlord.

12. All entrance doors in each tenants' demised premises shall be left locked, and all windows shall be left closed by the tenant when the tenant's demised premises are not in use. Entrance doors shall not be left open at any time.

13. Hand trucks not equipped with rubber tires and side guards shall not be used within the Building.

14. All windows in each tenant's demised premises shall be kept closed and all blinds therein above the ground floor shall be lowered when and as reasonably required because of the position of the sun, during the operation of the Building air conditioning system to cool or ventilate the tenant's demised premises.

15. Landlord reserves the right to rescind, alter, or waive any rule or regulation at any time prescribed for the Building when, in its judgment, it deems it necessary, desirable, or proper for its best interest and for the best interests of the tenants, and no alteration or waiver of any rule or regulation in favor of one tenant shall operate as an alteration or waiver in favor of any other tenant. Landlord shall not be responsible to any tenant for the non-observance or violation by any other tenant of any of the rules and regulations at any time prescribed by the Building.

EXHIBIT D

SIGNAGE

(Reserved)

EXHIBIT E

FURNITURE

Alexander Park
UroGen Pharma
4th floor furniture list

Room # 401 Pantry

- 4 Bar Chairs
- 1 Dishwasher
- 1 Small refrigerator
- 2 Small microwave

Ice Maker

Room # 402 conference room

- 1 rectangle conference table (6 persons)
- 6 white conference table chairs
- 1 credenza

Room # 406 Huddle Room

- 1 round coffee table
- 4 chairs
- 1 credenza

Room #'s 407,408,410,411 offices
each office has the following

- 1 u shaped desk
- 1 rolling desk chair
- 2 guest chairs
- 1 wall cabinet
- 1 wall hung white board

Room # 409 Huddle Room

- 1 Round Coffee Table
- 4 chairs
- 1 credenza

Room # 414 File room

- 5 file cabinet on floor tracks

Room # 415, Open Office Space

- 4 Cubicle work stations with table tops
- 4 rolling chairs
- 1 work table
- 4 under cabinet file cabinets
- 3 4' file cabinets
- 4 upper shelf units

4x

Room #412 large office

- 1 u shaped desk
- 1 Credenza
- 1 wall cabinet
- 1 round conference table
- 1 rolling desk chair
- 4 chairs
- 1 credenza

Repeat from Credenza above

Room # 416 Exec Pantry

- 8 fabric back campus chairs
- 2 marble top coffee tables

Room # 417 Board Room

- 1 Conference table seating 18
- 18 rolling high back leather conference table chairs

1 Narrow pine table
1 area rug
2 under counter s/s refrigerators
1 s/s dishwasher
1 wall cabinet
1 s/s microwave

Room # 419 CEO Office

1 wall credenza
2 cloth back chairs
1 cloth back sofa
1 coffee table
1 round conference table
5 conference chairs
1 u shaped desk
1 rolling desk chair
1 end table

Room # 427 Conference room

1 rectangle conference table seats 6
6 leather back rolling chairs
1 credenza

Rooms #'s 424, 426, 430, 429, 428, 431

1 each u shaped desk
2 each guest chairs
1 each white board (431 missing white board)
1 each upper desk cabinet (missing in 431)

Room # 432 corner office

1 cloth couch
1 round conference table
5 conference table chairs
1 u shaped desk
1 rolling desk chair
1 upper desk cabinets
1 wall credenza
1 white board
1 cloth chair

Room # 435 conference room

1 Credenza
1 6 section cloth wall couch with 2 small marble tables

Room # 421

1 room 419 private toilet

Room # 420

1 room 419 private restroom with shower

Room # 422

1 40-gallon hot water heater

Room # 423 Copy/Print Room

1 set of floor and wall cabinets

Room # 418 Admin Area

1 reception style desk
1 chair

Room # 425 open office area

2x
2 desk cubicles with tops
2 under cabinet file cabinets
1 storage shelf
2 rolling desk chairs
1 missing

Room # 433

1 u shaped desk
1 rolling desk chair
2 guest chairs
1 Upper desk cabinet

Room # 434

1 u shaped desk
1 rolling desk chair
2 guest chairs
1 Upper desk cabinet

Room 437 Open Office area

1 round conference table seats 8
8 white leather style rolling chairs
1 credenza

Room #'s 438,442, 443

1 each u shaped desk
1 each rolling desk chair
1 each white board
2 each guest chairs
1 Upper desk cabinet

Room # 444 Conference Room

1 rectangle table seats 10
10 white leather style rolling chairs
1 credenza

Room # 457

1 round conference table
5 guest chairs
1 u shaped desk
1 white board
1 credenza
1 Upper desk cabinet

Room # 449 Server Room

Room # 451 Admin Area

1 cubicle
1 under counter file cabinet
1 4" file cabinet
missing chair

Room # 460 open office area 1 -3

3 small desk

8 cubicles
8 under desk file cabinets
8 4' file cabinets
8 upper shelf units
5 rolling desk chairs cubes 4,5 and 8 missing

Room # 439 Storage

empty

Room # 446 Storage

2 5' black steel shelving

Rooms #'s 445, 454,455, 456, 452

1 each u shaped desk
1 each rolling desk chair
1 each white board
1 each wall cabinet

Rooms 448 & 447 Closets

Room # 453 Storage

Room # 458 Conference Room

1 round conference table seats 6
6 white leather back chairs
1 credenza

Room # 459

1 u shaped desk
1 rolling desk chair
2 guest chairs
1 white board
1 wall cabinet

Room # 460 open office area 4 - 9

6 cubicle stations

3 chairs
3 under desk file cabinets

Room # 461

1 u shaped desk
1 rolling office chair
2 guest chairs
1 white board

1 Upper desk cabinet

Room # 464

1 u shaped office desk
1 rolling office chair
1 white board
2 guest chairs

Room # 467 File room

1 small 5' s/s refrigerator with glass front
paint
spare cubicle parts

Room # 468

1 round coffee table
5 guest chairs
1 u shaped desk
1 rolling office chair
1 wall cabinet
1 large credenza
1 white board

Room # 403 Corridor

1 credenza
2 s/s refrigerators
1 s/s freezer

2x refrigerators with sliding freezer. No stand alone freezer

5 cubicle chairs station 9 missing
6 4' file cabinets
6 under counter file cabinets

Room # 462 Copy Room

1 wall cabinets

Room # 463 Huddle Room

1 round coffee table
1 guest chair
1 5 section cloth wall couch
1 wall credenza

Room # 446 Huddle Room

466

1 wall credenza
1 round coffee table
4 chairs

Room # 465 1& 2 Open Office area

2 cubicle stations
2 chairs
2 4" file cabinets
2 under cabinet file cabinets

1 missing

Rooms #'s 469, 470, 471

1 each u shaped Desk
1 each rolling desk chair
1 each white board
2 each guest chairs

1 Upper desk cabinet

EXHIBIT F

TENANT'S INITIAL IMPROVEMENTS

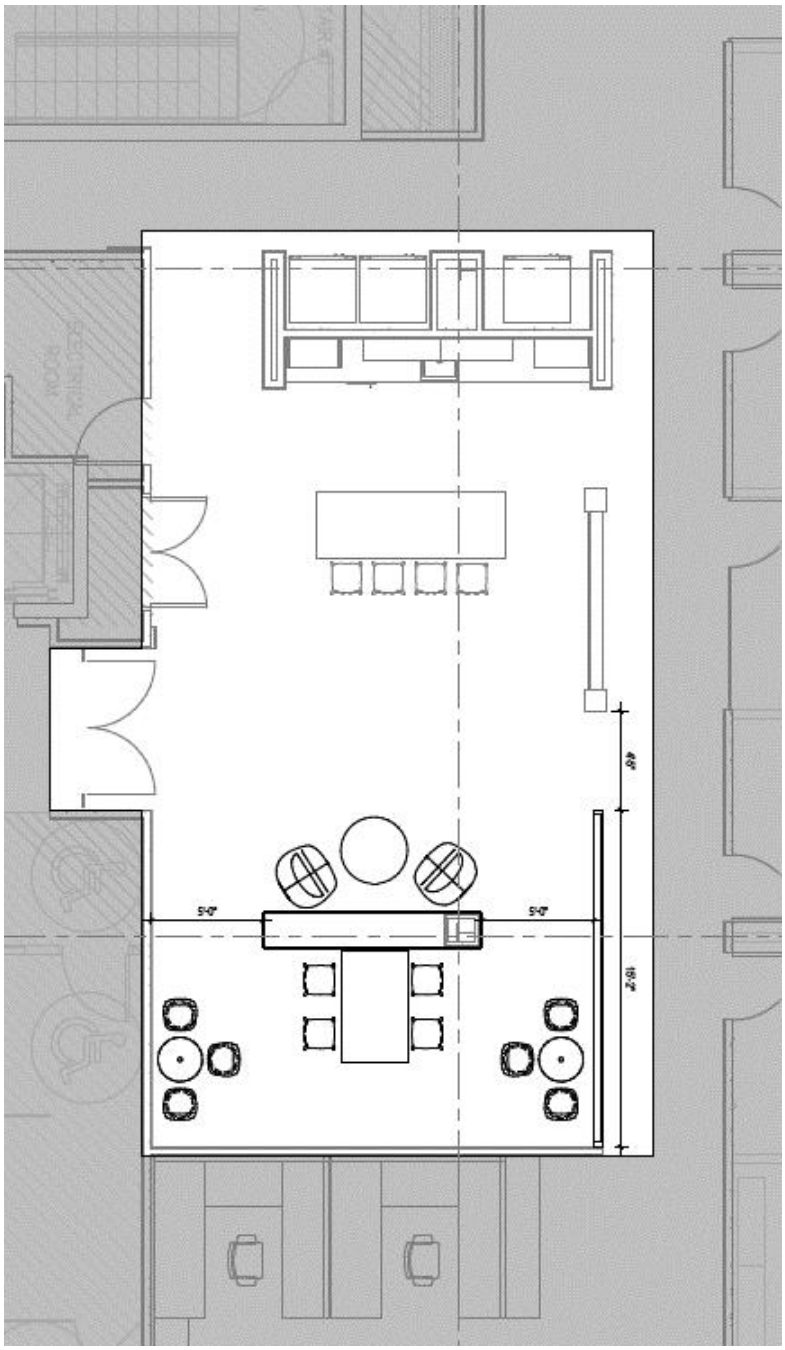


EXHIBIT G

CERTIFICATE OF OCCUPANCY

(attach copy)

EXHIBIT H

FORM OF SNDA

SUBORDINATION, NON-DISTURBANCE, ATTORNMENT AND ESTOPPEL AGREEMENT

This Subordination, Non-Disturbance, Attornment and Estoppel Agreement ("Agreement") is dated as of the __ day of _____, 20__ and is by and among _____, having an address at _____ (hereinafter called "Lender"); _____, having an office at _____, New Jersey _____ (hereinafter called "Tenant"); and _____, a _____ corporation/ limited liability company having an address at _____, New Jersey _____ (hereinafter called "Landlord").

Witnesseth

WHEREAS, Landlord and Tenant entered into a certain Lease dated _____ (the "Lease"), covering premises described in the Lease (the "Demised Premises"), located on that certain piece, parcel or tract of land commonly known as _____; and

WHEREAS, Lender has made a commercial loan to Landlord in the original principal sum of $_____, plus interest, as evidenced by a certain promissory note (the "Note") and secured by certain mortgage and assignment of rents and leases (collectively, the "Mortgage") recorded in the _____ Clerk's Office and other loan documents; and

WHEREAS, to memorialize the relationship between the parties, Landlord, Tenant and Lender desire to enter into this Agreement; and

WHEREAS, Tenant desires to be assured of continued occupancy of the Demised Premises under the terms of the Lease and subject to the terms of the Mortgage;

NOW, THEREFORE, in consideration of the sum of Ten Dollars ($10.00) by each party in hand paid to the other, the receipt of which is hereby acknowledged, to induce the Lender to make said loan and/or continue to extend credit to the Landlord and other valuable consideration, including of the mutual promises, covenants and agreements herein contained, the parties hereto, intending to be legally bound hereby, promise, covenant and agree as follows:

Terms and Conditions

1. The Lease has not been modified or amended, except as follows: _____. The Lease is in full force and effect and constitutes a complete statement of the agreements, covenants, terms and conditions under the Lease between Landlord and Tenant with respect to the Demised Premises. Tenant has not given Landlord any notice of termination under the Lease.

2. The term under the Lease commenced as of _____, _____, and shall terminate at 11:59 p.m. on _____ [or the day immediately prior to the _____ (____th) anniversary date of the referenced term commencement date], subject to further extension periods as may be permitted under the Lease.

3. The Lease and all estates, options, liens and charges therein contained or created thereunder are and shall be expressly subject and subordinate to the lien and effect of the Mortgage, and to all renewals, modifications, consolidations, replacements and extensions thereof, to the full extent of the principal sum secured thereby and interest thereon, with the same force and effect as if the Mortgage had been executed, delivered and duly recorded, in appropriate Clerk's Office , prior to the execution and delivery of the Lease.

4. The annual fixed rent (*i.e.*, net of common area maintenance charges, taxes, *etc*.) currently payable under the Lease is $_____.

5. Except for the security deposit, Tenant has not deposited any monies or instruments to secure any of its agreements or obligations under the Lease and has not paid any rent or any other amounts due under the Lease for periods subsequent to the date hereof.

6. Tenant has no known defenses, offsets or counterclaims against its obligations to pay the Rent or any other charges and to perform its other covenants under the Lease. Except as expressly set forth in the Lease, Tenant is entitled to no allowances, rent abatements, or other concessions.

7. Tenant has _____ (__) unexercised options to extend the Lease for up to successive periods of _____ (__) years each. Except as expressly set forth in the Lease, Tenant does not have any right to lease additional space, reduce the size of the Demised Premises, extend the term of the Lease, terminate the Lease, purchase the Demised Premises or any other rights or options with respect to the Demised Premises.

8. Tenant is in full and complete possession of the Demised Premises, has accepted the Demised Premises pursuant to the terms and provisions of the Lease, is in compliance with the Lease and the Demised Premises are satisfactory for Tenant's purposes.

9. To the best of Tenant's knowledge and belief, there are no rental, lease, or similar commissions payable with respect to the Lease, except as may be expressly set forth therein.

10. Tenant is obligated to pay rent to Landlord at the rate set forth in the Lease. Tenant is current with respect to, and is paying the full rent and other charges stipulated in the Lease with no offsets, deductions, defenses or claims known to Tenant as of the date hereof.

11. Tenant has not received any notice from Landlord of any default by Tenant under the Lease that has not been cured, except as follows: _____.

12. Tenant has no actual knowledge of any event which, with the giving of notice, the passage of time or both, would constitute a default by Tenant under the Lease, except as follows: _____.

13. Tenant has not delivered to Landlord any notice of any default by Landlord under the Lease that has not been cured, except as follows: _____.

14. Tenant has no actual knowledge of any event which, with the giving of notice, the passage of time or both, would constitute a default by Landlord under the Lease known to Tenant as of the date hereof, except as follows: _____.

15. Tenant has no actual knowledge of any existing defenses or offsets against the enforcement of the Lease known to Tenant as of the date hereof.

16. Tenant has not sublet, transferred, assigned or hypothecated its interest under the Lease, except as follows: _____.

17. The respective individuals executing this Agreement on behalf of each party are fully authorized and empowered to do so, and no consent, vote or approval is required which has not been given or taken.

18. Lender and Tenant acknowledge and agree that for so long as: (a) Tenant is not in default in the payment of rent or additional rent or in the performance or observance of any of the other terms, covenants, provisions or conditions of the Lease beyond any applicable notice and cure period, (b) Tenant is not in default under this Agreement beyond any applicable notice and cure period, and

(c) the Lease is in full force and effect, Lender agrees to the following: (i) Tenant's use, possession, and enjoyment of the Premises and Tenant's rights and privileges under the Lease shall not be diminished or interfered with by Lender for any reason whatsoever during the term of the Lease or any extensions or renewals permitted under the Lease under the terms existing as of the date of this Agreement; and (ii) Lender will not join Tenant as a party defendant in any action or proceeding to foreclose the Mortgage or to enforce any rights or remedies of Lender under the Mortgage which would cut-off, destroy, terminate, or extinguish the Lease under the terms existing as of the date of this Agreement.

After notice is given by the Lender to Tenant that the Mortgage is in default and that the rents under the Lease should be paid to Lender, Tenant will attorn to Lender and pay to Lender, or in accordance with the directions of Lender, all rents and other monies thereafter due and to become due to Landlord under the Lease. Tenant shall have no responsibility to ascertain whether such demand by Lender is permitted under the Mortgage or any assignment of rents thereunder. Landlord waives any right, claim or demand it may now or later have against Tenant by reason of such payment to Lender, and any such payment to Lender shall discharge of the obligations of Tenant to make such payment to Landlord.

19. In the event that Lender succeeds to the interest of Landlord under the Lease and/or to title to the Demised Premises, Tenant agrees to attorn to Lender, and Lender and Tenant hereby agree to be bound to one another under all of the terms, covenants and conditions of the Lease; accordingly, from and after such event, Lender and Tenant shall have the same remedies against one another for the breach of an agreement contained in the Lease as Tenant and Landlord had before Lender succeeded to the interest of Landlord; provided, however, that Lender shall not be:

a. liable for any act or omission of any prior landlord (including the Landlord), including but not limited to monetary damages or injunctive relief; or

b. subject to any offsets or defenses which Tenant might have against any prior landlord (including the Landlord), except as expressly set forth in the Lease; or

c. liable for the return of any security deposit unless it actually receives such security deposit; or

d. bound by the payment (to any prior landlord including the Landlord) of any rent or additional rent intended to cover any period of time more than the lesser of either (i) thirty (30) days, or (ii) two business day from Lender's delivery of notice to Tenant next following the date on which the Lender succeeds to the interest of Landlord under the Lease and/or to title to the Demised Premises; or

e. bound by any modification of the Lease unless previously approved in writing by Lender.

Nothing in this paragraph shall be deemed to waive any of Tenant's rights and remedies against any prior landlord including Landlord.

20. Tenant will not pay to Landlord an installment of rent or additional rent or any part thereof more than one (1) month prior to the due date of such installment.

21. In the event that Lender or any other party acquires title to or the right to possession of the Demised Premises upon the foreclosure of the Mortgage, or upon the sale of the Demised Premises by Lender after foreclosure or acquisition of title in lieu thereof, Tenant agrees not to seek to terminate the Lease by reason thereof, but shall remain bound unto the new owner so long as the new owner agrees to be bound to Tenant under all of the terms, covenants and conditions of the Lease, as provided in this Agreement, and subject to the same provisions contained in this Agreement.

22. If Lender (or its nominee, designee or assignee) shall succeed to the rights of Landlord under the Lease through possession or foreclosure action, delivery of a deed or otherwise, or another person purchases the Premises upon or following foreclosure of the Mortgage, then at the request of Lender (or its nominee or designee) or such purchaser (Lender, its nominee and designees, and such purchaser, each being a "Successor-Landlord"), (i) subject to the terms and conditions of this Agreement, Tenant shall

attorn to and recognize Successor-Landlord as Tenant's landlord under the Lease, (ii) Successor-Landlord will accept the attornment of Tenant, and subject to the limitations contained in this Agreement, it will assume and perform all of Landlord's obligations under the Lease, and (iii) Successor-Landlord and Tenant shall each promptly execute and deliver any instrument that the requesting party may reasonably request to evidence the foregoing.

23. Any notice, request, demand, statement or consent made hereunder shall be in writing and shall be sent by registered or certified mail, postage prepaid, return receipt requested, and shall be deemed given when postmarked and addressed as follows:

If to Landlord:

_____
_____
_____
Attn: _____

If to Lender:

_____
_____
_____
Attn: _____

With a copy to:

_____
_____
_____
Attn: _____

If to Tenant:

At the Demised Premises, with a copy sent simultaneously and in like manner to Tenant at:
499 Park Avenue, Suite1200
New York, NY 10022
Attn: Legal

And with an additional copy sent by email to legal@urogen.com

Each party may designate a change of address by notice to the other parties by giving at least five (5) business days before such change of address is to become effective.

25. This Agreement shall bind and inure to the benefit of and be enforceable by the parties hereto and their respective heirs, personal representatives, successors, and assigns.

26. This Agreement contains the entire agreement between the parties on the subject set forth herein and cannot be changed, modified, waived, or cancelled except by an agreement in writing executed by the party against whom enforcement of such modification, change, waiver of cancellation is sought.

27. THE PARTIES TO THIS AGREEMENT WAIVE TRIAL BY JURY IN CONNECTION WITH ANY AND ALL CLAIMS OR ACTIONS INVOLVING OR ARISING IN CONNECTION THIS AGREEMENT. THE PARTIES FURTHER AGREE THAT THE PREVAILING PARTY OR PARTIES IN ANY LITIGATION OR OTHER DISPUTE SHALL BE ENTITLED TO RECOVER FROM THE NON-PREVAILING PARTY OR PARTIES ALL LEGAL FEES AND COSTS INCURRED IN CONNECTION WITH A BREACH OF THE TERMS OF THIS AGREEMENT.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the date(s) set forth below.

Attest:

LENDER

By: _____
Name: _____ Name: _____
Title: _____ Title: _____

Dated:

Attest:

LANDLORD

By: _____
Name: _____ Name: _____
Title: _____ Title: _____

Dated:

Attest:

TENANT

By: _____
Name: _____ Name: _____
Title: _____ Title: _____

Dated:

(Lender Acknowledgment)

STATE OF)
):ss.
COUNTY OF)

On the _____ day of _____, in the year _____, before me, the undersigned, a notary public in and for said state, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is (are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

_____
Notary Public

(Landlord Acknowledgment)

STATE OF)
):ss.
COUNTY OF)

On the _____ day of _____, in the year _____, before me, the undersigned, a notary public in and for said state, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is (are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

_____
Notary Public

(Tenant Acknowledgment)

STATE OF)
):ss.
COUNTY OF)

On the _____ day of _____, in the year _____, before me, the undersigned, a notary public in and for said state, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is (are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their capacity(ies), and that by his/her/their signature(s) on the instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

_____
Notary Public

EXHIBIT I

FORM OF LETTER OF CREDIT

Irrevocable Standby Letter of Credit

Issue Date:
Our Reference No.

Applicant:

Beneficiary:

Amount:

Date of Initial Expiration:

We hereby issue this Irrevocable Standby Letter of Credit (the "Letter of Credit") in favor of Beneficiary, payable in immediately available funds in one or more drafts drawn upon us at sight when accompanied by:

1. Beneficiary's statement, signed by an authorized representative of Beneficiary (signing as such), indicating name and title and stating exactly as follows:

"The amount of this draw $_____under Irrevocable Standby Letter of Credit No._____ is being made pursuant to that certain Lease Agreement dated as of _____, between [Name of Beneficiary], a New Jersey general partnership ("Landlord"), as landlord, and [Name of Applicant], a New Jersey limited liability company, ("Tenant"), as tenant for the premises located at [--- Need Address ---] (such Lease Agreement, as amended from time to time, being sometimes hereinafter referred to, collectively, as the "Lease") and represents funds due to Landlord from Tenant as a result of Tenant's failure to cure a default (as such term is defined in the Lease) under the Lease after expiration of any applicable notice and cure periods.

Landlord certifies that 1) it mailed the attached notice of default in the manner permitted under the Lease to the Tenant at the notice address for the Tenant set forth in the Lease, and 2) Landlord is authorized to draw upon this Letter of Credit in accordance with the terms and conditions of this Lease".

2. Copy of Landlord's notice of default to Tenant.

Partial draws shall be permitted.

THIS LETTER OF CREDIT IS TRANSFERABLE, BUT ONLY IN ITS ENTIRETY AND MAY BE SUCCESSIVELY TRANSFERRED. TRANSFER OF THIS LETTER OF CREDIT SHALL BE EFFECTED BY US UPON YOUR SUBMISSION OF THIS ORIGINAL LETTER OF CREDIT, INCLUDING ALL ORIGINALS OF AMENDMENTS, IF ANY, ACCOMPANIED BY OUR TRANSFER REQUEST FORM DULY COMPLETED AND EXECUTED. IF YOU WISH TO TRANSFER THE LETTER OF CREDIT, PLEASE CONTACT US TO OBTAIN THE REQUIRED TRANSFER REQUEST FORM AND APPLICABLE CHARGES, IF ANY. IN ANY EVENT, THIS LETTER OF CREDIT MAY NOT BE TRANSFERRED TO ANY PERSON OR ENTITY LISTED IN OR OTHERWISE SUBJECT TO, ANY SANCTION OR EMBARGO UNDER ANY APPLICABLE RESTRICTIONS. ALL CHARGES AND FEES RELATED TO SUCH TRANSFER SHALL BE FOR THE ACCOUNT OF THE APPLICANT.

It is a condition of this Letter of Credit that is shall be automatically extended for additional periods of one (1) year from the date of the initial expiration date of this Letter of Credit set forth above and upon each anniversary of such date, unless at least sixty (60) days prior thereto we send notice to Beneficiary in writing by certified mail, postage prepaid, return receipt requested, or by courier at the above address or such other address as Beneficiary may provide

to us in writing specifically mentioning the number of this Letter of Credit, for the delivery of notices hereunder, that we elect not to extend this Letter of Credit for such additional one (1) year period. Following Beneficiary's receipt of such notice, Beneficiary may draw by presentation of drafts on us at sight within the then applicable expiration date of this Letter of Credit for an amount not to exceed the balance remaining in this Letter of Credit.

All drafts drawn under this Letter of Credit must be marked, "Drawn under JPMorgan Chase Bank, N.A. Letter of Credit No. ----------".

Any demand for payment made by Beneficiary shall be presented during business hours on any business day on or prior to the then current expiration date of this Letter of Credit. All demands for payment shall be deemed to be presented on the date received by us; provided however, that if a demand for payment is actually received on a non-business day or during non-business hours, then it shall be deemed received on the immediately succeeding business day. "Business day" means any weekday that is not a holiday and on which banking institutions are authorized or required by law to remain open in the State of New Jersey, and a day of which inter-bank payments can be effected on Fedwire System.

We hereby engage and agree with Beneficiary that drafts drawn under and in accordance with the terms of this Letter of Credit will be duly honored by us as provided herein, and at our counters at 10420 Highland Manor Dr., 4th Fl, Tampa, FL 33610, Attn: Standby LC Unit on or before the expiry date hereof.

We will accept any and all statements and documents made or delivered to us pursuant to this Letter of Credit as conclusive, binding and correct without investigating the truthfulness, accuracy, correctness or validity thereof, and notwithstanding the claim of the Applicant.

This Letter of Credit is subject to the terms and conditions of the International Standby Practices 1998 (ISP98), International Chamber of Commerce Publication No. 590 and the Laws of State of New Jersey. In the event of a conflict, Laws of State of New Jersey will control without regard to the principles of conflict of Laws.

This Letter of Credit sets for in full the terms of our undertaking and neither such undertaking nor any of the terms of this Letter of Credit may be modified, amended, amplified or limited by reference to any document, instrument or agreement referred to in this Letter of Credit, or by any document, instrument or agreement in which this Letter of Credit is referred to, or to which this Letter of Credit relates, and any such reference shall not be deemed to incorporate in this Letter of Credit by reference any such document, instrument or agreement.

_____ BANK
By:_____

EXHIBIT J

LEED CORE & SHELL TENANT LEASE REQUIREMENTS

400 Alexander Park – LEED Core & Shell Tenant Lease Requirements

Tenant shall comply with the following build-out requirements:

1. EAp3. In order to reduce stratospheric ozone depletion, Tenant shall not specify or install HVAC equipment in the 400 Alexander Park facility that uses chlorofluorocarbon (CFC) based refrigerants.

2. EAp2/EAc1. In order to comply with the assumptions of the Energy Model used for base building LEED credit purposes, the overall power consumption for the tenant lighting system shall not exceed 1.0 watts/sf.

3. WEp1/WEc3. In order to comply with the Water Use Reduction projection used for the base building LEED credit purposes, new plumbing fixtures in a Tenant Build-out to comply with the following fixture flow ratings:
   a. Water closets – 1.1 GPF weighted flush rate or 1.28 GPF
   b. Lavatory faucets – 0.07 GPC (Calculation based on a 0.5 GMP metering faucet with 0.35 GPM aerator using a default 12 second duration of flow)
   c. Kitchen sinks – 1.5 GPM
   d. Showers – 1.5 GPM
   e. Urinals – 0.125 GPF

4. IEQp1/IEQc2. Tenants must comply with the requirements of IEQp1 and IEQc2 for Mechanically Ventilated Spaces, and meet the minimum requirements of Sections 4 through 7 of ASHRAE Standard 62.1-2007, Ventilation for Acceptable Indoor Air Quality. Ventilation Rate shall include a 30% increase above ASHRAE calculation rate.

5. IEQc3. In order to reduce indoor air quality (IAQ) problems resulting from construction and promote the comfort and well-being of construction workers and building occupants, develop and implement and IAQ management plan for the construction phases of the space as follows:
   a. During construction, meet or exceed the recommended design approaches of the SMACNA IAQ Guidelines for Occupied Buildings under Construction, 2nd Edition 2007, ANSI/SMACNA 008-2008 (Chapter 3).
   b. Protect stored on-site and installed absorptive materials from moisture damage.
   c. If permanently installed air handlers are used during construction, a minimum of MERV 8 filtration media must be used at each return air grille that meets one of the following criteria below. Replace all filtration media immediately prior to occupancy.

EXHIBIT K

HVAC ZONES

WOODMONT properties

MEMORANDUM

TO: Stephen Mullennix, Chief Operating Officer, UroGen Pharma

FROM: George Buchmann, Director of Commercial Property Management, Woodmont Properties

RE: 400 Alexander HVAC System - Explanation of 4th Floor Functionality

DATE: October 23, 2019

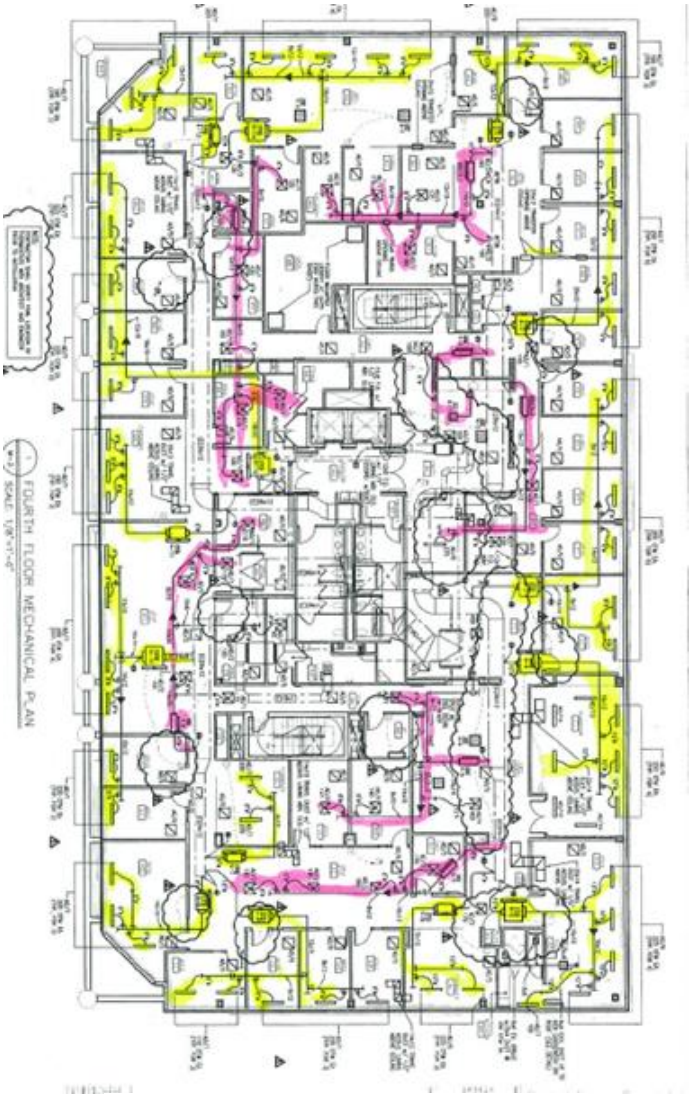
---

400 Alexander Park has a newly installed LEED certified HVAC system controlled by the state-of-the-art Building Management System (BMS) which allows the building to provide comfortable temperatures while operating economically and efficiently. The BMS provides the ability to adjust HVAC operations during occupied and after hours by adjusting temperatures based on the time of year. The system is never shut down, operating at higher/lower temperatures, saving expenses during non-occupied times and significantly reducing time for temperatures to adjust for occupancy. The BMS provides the ability to adjust temperature settings automatically prior to tenants arriving in the morning and after departure. After "Regular Hours", the system can be adjusted to specific areas and times by zone.

To help illustrate the zoning of the system, we have prepared the attached exhibit. The floor plan exhibit illustrates the central system zones (pink) and the auxiliary system zones (yellow). The 4th floor consists of 7 zones from the central system (VAV boxes) considered the main zones (cooling is chargeable to the tenant), and 14 zones from the ancillary system, (FPB's) (cooling not charged to the tenant), providing heated or cooled air. Both VAV's and FPB's are programed and controlled by the BMS and can be adjusted by our BMS technician by remotely logging into the system. The central and auxiliary zones work in concert with each other, i.e. if the tenant requests to have the North East Corner of the 4th floor conditioned after "Regular Hours", we have the ability, through the BMS, to adjust VAV's 4-3 and 4-5, FPB's 4-3,4,5,6,8 to occupied temperature settings for the time requested by the tenant. This example is for illustrative purposes. The zone areas can be adjusted by specific room areas as well.

In addition, the 4th floor has approximately 24 Slide Thermostats allowing tenants to adjust temperatures 2 to 3 degrees, up or down during "Regular Hours". This feature allows tenants to make minor adjustments in temperatures as they see fit. Typically, the occupied temperature is set to 72 degrees.

As stated, the system is running 24/7. During non-"Regular Hours", the temperature for heat is set at 64 degrees and for cooling is set at 82 degrees. The system and building are very efficient and utilize outside air to heat or cool the building.



FAN POWERED BOX SCHEDULE

DESIGNATION	PRIMARY AIR CFM MIN	PRIMARY AIR CFM MAX	DESIGNED FAN CFM	INLET	STATUS	SERVED ZONE	ELECT. HEATER KW	ELECTRIC	ENVIROTEC MODEL #	REMARKS
FPB/4-1	170	790	790	8"ø	NEW	PERIMETER	6.0	480/3	CFL0808E4	①②
FPB/4-2	256	1050	1050	10"ø	NEW	PERIMETER	8.0	480/3	CFL1010E4	①②
FPB/4-3	300	1200	1200	12"ø	RELOC.	PERIMETER	10.0	480/3	CFL1212E4	①②
FPB/4-4	256	1050	1050	12"ø	NEW	PERIMETER	8.0	480/3	CFL1010E4	①②
FPB/4-5	256	1050	1050	12"ø	NEW	PERIMETER	8.0	480/3	CFL1010E4	①②
FPB/4-6	115	450	450	8"ø	NEW	PERIMETER	4.0	277/1	CFL0606E4	①②
FPB/4-7	100	400	400	8"ø	NEW	INTERIOR	1.0	277/1	CFL0606E4	①②
FPB/4-8	205	880	880	10"ø	NEW	PERIMETER	7.0	480/3	CFL1008E4	①②
FPB/4-9	150	600	600	8"ø	NEW	PERIMETER	5.0	480/3	CFL0808E4	①②
FPB/4-10	305	1240	1240	12"ø	DWG/FIELD	PERIMETER	10.0	480/3	CFL1212E4	①②
FPB/4-11	140	580	505	8"ø	NEW	PERIMETER	5.0	480/3	CFL0808E4	①②
FPB/4-12	266	1123	1100	12"ø	RELOC.	PERIMETER	10.0	480/3	CFL1210E4	①②
FPB/4-13	140	570	570	8"ø	NEW	PERIMETER	5.0	480/3	CFL0808E4	①②
FPB/4-14	225	920	920	12"ø	RELOC.	PERIMETER	9.0	480/3	CFL1010E4	①②

① CONNECT TERMINAL BOX TO BUILDING AUTOMATION SYSTEM. REVIEW PARTICULARS WITH LANDLORD PRIOR TO INSTALLATION.
② PROVIDE DISCONNECT SWITCH.
③ CONTRACTOR SHALL INSPECT, TEST, CLEAN AND REPAIR/REFURBISH EXISTING FAN POWERED BOX AS REQUIRED TO ENSURE IT IS OPERATING WITHIN ALL STANDARD PARAMETERS.
④ REMOVE AND RELOCATE EXISTING FAN POWERED BOX. EXTEND ALL POWER AND CONTROL WIRING AND DAP MEDIUM PRESSURE DUCTWORK. INSTALL NEW DUCTWORK AS INDICATED AND CONNECT TO BUILDING AUTOMATION SYSTEM WITH NEW DESIGNATION.
⑤ EXISTING FAN POWERED BOX TO REMAIN. INSTALL NEW DUCTWORK AS INDICATED AND CONNECT TO BUILDING AUTOMATION SYSTEM WITH NEW DESIGNATION.

VAV BOX SCHEDULE

UNIT NUMBER	CFM MIN	CFM MAX	INLET	ELECTRIC HEATER KW	ELECTRIC HEATER VOLTAGE	MANUFACTURER	REMARKS
VAV/4-1	210	1050	10"ø	3.0	277/1	ENVIROTEC SDR10	①②
VAV/4-2	160	400	8"ø	2.0	277/1	ENVIROTEC SDR08	①②
VAV/4-3	190	570	8"ø	2.0	277/1	ENVIROTEC SDR08	①②
VAV/4-4	305	1385	12"ø	4.0	277/1	ENVIROTEC SDR12	①②
VAV/4-5	190	890	8"ø	2.0	277/1	ENVIROTEC SDR08	①②
VAV/4-6	190	745	8"ø	2.0	277/1	ENVIROTEC SDR10	①②
VAV/4-7	190	730	8"ø	2.0	277/1	ENVIROTEC SDR10	①②

① CONNECT TERMINAL BOX TO BUILDING AUTOMATION SYSTEM. REVIEW PARTICULARS WITH LANDLORD PRIOR TO INSTALLATION.
② PROVIDE DISCONNECT SWITCH.

Exhibit 21.1

UroGen Pharma Ltd.
Subsidiary of the Registrant

Urogen Pharma, Inc., a Delaware corporation.

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-3 (No. 333-235642) and S-8 (Nos. 333-232034, 333-227812, 333-222955, 333-221212 and 333-218992) of UroGen Pharma Ltd. of our report dated March 2, 2020 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

Tel-Aviv, Israel
March 2, 2020

/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: March 2, 2020

/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: March 2, 2020

/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, 2019, 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: March 2, 2020

In Witness Whereof, the undersigned have set their hands hereto as of the 2nd day of March, 2020.

/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."