As confidentially submitted to the Securities and Exchange Commission on April 20, 2016 as Confidential Submission No. 2. This draft registration statement has not been filed with the Securities and Exchange Commission and all information contained herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

UroGen Pharma Ltd.
(Exact name of Registrant as specified in its charter)

Not Applicable
(Translation of Registrant's name into English)

State of Israel	**2834**	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐
If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐
If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐
If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE (1)	AMOUNT OF REGISTRATION FEE (2)
Ordinary Shares, par value NIS 0.01 per share	$	$

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the ordinary shares that the underwriters have the option to purchase.
(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information contained in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 20, 2016

PRELIMINARY PROSPECTUS

Ordinary Shares

UroGen Pharma Ltd.

We are offering ordinary shares. This is our initial public offering and no public market currently exists for our ordinary shares. We expect the initial public offering price to be between $ and $ per share. We intend to apply to have our ordinary shares listed on the NASDAQ Global Market under the symbol "URGN."

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our ordinary shares involves a high degree of risk. Please read "Risk Factors" beginning on page 14 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public Offering Price	$	$
Underwriting Discounts and Commissions (1)	$	$
Proceeds to UroGen Pharma Ltd. Before Expenses	$	$

(1) We have agreed to reimburse the underwriters for certain expenses. See "Underwriting."

Delivery of the ordinary shares is expected to be made on or about , 2016. We have granted the underwriters an option for a period of 30 days to purchase up to an additional ordinary shares. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Jefferies **Cowen and Company**

Prospectus dated , 2016

TABLE OF CONTENTS

	PAGE
Prospectus Summary	1
Risk Factors	14
Special Note Regarding Forward-Looking Statements	54
Use of Proceeds	55
Dividend Policy	56
Capitalization	57
Dilution	59
Selected Financial Data	61
Management's Discussion and Analysis of Financial Condition and Results of Operations	62
Business	74
Management	110
Principal Shareholders	128
Certain Relationships and Related Party Transactions	131
Description of Share Capital	133
Shares Eligible for Future Sale	141
Taxation	144
Underwriting	150
Expenses of this Offering	158
Legal Matters	159
Experts	159
Enforcement of Civil Liabilities	160
Where You Can Find More Information	161
Index to Financial Statements	F-1

Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus, any amendment or supplement to this prospectus, or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell ordinary shares and seeking offers to purchase ordinary shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front of this prospectus, regardless of the time of delivery of this prospectus or any sale of ordinary shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

For investors outside of the United States: Neither we nor any of the underwriters have taken any action to permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

MitoGel, VesiGel, Vesimune, BotuGel, UroGen and RTGel are trademarks of ours that we use in this prospectus. This prospectus 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 prospectus 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.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business, and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Special Note Regarding Forward-Looking Statements."

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our ordinary shares, you should read this entire prospectus carefully, including the sections of this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. Unless the context otherwise requires, references in this prospectus to the "company," "UroGen Pharma," "we," "us" and "our" refer to UroGen Pharma Ltd. and its subsidiary, Urogen Pharma, Inc. 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 prospectus refer to ordinary shares of UroGen Pharma Ltd., par value NIS 0.01 per share.

Overview

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

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 be at least $4 billion in 2010 and are projected to be at least $5 billion in 2020. The majority of the historical expenditures was spent on tumor resection surgeries such as transurethral resection of bladder tumor, or TURBT, and bladder, kidney and upper urothelial tract removals. In 2012, the estimated prevalence of urothelial cancer in the United States was 625,000 with an annual incidence of approximately 80,000. The 2012 prevalence of each of low-grade non-muscle invasive bladder cancer, or NMIBC, and low-grade UTUC in the United States was approximately 325,000 and 14,500, respectively. No drugs have been approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of UTUC, and no drugs have been approved by the FDA for the treatment of bladder cancer in more than 15 years.

MitoGel and VesiGel are formulated using our proprietary reverse thermally triggered hydrogel, or RTGel, technology. We believe that RTGel-based drug formulations, which provide for the sustained release of an active drug, may improve the efficacy of treatment of various types of urothelial cancer without compromising the safety of the patient or interfering with the natural flow of fluids in the urinary tract. Our formulations are designed to achieve this by increasing the dwell time as well as the tissue coverage throughout the organ 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.

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

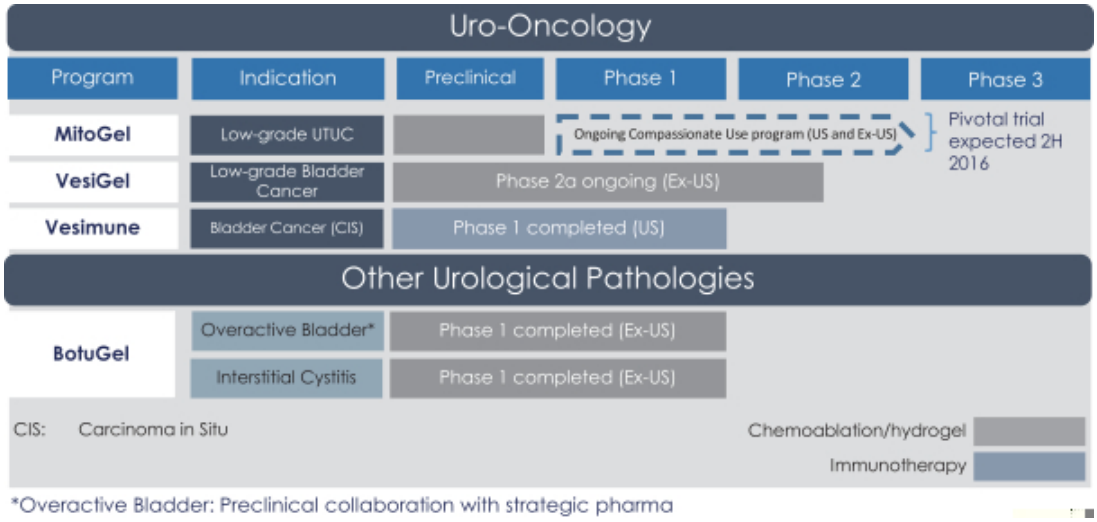
We are currently evaluating the safety and efficacy of MitoGel, our novel sustained-release formulation of MMC, in UTUC patients pursuant to an ongoing "Compassionate Use" program. "Compassionate Use" is the use outside of a clinical trial of an investigational, or not approved, medical product when patient enrollment in a clinical trial is not possible, typically due to patient ineligibility or a lack of ongoing clinical trials. Of the seven low-grade UTUC patients with confirmed low-grade UTUC evaluated in the program to date, four achieved a complete response and three achieved a partial response. Thus far, MitoGel has been observed to be well-tolerated. We have obtained Orphan Drug Designation for MitoGel for the treatment of UTUC. We expect to file an investigational new drug, or IND, application for MitoGel with the FDA in the second half of 2016, and, if accepted, to commence a single pivotal, open-label, single-arm Phase 3 clinical trial for the treatment of low-grade UTUC also in the second half of 2016. We intend to pursue the FDA's 505(b)(2) regulatory pathway for MitoGel, which is a streamlined, lower-cost and more well-defined pathway to drug approval when compared to traditional drug development. We believe that MitoGel has the potential to become the first FDA-approved drug for the treatment of low-grade UTUC and to serve as a first-line chemoablation agent, sparing patients from repeated tumor resection surgeries and potentially reducing the need for kidney and upper urothelial tract removals.

In addition, we are currently evaluating the safety and efficacy of VesiGel, our novel sustained-release high dose formulation of MMC, for the treatment of low-grade NMIBC. To date, 18 of 20, or approximately 90%, of the patients evaluated in our ongoing Phase 2a clinical trial who were treated in the VesiGel high dose group (80mg MMC) achieved a complete response. Moreover, in the clinical program to date, comprised of the Phase 2a and earlier Phase 1 clinical trials, over 80% of the patients who achieved a complete response and who have been followed for 12 months thereafter remained recurrence free. This compares to approximately 40% of patients who historically achieve a 12-month durable complete response with TURBT as first-line treatment. We plan to file an IND for VesiGel in the first half of 2017 and, if accepted, to commence a Phase 2b clinical trial for VesiGel also in the first half of 2017. We also intend to pursue a 505(b)(2) regulatory pathway for VesiGel. We believe that VesiGel has the potential to replace tumor resection surgery and become the new first-line standard of care for the treatment of low-grade NMIBC.

Our clinical stage pipeline also includes Vesimune, our proprietary immunotherapy product candidate for the treatment of high-grade NMIBC, as well as BotuGel, which we are developing for the treatment of overactive bladder and interstitial cystitis, also known as painful bladder syndrome. Vesimune is a novel, liquid formulation of Imiquimod, a generic toll-like receptor 7, or TLR7, agonist. Toll-like receptor agonists play a key role in initiating the innate immune response system. We believe that Vesimune could represent a valid alternative to the current standard of care for the adjuvant post TURBT treatment of high-grade NMIBC. BotuGel is our proprietary novel RTGel-based formulation of botulinum toxin, a branded drug, that we believe can potentially serve as an effective treatment option for patients suffering from overactive bladder and interstitial cystitis.

Our Product Candidate Pipeline

The following chart summarizes the current status of our clinical stage product candidate pipeline.



Overview of Upper Tract Urothelial Carcinoma

UTUC refers to malignant changes of the transitional urothelial cells lining in the upper urothelial tract, comprised of the renal pelvis and ureter. UTUC is nearly three times more common in men than women and affects mostly the elderly. UTUC accounts for approximately 5% to 10% of all new cases of urothelial cancer, which corresponds to an estimated annual incidence in the United States of up to 7,500 cases. In 2012, the estimated prevalence of UTUC in the United States was approximately 45,000, of which approximately 14,500 had low-grade disease.

The key prognostic factor at the time of diagnosis of UTUC is whether the tumor is in the muscle-invasive or non-muscle invasive stage. The number, size and location of tumors presented also represent important prognostic factors for UTUC. Approximately 40% of the patients diagnosed annually with UTUC in the United States present with non-muscle invasive UTUC.

Limitations of Current Treatment Options for Upper Tract Urothelial Carcinoma

There are currently no drugs approved by the FDA for the treatment of UTUC, representing a significant unmet medical need. Moreover, the anatomical complexity of the upper urothelial tract, particularly the renal pelvis, presents significant challenges to the proper identification and ability to reach and resect all tumors in tumor resection surgical procedures. Consequently, patients with high-grade disease or patients with low-grade disease that present with a large number of tumors typically undergo nephroureterectomy, which is kidney and upper urothelial tract removal.

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

MitoGel: Our Solution for the Treatment of Low-Grade Upper Tract Urothelial Carcinoma

We believe that MitoGel, our novel sustained-release RTGel-based formulation of MMC, has the potential to become the first FDA-approved drug for the treatment of low-grade UTUC and to serve as a first-line chemoablation agent, sparing patients from repeated tumor resection surgical procedures and potentially reducing the need for kidney and upper urothelial tract removal. We believe that MitoGel can overcome the significant anatomical and physiological constraints presented by the upper urothelial tract. MitoGel is administered directly into the upper urothelial tract using standard catheters and conforms to the complex anatomy of the upper urothelial tract. Once instilled, MitoGel converts into gel form in less than 10 minutes at body temperature. Subsequently, upon contact with urine, MitoGel gradually dissolves and releases the active drug, MMC, over a period of several hours versus several minutes for MMC in its current water-based formulation, without compromising the safety of the patient or interfering with the natural flow of fluids from the upper urothelial tract to the bladder. We believe that this substantial increase in dwell time of MMC positions MitoGel as a potential first-line chemoablation treatment alternative to tumor resection surgery for the treatment of low-grade UTUC, sparing patients from repeated and frequent tumor resection surgical procedures, and may also reduce the need for kidney and upper urothelial tract removal.

Overview of Non-Muscle Invasive Bladder Cancer

Bladder cancer accounts for approximately 90% to 95% of all new cases of urothelial cancer in the United States, with a prevalence of approximately 580,000. Bladder cancer is nearly three to four times more common in men than women, and, with an average age at diagnosis of 73, mostly affects the elderly. Bladder cancer is described as non-muscle invasive or muscle-invasive based on how far into the wall of the bladder the cancer has invaded. Muscle-invasive bladder cancer, or MIBC, has an average five-year survival of 15% to 63%, depending on severity. MIBC has a worse prognosis than NMIBC, which has a five-year survival rate of approximately 90%.

NMIBC accounts for approximately 80% of all new cases of bladder cancer diagnosed in the United States each year, which corresponds to an estimated annual incidence and prevalence of approximately 60,000 and 465,000 cases, respectively. NMIBC is divided into two grades, low and high, with high-grade tumors more likely to recur and progress into muscle-invasive tumors. Overall, approximately 70% of patients with NMIBC present with low-grade disease at diagnosis.

Limitations of Current Treatment Options for Non-Muscle Invasive Bladder Cancer

The standard of care for treating NMIBC patients is TURBT followed by adjuvant chemotherapy or immunotherapy treatment. TURBT is a surgical operation for tumor removal conducted under general anesthesia in a hospital setting and often requires at least 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. Patients treated with the current standard of care have up to an approximately 60% rate of recurrence of NMIBC within one year, and the rate of progression of NMIBC to MIBC is between 20% and 30%. As a consequence, NMIBC patients have to undergo periodic and expensive follow-ups that can include multiple repeated TURBT procedures and adjuvant chemotherapy and immunotherapy treatments.

No drugs have been approved by the FDA as first-line treatment for NMIBC and only three drugs have been approved by the FDA for NMIBC, all used as adjuvant treatment, following TURBT. Efficacy of drug treatments has historically been limited due to challenges presented by bladder physiology, specifically the fact that urine is produced and voided frequently, thus diluting the concentration of the drug almost immediately and causing the excretion of the drug from the bladder at first urine voiding.

VesiGel: Our Solution for the Treatment of Low-Grade Non-Muscle Invasive Bladder Cancer

We believe that VesiGel, our novel sustained-release RTGel-based formulation of high dose MMC, has the potential to replace TURBT and become the new first-line standard of care for the treatment of low-grade NMIBC. VesiGel, a chemoablation agent, is administered locally using standard catheters in a physician's office as a same-day treatment, in comparison with TURBT surgical procedures, which are operations conducted under general anesthesia in a hospital setting and often require at least an overnight stay. Once

instilled, VesiGel converts into gel form in approximately 15 minutes at body temperature. Subsequently, upon contact with urine, VesiGel gradually dissolves and releases the active drug, MMC, over a period of several hours versus the time until first voiding, often less than an hour, for MMC 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 designed VesiGel to conform to the bladder's anatomy and persist in the bladder despite urine flow and bladder movement. VesiGel has demonstrated significantly increased dwell time of MMC in the bladder and prolonged exposure of MMC to the tissue, enabling the chemoablation of both visible and undetected tumors. We are not aware of any drugs currently in development for the treatment of NMIBC, other than VesiGel, that take into consideration the specific challenges of bladder physiology.

RTGel: Our Reverse Thermally Triggered 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 urothelial tract, by conforming to the anatomy of the target organ while preventing rapid excretion of the drug. RTGel's components are polymer-based and are all FDA approved as inactive ingredients. We formulate RTGel with an active drug: MMC in the case of MitoGel and VesiGel, and botulinum toxin in the case of BotuGel.

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 in the urinary tract. RTGel achieves this by:

- increasing the exposure of active drugs in the bladder and upper urothelial tract by significantly extending the dwell time of such drugs while conforming to the anatomy of the bladder and the upper urothelial tract, which allows for enhanced drug tissue coverage;
- administering higher doses of an active drug than would otherwise be possible using standard water-based formulations; and
- maintaining the active drug's molecular structure and mode of action.

These characteristics of RTGel enable sustained release of MMC in the urinary tract for both MitoGel and VesiGel, and of botulinum toxin in the case of BotuGel. Further, RTGel may be particularly effective in the bladder and upper urothelial tract where tumor visibility and access are challenging, and where there exists a significant amount of urine flow and voiding.

Our Competitive Strengths

Potential ability to develop non-surgical, first-line drug therapies for uro-oncology. Leveraging our innovative formulation technology, we are developing two lead product candidates, MitoGel and VesiGel, as potential replacements to first-line therapy for low-grade UTUC and NMIBC, respectively. Both MitoGel and VesiGel 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 MMC. Clinical data generated to date supports our belief that our lead product candidates may be able to replace the current first-line tumor surgical procedures, providing a chemoablation treatment that has the potential to better eradicate tumors irrespective of their detectability and location within the urinary tract.

Expertise in developing proprietary formulations of drugs for clinical benefit. We focus on developing proprietary RTGel formulations of previously approved drugs whose efficacy for a particular indication is limited by current formulations or routes of administration. While we have not yet brought a drug to market, our expertise has enabled us to develop proprietary RTGel-based formulations for several previously approved drugs to date, including clinical stage proprietary formulations of MMC and botulinum toxin. With 10 Ph.D. or medical doctors on our staff, we have a strong research and development team to advance our product candidates.

Lower development risks and costs for our pipeline product candidates. We expect the approval process for each of our current uro-oncology product candidates to be conducted according to the FDA's 505(b)(2) regulatory pathway, a streamlined, lower-cost and more well-defined pathway to drug approval when compared to traditional drug development. Furthermore, two of our product candidates, MitoGel and Vesimune, have received Orphan Drug Designation from the FDA for the treatment of UTUC and Carcinoma in Situ, or CIS, respectively, which we expect will provide seven years of marketing exclusivity following FDA approval, if received.

***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.

Strong intellectual property position. We have a robust intellectual property portfolio that includes four issued patents in the United States and several patent applications worldwide related to methods, systems and compositions for treating bladder cancer related to our lead product candidates, MitoGel and VesiGel, as well as RTGel, both on its own and formulated with other drugs. The four issued patents are expected to expire between 2024 and 2030. We also have 11 granted patents worldwide related to our other product candidates, which are expected to expire between 2030 and 2031. We also have approximately 60 pending patent applications worldwide covering our product candidates.

***Experienced and accomplished leadership team with proven track record*.** We have an experienced management team, with each member possessing more than 15 years of biopharmaceutical and related industry experience. 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

Establish each of our lead product candidates, MitoGel and VesiGel, as the first-line therapy in its target indication. We believe that our lead product candidates have the potential to replace costly, sub-optimal and burdensome tumor resection procedures as first-line therapy and may also reduce the need for bladder, kidney and upper urothelial tract removals. We believe that data from an ongoing Compassionate Use program provide preliminary evidence of the potential safety and efficacy of MitoGel for the treatment of low-grade UTUC. We expect to file an IND in the second half of 2016 and, if accepted, to commence a single pivotal Phase 3 clinical trial for MitoGel also in the second half of 2016 pursuant to the FDA's 505(b)(2) regulatory pathway. For VesiGel, which is currently in a Phase 2a clinical trial for the treatment of low-grade NMIBC, we expect to file an IND in the first half of 2017 and, if accepted, to commence a Phase 2b clinical trial also in the first half of 2017.

Expand our uro-oncology product pipeline. A Phase 1 clinical trial of Vesimune was completed under an IND in 12 patients with CIS, an aggressive type of high-grade NMIBC. In the study, 10 patients were evaluated for response and a 40% complete response rate with Vesimune as a single-agent treatment was observed. We believe that Vesimune has the potential to serve as a treatment option for high-grade urothelial tumors. We are also pursuing preclinical oncology programs that take advantage of our RTGel technology.

Develop our non-oncology product candidates. We are developing additional product candidates designed to take advantage of our proprietary RTGel formulation technology to better adapt to the specific anatomy and physiology of the urological system. The most notable of these product candidates is BotuGel, our proprietary novel RTGel-based formulation of botulinum toxin for the treatment of overactive bladder and interstitial cystitis.

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 and sustained release of active drugs to a variety of targeted body cavities and for multiple indications. Beyond the urinary tract, we may target the gastrointestinal tract and female reproductive system.

Evaluate and selectively pursue potential collaborations to develop improved formulations and product life-cycle management strategies. We intend to evaluate and selectively pursue collaborations with pharmaceutical companies through a combination of in-licensing, out-licensing, joint venture and partnership transactions in order to formulate additional drugs using such companies' products or product candidates in combination with RTGel. In addition, we may in-license or acquire additional product candidates for urological indications.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include the following:

- We have a limited operating history and have incurred since inception, and expect to continue to incur for the foreseeable future, significant losses and negative cash flows.
- We have limited clinical trial experience with our product candidates and to date have generated only limited clinical data for our product candidates. Results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates.
- We have not conducted Phase 3 or similar pivotal, or equivalent, registration clinical trials for any of our product candidates, nor have we applied for regulatory approvals to market any of our other product candidates, and we may be delayed in obtaining or fail to obtain such regulatory approvals and to commercialize our product candidates.
- If the FDA does not conclude that MitoGel, VesiGel or our other product candidates satisfy the requirements under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act or a similar regulatory pathway for biologics as it relates to BotuGel, or if the requirements for such product candidates are not as we expect, the regulatory 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.
- 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. Further, if MitoGel or VesiGel or any of our other product candidates produces undesirable side effects that we may not have detected in our previous preclinical studies and clinical trials, our ability to obtain and maintain marketing approval or physician and market acceptance for these product candidates would be significantly harmed.
- We are and expect to continue to be dependent on third-party subcontractors and single-source suppliers for the supply of sufficient quantities at acceptable costs of certain raw materials, compounds and components necessary to produce MitoGel, VesiGel, Vesimune and BotuGel for preclinical studies, clinical trials and, if approved, commercial supply.
- We may receive only limited protection, or no protection, from our issued patents and patent applications. 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.
- 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.
- Our product candidates, if approved, will face significant competition from competing technologies and our failure to compete effectively may prevent us from achieving significant market penetration.
- 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.
- We expect to be classified as a passive foreign investment company, or PFIC, for U.S. income tax purposes for the taxable year ending December 31, 2016, and our U.S. shareholders may suffer adverse tax consequences as a result (such as having gains realized on the sale of our ordinary shares

treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. shareholders, and having interest charges apply to distributions by us and gains from the sale of our shares), and we do not currently intend to provide investors with the information that would enable them to make the Qualified Electing Fund election. If we are classified as a PFIC, each holder of our ordinary shares who is a U.S. person will generally be required to file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund).

Corporate Information

We were incorporated under the laws of the State of Israel in April 2004 under the name TheraCoat Ltd. In September 2015, we changed our name to UroGen Pharma Ltd. Our principal executive offices are located at 9 Ha'Ta'asiya Street, Ra'anana 4365007, Israel, and our telephone number is +972 (9) 770-7601. Our website address is *http://www.urogen.com*. The information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus. We have included our website address as an inactive textual reference only. Our agent for service of process in the United States is Urogen Pharma, Inc., located at 689 Fifth Avenue, 14th Floor, New York, New York 10022, and its telephone number is .

Implications of Being an "Emerging Growth Company" and a Foreign Private Issuer

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- a requirement to have only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in our initial registration statement; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: (1) the last day of the fiscal year in which we have total annual gross revenues of $1.0 billion or more; (2) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (3) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or the SEC. We may choose to take advantage of some but not all of these reduced burdens, and therefore the information that we provide holders of our ordinary shares may be different than the information you might receive from other public companies in which you hold equity. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. We have irrevocably elected to opt out of such extended transition period.

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we continue to qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial statements and other specified information, and current reports on Form 8-K upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

THE OFFERING

Ordinary shares offered by us	ordinary shares
Ordinary shares to be outstanding immediately after this offering	ordinary shares
Option to purchase additional ordinary shares	We have granted the underwriters an option for a period of 30 days after the date of this prospectus to purchase up to additional ordinary shares.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional ordinary shares in full, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, based on an assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus. We expect to use the net proceeds from this offering, together with our existing cash resources, to advance our clinical pipeline, including specifically to file an IND for, and to initiate and complete our planned single pivotal Phase 3 clinical trial of, MitoGel; to file an IND for, and to initiate our planned Phase 2b clinical trial of, VesiGel; to fund continued research and clinical development of our other product candidates and for working capital and other general corporate purposes. See “Use of Proceeds” for more information about the intended use of proceeds from this offering.
Tax considerations	Because we have no current revenue-producing operations, we expect to be treated as a PFIC for our current taxable year and possibly thereafter. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences. See “Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders—Passive Foreign Investment Company Considerations.”
Risk factors	See “Risk Factors” and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our ordinary shares.
Proposed NASDAQ Global Market symbol	We intend to apply to have our ordinary shares listed on the NASDAQ Global Market under the symbol “URGN.”

Unless otherwise stated, the number of ordinary shares to be outstanding after this offering is based on ordinary shares outstanding as of December 31, 2015 and assumes:

- the issuance by us of ordinary shares in this offering;
- the issuance of Series A-1 preferred shares upon the exercise for cash of all outstanding warrants to purchase Series A-1 preferred shares; and
- the issuance of ordinary shares upon the conversion of all Series A preferred shares and Series A-1 preferred shares into ordinary shares, which will occur automatically upon the closing of this offering;

but excludes:

- ordinary shares reserved for issuance under our 2010 Israeli Share Option Plan, including ordinary shares reserved for issuance upon the exercise of outstanding options at a weighted average exercise price of $ per share, and ordinary shares reserved for issuance upon the vesting of outstanding restricted share units; and
- ordinary shares reserved for issuance upon the achievement of certain milestones under the Vesimune asset purchase agreement with Telormedix SA.

Unless otherwise indicated, all information in this prospectus:

- assumes an initial public offering price of $ per ordinary share, the midpoint of the range set forth on the cover of this prospectus;
- assumes no exercise of the underwriters' option to purchase up to additional ordinary shares;
- reflects a -for-1 share split to be effected on , 2016, by means of distribution of a share dividend of ordinary shares for each ordinary share then outstanding; and
- gives effect to the adoption of our amended and restated articles of association prior to the closing of this offering, which will replace our amended and restated articles of association as currently in effect.

SUMMARY FINANCIAL DATA

The following tables present summary financial data for our business. We derived the summary statements of operations data for the years ended December 31, 2015 and 2014 from our audited financial statements included elsewhere in this prospectus. 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. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the information under the captions "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

	YEAR ENDED DECEMBER 31,	
	2015	2014
	(in thousands, except share and per share data)	
Statements of Operations Data:		
Research and development expenses, net	$ 10,515	$ 3,479
General and administrative expenses	1,895	890
Operating loss	12,410	4,369
Finance expenses (income), net	279	107
Net loss for the period	$ 12,689	$ 4,476
Loss per ordinary share, basic and diluted	$ 18.83	$ 6.34
Weighted average number of ordinary shares outstanding used in computing basic and diluted loss per ordinary share	719,060	719,060

	AS OF DECEMBER 31, 2015		
	ACTUAL	PRO FORMA (1)	PRO FORMA AS ADJUSTED (2)
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$17,975	$ 23,665	$
Working capital (3)	$16,894	$ 22,584	$
Total assets	$19,390	$ 25,080	$
Total liabilities	$ 3,109	$ 2,237	$
Total shareholders' equity	$16,281	$ 22,843	$

(1) Data presented on a pro forma basis to reflect the exercise for cash of all outstanding warrants to purchase Series A-1 preferred shares, and the conversion thereafter of all outstanding preferred shares into an aggregate of 1,850,559 ordinary shares.

(2) Data presented on a pro forma as adjusted basis to give further effect to the sale of ordinary shares in this offering at an assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase or decrease in the assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus, would increase or decrease, respectively, the amount of cash and cash equivalents, total assets and total shareholders' equity by $, assuming the number of ordinary shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. An increase or decrease of 100,000 in the number of ordinary shares we are offering would increase or decrease, respectively, the amount of securities, cash and cash equivalents, total assets and total shareholders' equity by

$, assuming the assumed initial public offering price per ordinary share, as set forth on the cover of this prospectus, remains the same. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

(3) Working capital is defined as total current assets minus total current liabilities.

RISK FACTORS

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the risks and uncertainties described below, in addition to the other information set forth in this prospectus, including the financial statements and the related notes included elsewhere in this prospectus, before purchasing our ordinary shares. If any of the following risks actually occurs, our business, financial condition, cash flows and results of operations could be negatively impacted. In that case, the trading price of our ordinary shares would likely decline and you might lose all or part of your investment. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, cash flows and results of operations.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

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

We are a 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 year since we commenced operations in 2004, including net losses of $12.7 million and $4.5 million for the years ended December 31, 2015 and 2014, respectively. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our ability to ultimately achieve revenues and profitability is dependent upon our ability to successfully complete the development of our product candidates, obtain necessary regulatory approvals for and successfully manufacture, market and commercialize our products.

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

Our future capital requirements depend on many factors, including:

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

- scientific breakthroughs in the field of urothelial cancer treatment and diagnosis that could significantly diminish the need for our product candidates or make them obsolete; and
- changes in reimbursement policies that could have a negative impact on our future revenue stream.

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

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 of our resources have been dedicated to the preclinical and clinical development of our lead product candidates, MitoGel and VesiGel. As of December 31, 2015, we had cash and cash equivalents of $18.0 million.

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

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

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

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates or any of our future product candidates;
- delay, limit, reduce or terminate our other research and development activities; or
- delay, limit, reduce or terminate our establishment or expansion of manufacturing, sales and marketing or distribution capabilities or other activities that may be necessary to commercialize MitoGel, VesiGel 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, including purchasers of ordinary shares in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity, convertible debt or debt financings, as well as selectively continuing to enter into collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, 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 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 collaborations, strategic alliances or licensing arrangements, we may be required to terminate product development or future commercialization efforts or to cease operations altogether.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

As described in Note 1 of our accompanying financial statements, our auditors issued a going concern explanatory paragraph in their opinion concerning our financial statements for the two years ended December 31, 2015, expressing substantial doubt that we can continue as an ongoing business for the next 12 months after issuance of their report based on our having suffered cumulative losses and negative cash flows from operating activities since inception and having an accumulated deficit as of December 31, 2015 of $25.3 million, which they have indicated raises substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot continue as a viable entity, our shareholders may lose some or all of their investment in us. Following completion of this offering, we expect to have sufficient funds to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, no assurance can be provided that such amount of capital will be sufficient to run our operations.

Risks Related to Our Business and Strategy

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

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

- our timely completion of our investigational new drug, or IND, enabling work for MitoGel, including the ongoing work required to obtain the necessary toxicology and chemistry, manufacturing controls, or CMC, data and the FDA's timely acceptance of such data;
- the FDA's timely acceptance of our IND filing for MitoGel, which we intend to submit in the second half of 2016, and for VesiGel, which we intend to submit in the first half of 2017, and our other product candidates for which we plan to file an IND. Without such IND acceptances, we will be unable to commence clinical trials in the United States;
- the FDA's acceptance of our parameters for regulatory approval relating to MitoGel, VesiGel and our other product candidates, including our proposed indications, primary and secondary endpoint assessments and measurements, safety evaluations and regulatory pathways;

- the FDA's acceptance of the number, design, size, conduct and implementation of our clinical trials, our trial protocols and the interpretation of data from preclinical studies or clinical trials;
- our ability to successfully complete the clinical trials of our product candidates, including timely patient enrollment and acceptable safety and efficacy data and our ability to demonstrate the safety and efficacy of the product candidates undergoing such clinical trials;
- the FDA's acceptance of the sufficiency of the data we collected from our preclinical studies and are collecting from the ongoing "Compassionate Use" program of MitoGel in upper tract urothelial carcinoma, or UTUC, to support the submission of an IND without requiring additional preclinical studies or clinical trials, and our ability to commence a single pivotal Phase 3 clinical trial for MitoGel for the treatment of low-grade UTUC following an IND submission, if accepted, and that the single pivotal Phase 3 clinical trial, even if successfully completed, will be sufficient to support a New Drug Application, or NDA, submission;
- the FDA's acceptance of the sufficiency of the data we collected from our preclinical studies and are collecting from our ongoing Phase 2a clinical trial with VesiGel in low-grade non-muscle invasive bladder cancer, or NMIBC, and expect to collect from toxicological studies that we may conduct to support the submission of an IND without requiring additional preclinical studies or clinical trials, and our ability to commence a Phase 2b clinical trial in the United States for VesiGel in low-grade NMIBC following an IND submission, if accepted;
- the FDA's willingness to schedule an advisory committee meeting in a timely manner to evaluate and decide on the approval of our NDAs for MitoGel and VesiGel;
- the recommendation of the FDA's advisory committee to approve our applications to market MitoGel and VesiGel 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 satisfaction with the safety and efficacy of our product candidates;
- the prevalence and severity of adverse events associated with our product candidates;
- 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 UTUC and the FDA has not approved a drug for the treatment of bladder cancer 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; and
- our ability to obtain, protect and enforce our intellectual property rights with respect to our product candidates.

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 in other countries. These regulations differ from country to country. To gain approval to market our product candidates, we must provide clinical data that adequately demonstrate the safety and efficacy of the product for the intended indication. We have not yet obtained regulatory approval to market any of our product candidates in the United States or any other

country. Our business depends upon obtaining these regulatory approvals. There are currently no drugs approved by the FDA for the treatment of UTUC and only three drugs have been approved by the FDA for NMIBC, with the last approval having occurred over 15 years ago. The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to satisfactorily demonstrate that the product candidates are safe and effective for the target indication;
- the FDA's disagreement with our trial protocol, the interpretation of data from preclinical studies or clinical trials, or adequate conduct and control of clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full 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) or 351(k) regulatory pathway is not available for our product candidates;
- the FDA's determination that additional preclinical studies or clinical trials are required;
- the FDA's non-approval of the formulation, labeling or the specifications of our product candidates;
- 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.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly and potentially time-consuming additional post-approval clinical trials or subject to restrictive Risk Evaluation and Mitigation Strategies. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would thus negatively impact our business, results of operations and prospects.

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

Positive results in preclinical testing and early clinical trials do not ensure that later clinical trials will be successful. A number of pharmaceutical companies have suffered significant setbacks in clinical trials, including in Phase 3 clinical trials, after promising results in preclinical testing and early clinical trials. These setbacks have included negative safety and efficacy observations in later clinical trials, including previously unreported adverse effects. For example, to date, we have enrolled only 18 patients into the ongoing UTUC Compassionate Use program of MitoGel. Thus far only seven patients who were confirmed with low-grade UTUC disease have been evaluated for response, and four achieved a complete response and the remaining three achieved a partial response. Further, we have only evaluated patients who have been diagnosed with tumors up to three centimeters in diameter. To date in our clinical trials, we have observed several adverse events and serious adverse events, consisting primarily of burning sensation, rash, urgency in urination and pain during urination. These adverse events are known MMC-related adverse events and are indicated as potential side effects of MMC usage on the MMC label. However, we cannot assure you that adverse events related to MitoGel and VesiGel that are not directly attributable to MMC specifically will not occur. While the preliminary data indicates that the product candidate appears to be safe and efficacious for the treatment of low-grade UTUC, our Compassionate Use program is ongoing and these results may not be replicated in additional Compassionate Use patients or in patients with tumors larger than three centimeters in diameter, or in the planned single pivotal Phase 3 clinical trial, which is currently expected to evaluate between 50 and 70 patients. We expect to enroll and evaluate additional patients in our Compassionate Use program and any negative results or new adverse events could delay our IND filing for MitoGel. After the IND filing, if accepted, we plan to commence a single pivotal

Phase 3 clinical, or equivalent, registration trial for MitoGel in patients with low-grade UTUC. This trial may not be successful. If our clinical trials do not ultimately indicate that our product candidates are safe or efficacious for their intended application, the FDA may not approve any NDA that we may file to market such product candidates, and our business would not be able to generate revenue from the sale of any such product candidates.

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 urothelial cancers over the past 15 years, neither we nor any third-party clinical investigators, clinical research organizations, or CROs, and/or consultants are likely to have extensive experience conducting clinical trials for the indications we are targeting. Third-party clinical investigators do not operate under our control. Any performance failure on the part of such third parties could delay the clinical development of our product candidates or delay or prevent us from obtaining regulatory approval or commercializing our current or future product candidates, depriving us of potential product revenue and resulting in additional losses.

We have not conducted Phase 3 or similar pivotal, or equivalent, registration clinical trials for any of our product candidates, nor have we applied for regulatory approvals to market any of our other product candidates, and we may be delayed in obtaining or fail to obtain such regulatory approvals and to commercialize our product candidates.

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

Before we can submit an NDA to the FDA or comparable similar applications to foreign regulatory authorities, we must conduct Phase 3 clinical trials, or a pivotal/registration trial equivalent, for each product candidate. We expect to commence a single pivotal Phase 3 clinical trial of MitoGel for the treatment of low-grade UTUC in the second half of 2016, pursuant to the FDA's 505(b)(2) regulatory pathway. These clinical trials will be substantially broader than our previous and ongoing Phase 1 and Phase 2 clinical trials and the Compassionate Use program for MitoGel for the treatment of patients with UTUC and will require us to enroll a considerably larger number of patients in multiple clinics and medical centers across a number of different countries. For example, based on our discussion with the FDA, our current expectation is that our pivotal clinical trial for MitoGel will be an open-label, single-arm study, evaluating between 50 and 70 patients with low-grade UTUC in the United States, Europe and Israel. We are also planning to commence a Phase 2b clinical trial of VesiGel in the first half of 2017. Before commencing these clinical trials in the United States, we must first file an IND, which must be accepted by the FDA. We have not yet discussed the clinical development of VesiGel with the FDA. Also, while we believe that we have received adequate clarity from the FDA regarding the key safety and efficacy parameters for the planned pivotal trial of MitoGel in low-grade UTUC, we cannot assure you that the FDA will not decide to materially alter these parameters, including potentially requiring a pivotal study with a control arm, before or during the trial or require us to conduct more than one pivotal trial before submitting an NDA. We have not received regulatory clearance to commence the clinical trials that we believe are necessary to submit an NDA to the FDA or comparable applications to foreign regulatory authorities.

Phase 3 clinical trials often produce unsatisfactory results even though prior clinical trials were successful. Moreover, the results of clinical trials may be unsatisfactory to the FDA or foreign regulatory authorities even if we believe those clinical trials to be successful. The FDA or applicable foreign regulatory agencies may suspend one or all of our clinical trials or require that we conduct additional clinical, preclinical, manufacturing, validation or drug

product quality studies and submit that data before considering or reconsidering any NDA or comparable foreign regulatory application that we may submit. Depending on the extent of these additional studies, approval of any applications that we submit may be significantly delayed or may cause the termination of such programs, or may require us to expend more resources than we have available.

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

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

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

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

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

Our BotuGel product candidate is subject to a preclinical material transfer collaboration agreement with a large pharmaceutical company. If that collaboration is terminated or the pharmaceutical company decides not to progress BotuGel into clinical trials even upon successful completion of the preclinical collaboration, our business may be harmed.

We have a preclinical material transfer collaboration with a large pharmaceutical company for the conduct of IND-enabling work, including formal preclinical toxicology and CMC experiments for our BotuGel product candidate for the treatment of overactive bladder. Our current agreement with the large pharmaceutical company grants the large pharmaceutical company an option to obtain, at any time during the course of the collaboration, a license for the clinical development and potential commercialization of BotuGel for the treatment of overactive bladder. If the large pharmaceutical company exercises its option, the parties will negotiate a license agreement in good faith. We cannot assure you that the preclinical collaboration will be successfully completed, and even if it is successfully completed, that it will lead to an acceptable licensing transaction with the large pharmaceutical company. BotuGel’s development in overactive bladder therefore is subject to many risks, including:

- generating adequate and sufficient preclinical data to support the decision of the large pharmaceutical company to negotiate a license from us, including satisfactory toxicology and CMC data;
- reaching a license agreement on acceptable terms with the pharmaceutical company;
- generating sufficient data to support the initiation or continuation of clinical trials whether on our own or with a licensing partner;
- obtaining regulatory approval to commence clinical trials, including the risk that the IND, if filed for BotuGel by the pharmaceutical company, will not be accepted by the FDA;
- contracting with the necessary third parties to conduct a clinical trial;
- enrolling sufficient numbers of patients in clinical trials;
- timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

The pharmaceutical company may not cooperate with us or perform its obligations under the agreement. Furthermore, the pharmaceutical company does not face penalties or other repercussions for failing to develop BotuGel within the designated timetable. We cannot control the scope or timing of the resources that will be devoted by the pharmaceutical company to performing its responsibilities under the agreement. The pharmaceutical company may choose to pursue alternative technologies in preference to those being developed with us. The agreement may also be terminated for convenience by the pharmaceutical company. The development and commercialization of the licensed product candidates as well as the anticipated contingent payments and royalties we hope to generate from them will be delayed or never obtained if the pharmaceutical company fails to conduct its responsibilities in a timely manner or in accordance with applicable regulatory requirements, or if it breaches its agreements with us. Disputes with the pharmaceutical company could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

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 future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, in order to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites, and have such CROs and sites effect the proper and timely conduct of our clinical trials;
- obtain and maintain institutional review board, or IRB, approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a trial;
- have a sufficient number of patients complete a trial or return for post-treatment follow-up;
- ensure clinical investigators and clinical trial sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites;
- manufacture sufficient quantities at the required quality of product candidate for use in clinical trials; or
- raise sufficient capital to fund a trial.

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

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

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

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

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

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers who have previously failed prior treatments, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or 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. 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.

MitoGel or VesiGel or any of our other product candidates may produce undesirable side effects that we may not have detected in our previous preclinical studies and clinical trials. 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 MitoGel or VesiGel or our other product candidates could 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 MitoGel and VesiGel, has not undergone extensive testing in humans. Side effects or adverse events associated with the use of MitoGel and VesiGel 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 clinical trials, we have observed several adverse events and serious adverse events, consisting primarily of burning sensation, rash, urgency in urination and pain during urination. These adverse events are known MMC-related adverse events and are indicated as potential side effects of MMC usage on the MMC label. However, we cannot assure you that we will not observe additional drug-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, the planned single pivotal Phase 3 clinical trial for MitoGel and the planned Phase 2b clinical trial for VesiGel will involve a larger patient base than that previously studied, and the commercial marketing of MitoGel and

VesiGel, 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 file 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 withdrawing their approval of the product;
- the FDA or foreign regulatory authorities requiring the addition of labeling statements, such as 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 respect to the safety-related claims that we can make in our marketing or promotional materials;
- our being required to change the way the product is administered, conduct additional preclinical studies or clinical trials or restrict or cease the distribution or use of the product; and
- our being sued and held liable for harm caused to patients.

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

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

Even if we complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA or applicable foreign regulatory agency may grant approval contingent on the performance of additional costly post-approval clinical trials, risk mitigation requirements and surveillance requirements to monitor the safety or efficacy of the product, which could negatively impact us by reducing revenues or increasing expenses, and cause the approved product candidate not to be commercially viable. Absence of long-term safety data may further limit the approved uses of our products, if any.

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

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

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

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

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

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

- the clinical indications for which the product is approved;
- the prevalence and severity of adverse side effects;
- 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 in relation to alternative treatments;
- the extent to which the costs of our product candidates are reimbursed by third-party payors, and patients' willingness to pay for our products;
- whether treatment with our product candidates, including the treatment of low-grade UTUC with MitoGel and the treatment of low-grade NMIBC with VesiGel, 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 and administration of our products by physicians or nurses;
- 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, clinics and any direct-to-consumer marketing efforts we may initiate.

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

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

Although we will devote a substantial portion of our resources on the continued clinical testing and potential approval of MitoGel for the treatment of low-grade UTUC and VesiGel for the treatment of low-grade NMIBC, another key element of our strategy is to discover, develop and commercialize a portfolio of products based on our proprietary RTGel platforms to serve additional therapeutic markets. We are seeking to do so through our internal research programs, but our resources are limited, and those that we have are geared towards clinical testing and seeking regulatory approval of MitoGel, VesiGel and our other existing product candidates. We may also explore strategic collaborations for the development or acquisition of new products, but we may not be successful in entering into such relationships. While we expect our lead product candidates, MitoGel and VesiGel, to commence a single pivotal Phase 3 clinical trial and a Phase 2b clinical trial, respectively, all of our other potential product candidates remain in the preclinical and/or early clinical stages of development. Research programs to identify product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- a product candidate may in a subsequent trial be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable; and
- intellectual property or other proprietary rights of third parties for product candidates we develop may potentially block our entry into certain markets, or make such entry economically impracticable.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidates.

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

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

We are aware that other companies, such as Merck Sharp & Dohme Corp., Viventia Bio Inc., Telesta Therapeutics Inc., Heat Biologics, Inc., Viralytics Limited, AADi, LLC, Biocancell Ltd., Halozyme Therapeutics, Inc., Astellas Pharma Inc., Cold Genesys, Inc., Altor BioScience Corporation, FKD Therapies Oy, Nippon Kayaku Co., Ltd, Spectrum Pharmaceuticals, Inc., and Handok Inc., are conducting or have recently conducted clinical trials for product candidates for the treatment of low-grade and high-grade NMIBC, including Carcinoma in Situ, or CIS. In addition, we are aware of several pharmaceutical companies that are developing drug candidates for muscle-invasive bladder cancer. We do not know whether these potential competitors are already developing, or plan to develop, low-grade UTUC or high-grade UTUC treatments or treatments for other indications that we are pursuing, and we may be unable to ascertain whether such activities are underway in the future.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in this industry. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis products that are more effective, easier to administer or less costly than our product candidates.

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

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

We have not yet established a commercial organization for the marketing, sale and distribution of our product candidates. Therefore, even if we receive approval to market our product candidates in the United States or other markets, in order to successfully commercialize our product candidates, we will need to either build marketing, sales, distribution, managerial and other non-technical capabilities or contract with third parties to obtain these capabilities. This involves many challenges, such as recruiting and retaining talented personnel, training employees, setting the appropriate system of incentives, managing additional headcount and integrating new business units into an existing corporate infrastructure. The development of our own sales infrastructure or contracting with third parties will involve substantial expense, much of which we will incur well in advance of any marketing or sales. Moreover, we do not have experience as a company in establishing a significant sales infrastructure, and we cannot be certain that we will successfully develop this capability or contract successfully with third parties for the necessary services. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain personnel for medical affairs, marketing and sales. If we fail to establish an effective sales and marketing infrastructure or contract with third parties to do so, we will be unable to successfully commercialize our product candidates, which in turn would have an adverse effect on our business, financial condition and results of operations.

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

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

We currently contract with third-party subcontractors and single-source suppliers for certain raw materials, compounds and components necessary to produce MitoGel, VesiGel, Vesimune and BotuGel for preclinical studies and clinical trials and expect to continue to do so to support commercial scale production of MitoGel, VesiGel, Vesimune or BotuGel, if approved. This increases the risk that we will not have sufficient quantities of MitoGel, VesiGel, Vesimune or BotuGel 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 MitoGel, VesiGel, Vesimune and BotuGel for our preclinical studies and clinical trials. We currently depend on single sources for MMC and gel for MitoGel and VesiGel, and Imiquimod for Vesimune. 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 MitoGel, VesiGel or any of our other product candidates is approved for marketing by the FDA or foreign regulatory authorities.

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 MitoGel, VesiGel 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 MitoGel, VesiGel or any other product candidates or products that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. Regulatory approval processes outside the United States generally includes 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 file for marketing approvals and may not receive the necessary approvals to commercialize our product candidates in any particular market.

We intend to rely on third parties and consultants to assist us in conducting our single pivotal Phase 3 clinical trial for MitoGel, our Phase 2b clinical trial for VesiGel and certain clinical trials for our other product candidates. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize MitoGel, VesiGel or any of our other product candidates.

We do not have the ability to independently conduct many of our preclinical studies or our clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs to conduct clinical trials on our product candidates. Third parties play a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. Due to the limited drug development for 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 MitoGel for the treatment of low-grade UTUC, VesiGel and Vesimune for the treatment of bladder cancer and BotuGel for the treatment of overactive bladder and interstitial cystitis. 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, 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 MitoGel for treatment of low-grade 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. However, physicians are able, in their independent medical judgment, to use MitoGel on their patients in an off-label manner, such as for the treatment of other urology indications. If we are found to have promoted such off-label uses, we may receive warning letters and become subject to significant liability, which would harm our business. The federal government has levied large administrative, civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation with physicians, patients and caregivers, and our position within the industry.

Physicians may also misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our products are misused or used with improper technique, we may become subject to costly litigation. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. We currently carry product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Furthermore, the use of our products for conditions other than those approved by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

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

As of December 31, 2015, we had 24 full-time employees and four part-time employees, of which all except one are based in Israel. We will need to continue to expand our development, quality, sales, managerial, operational, finance, marketing and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our expansion strategy requires that we:

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

Due to our limited financial resources and our limited experience in managing a larger company, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage expansion could delay the execution of our development and strategic objectives,

or disrupt our operations; and if we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our revenues will suffer and we would incur significant additional losses.

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

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

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

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of products we may develop. We currently carry general clinical trial product liability insurance in an amount that we believe is adequate to cover the scope of our ongoing clinical programs. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing MitoGel, VesiGel or any other product candidate, we intend to expand our insurance coverage to include the commercialization of MitoGel, VesiGel 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. Moreover, although we have established a U.S. subsidiary, we are domiciled in Israel and are predominantly based in Israel, which may make it difficult to hire necessary U.S.-based personnel.

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 disclosure of unauthorized activities to us that violates: 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, education, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve 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 intend to adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, even if we are successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business. Violations of such laws subject us to numerous penalties, including, but not limited to, the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Our research and development activities and our third party subcontractors' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including Mitomycin C, or MMC, 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 2011, the rate of devaluation (inflation) of the dollar against the NIS was 0.3% and 12% in 2015 and 2014, respectively, which was compounded by inflation in Israel at a rate of (1.0)% and (0.2)%, respectively. If the dollar cost of our operations in Israel increases, 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 and interstitial cystitis topically without the need for injections, an in-dwelling ureter catheter system for optimal delivery of a drug into the renal cavity, and pharmaceutical compositions comprising an imidazoquinolin (amine) and lactic acid for use in a method for the treatment of bladder diseases.

We seek patent protection for all of our product candidates, and we have established several patent families comprised of issued patents and pending patent applications covering our proprietary RTGel formulation technology and the formulations, methods of use and manufacturing aspects of our product candidates. In the United States, we currently have three granted patents related to methods, systems and compositions for treating bladder cancer that relate to the product candidates RTGel, MitoGel and VesiGel and one patent claim related to our RTGel formulation, which are expected to remain in effect until between 2024 and 2030. We also have five pending patent applications relating to the product candidates MitoGel and VesiGel in Europe, the United States and Israel, and five

pending patent applications relating to the product candidate BotuGel in the United States and the European Union, as well as in each of Russia, China and Israel. In addition, we have two granted patents related to Vesimune in the United States as well as granted patents in the European Union, Japan, Australia, Mexico and China, each of which is expected to remain in effect until 2031. In addition to the issued patents mentioned above, our portfolio includes pending patent applications relating to Vesimune in the United States, the European Union, Canada, Korea, Brazil, Israel, Hong Kong and Japan. Moreover, we hold four granted patents in the United States as well as patent applications filed worldwide that relate to novel formulations of phospholipid drug analogs (saturated lipid conjugate compositions) for the treatment of urinary tract cancer.

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

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

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

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

Furthermore, even if they are not challenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. To meet such challenges, which are part of the risks and uncertainties of developing and marketing product candidates, we may need to evaluate third party intellectual property rights and, if appropriate, to seek licenses for such third party intellectual property or to challenge such third party intellectual property, which may be costly and may or may not be successful, which could also have an adverse effect on the commercial potential for MitoGel, VesiGel and any of our product candidates.

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

If we encounter delays in our clinical trials or regulatory approval of our product candidates, the period of time during which we could market any of our product candidates under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to hydrogel-based pharmaceutical compositions for optimal delivery of a drug in internal cavities such as the bladder, the method for treating urothelial cancer using hydrogel-based compositions, the method for treating overactive bladder and interstitial cystitis topically without the need for injections, an in-dwelling ureter catheter system for optimal delivery

of a drug into the renal cavity, and pharmaceutical compositions comprising an imidazoquinolin (amine) and lactic acid for use in a method for the treatment of bladder diseases or any of our product candidates or (ii) conceive and invent any of the inventions claimed in our patents or patent applications.

The patent application process, also known as patent prosecution, is expensive and time consuming, and we and 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 a 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 American 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 United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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

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

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

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

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

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

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

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert

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

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

We own trademarks that identify MitoGel, VesiGel, Vesimune and BotuGel and have registered these trademarks in the United States and Israel. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy.

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

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

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

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

In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the pharmaceutical industry. Recently, the AIA introduced new procedures including *inter partes* review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including those that patents perceived by our competitors 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 administration 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 licensor's 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 in the course of their employment for us. 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 all of 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, 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 expenditure. 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 MitoGel, VesiGel, BotuGel 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 a similar regulatory pathway for biologics as it relates to BotuGel, or if the requirements for such product candidates are not as we expect, the approval pathway for these product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We expect to commence a single pivotal Phase 3 clinical trial for MitoGel and a Phase 2b clinical trial of VesiGel under the FDA's 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act. We expect that BotuGel will be a candidate under the FDA's regulatory pathway for biosimilars that rely on previously approved products, as permitted by the Biologics Price Competition and Innovation Act of 2009 and referred to as the Section 351(k) regulatory pathway. Section 505(b)(2) and Section 351(k) permit the filing of an NDA or Biologic License Application 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 MitoGel, VesiGel, BotuGel and our other product candidates by potentially decreasing the amount of preclinical and clinical data that we would need to generate in order to obtain FDA approval. However, while we believe that our product candidates are reformulations of existing drugs or biologics and, therefore, will not be treated as new chemical entity, or NCEs, the submission of an NDA under the Section 505(b)(2) or similar regulatory pathway does not preclude the FDA from determining that the product candidate that is the subject of such submission is an NCE and therefore not eligible for review under such regulatory pathway.

If the FDA does not allow us to pursue the Section 505(b)(2) or similar regulatory pathway as anticipated, we may need to conduct additional preclinical experiments and clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely increase significantly. Moreover, inability to pursue the Section 505(b)(2) or similar

regulatory pathway could result in new competitive products reaching the market more quickly than our product candidates, which would likely harm our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) or similar regulatory pathway, our product candidates may not receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our 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 Section 505(b)(2) or the 351(k) 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 Affordability Reconciliation Act of 2010, or the Affordable Care Act, and collectively, ACA, a law 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 include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% 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 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.

Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the full effect of the ACA, it appears likely to continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Challenges and amendments have been made to the ACA, and we expect such challenges to continue in the future.

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 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, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 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 bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Further, the U.S. House of Representatives recently formed an Affordable Drug Pricing Task Force to advance legislation intended to control pharmaceutical drug costs and investigate pharmaceutical drug pricing, and the U.S. Senate has requested information from certain pharmaceutical companies in connection with an investigation into pharmaceutical drug pricing practices. 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 MitoGel, VesiGel or any of our other product candidates, these laws may result in additional reductions in healthcare funding, which could have an adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of MitoGel, VesiGel or our other product candidates may be.

Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what

circumstances healthcare providers will prescribe or administer our products. This could adversely affect our business by reducing our ability to generate revenues, raise capital, obtain additional licensees and market our products. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

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

Under the Orphan Drug Act of 1983, the 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 MitoGel orphan designation for the treatment of UTUC and to Vesimune for treatment of CIS, we may not receive orphan 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, 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.

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

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

If and when regulatory approval has been granted, our product candidates or any approved product will be subject to continual regulatory review by the FDA and/or non-U.S. 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, warnings letters or holds on clinical trials
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals; and
- product seizure or detention, or refusal to permit the import or export of products; and injunctions or the imposition of civil or criminal penalties.

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

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

We may currently be or may become subject to various U.S. federal and state health care laws, including those intended to prevent health care fraud and abuse.

The federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward 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, under 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 False Claims Act, or 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 improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program 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 Act, and their implementing regulations, also impose certain obligations, including mandatory contractual terms, on certain types of individuals and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information without proper written authorization.

Our operations will also be subject to the federal transparency requirements under the Affordable Care Act, which require 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 the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, information related to payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members.

If any of our business activities, including but not limited to our relationships with healthcare providers, violate any of the aforementioned laws, we may be subject to administrative, civil and/or criminal penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

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

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

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

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

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

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

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

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

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

In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of MitoGel, VesiGel and our other product candidates, if approved, will depend on the coverage and reimbursement policies of government authorities and third-party payors. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement levels.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third party payors decide which drugs they will pay for and establish reimbursement and co-payment levels. 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 MitoGel, VesiGel or our other product candidates, if approved, or, if coverage is available, the level of reimbursement.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the U.S. Department of HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors often follow CMS. It is difficult to predict what CMS as well as other 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 comparable 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 MitoGel, VesiGel 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 MitoGel, VesiGel 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 MitoGel, VesiGel 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 MitoGel, VesiGel 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; requesting 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 an Investment in Our Ordinary Shares

An active, liquid and orderly trading market for our ordinary shares may not develop, which may inhibit the ability of our shareholders to sell ordinary shares following this offering.

Prior to this offering there has been no public market for our ordinary shares. An active, liquid or orderly trading market in our ordinary shares may not develop upon completion of this offering, or if it does develop, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital in the future by selling shares and may impair our ability to acquire other companies by using our shares as consideration.

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

The initial public offering price for the shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of prices that will prevail in the trading market. The price of our ordinary shares may decline following this offering. The stock market in general has been, and the market price of our ordinary shares in particular will likely 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 earnings estimates or recommendations by securities analysts, if our ordinary shares are covered by analysts;
- development of technological innovations or new competitive products by others;
- announcements of technological innovations or new products by us;
- publication of the results of preclinical or clinical trials for MitoGel, VesiGel 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 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 will rely 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.

Substantially all of our shares outstanding prior to this offering and our shares issuable upon the exercise of warrants and vested options are subject to lock-up agreements with the underwriters that restrict the ability of their holders to transfer such shares for 180 days after the date of this prospectus. Consequently, upon expiration of the lock-up agreements, an additional approximately of our ordinary shares, including ordinary shares issuable upon the exercise of our outstanding options or warrants, will be eligible for sale in the public market, of which approximately ordinary shares will be subject to restrictions on volume and manner of sale pursuant to Rule 144 under the Securities Act of 1933, as amended. However, we intend to file one or more registration statements on Form S-8 with the SEC covering all of the ordinary shares issuable under our 2010 Israeli Share Option Plan and such shares will be available for resale following the expiration of the restrictions on transfer.

After this offering, the holders of approximately ordinary shares will be entitled to registration rights, subject to the terms of the lock-up agreements described above. The market price of our ordinary shares may drop significantly when the restrictions on resale by our existing shareholders lapse and these shareholders are able to sell our ordinary shares into the market. 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.

Investors in this offering will experience immediate substantial dilution in net tangible book value.

The initial public offering price of our ordinary shares in this offering is considerably greater than the net tangible book value per share of our outstanding ordinary shares immediately after this offering. Accordingly, investors in this offering will incur immediate dilution of $ per share, as of December 31, 2015, based on an assumed initial public offering price of $ per share, the midpoint of the estimated initial public offering price range shown on the cover of this prospectus. In addition, if outstanding options to purchase our ordinary shares are exercised in the future, you will experience additional dilution. Please see the section entitled “Dilution.”

The significant share ownership position of affiliates of directors may limit your ability to influence corporate matters.

After giving effect to this offering, corporate entities affiliated with our directors will beneficially own or control, directly or indirectly, approximately % of our outstanding ordinary shares (or % if the underwriters exercise their option in full to purchase additional ordinary shares). Accordingly, these entities will be 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 entities’ 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 broad discretion as to the use of the net proceeds from this offering and may not use them effectively.

We currently intend to use the net proceeds we receive from this offering, together with our existing cash resources, to advance our clinical pipeline and specifically, to file an IND for, and initiate and complete our planned single pivotal Phase 3 clinical trial of, MitoGel for the treatment of low-grade UTUC, to file an IND for, and to initiate our Phase 2b clinical trial of, VesiGel for the treatment of low-grade NMIBC, and to fund continued research and clinical development of our other product candidates and for other general corporate purposes. However, our management will have broad discretion in the application of the net proceeds. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from this offering. The failure by our management to apply these funds effectively could harm our business, financial condition and results of operation. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income.

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

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

We will incur significant increased costs as a result of operating as a public company in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a public company whose ordinary shares are listed in the United States, we will be subject to an extensive regulatory regime, requiring us, among other things, to maintain various internal controls and facilities and to prepare and file periodic and current reports and statements, including reports on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. Complying with these requirements will be costly and time consuming. We will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In the event that we are unable to demonstrate compliance with our obligations as a public company in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or the NASDAQ Global Market, and investors may lose confidence in our operating results and the price of our ordinary shares could decline.

Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting, and as long as we remain an emerging growth company, as such term is defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we will be exempt from the requirement to have an independent registered public accounting firm perform such audit. Accordingly, no such opinion was expressed or will be expressed any during any such period. Once we cease to qualify as an emerging growth company our independent registered public accounting firm will be required to attest to our management's annual assessment of the effectiveness of our internal controls over financial reporting, which will entail additional costs and expenses.

Furthermore, we are only in the early stages of determining formally whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. These controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

We expect to be classified as a passive foreign investment company, and our U.S. shareholders may suffer adverse tax consequences as a result.

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in offerings of our shares) and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and gains from the sales of our shares.

Our status as a PFIC may also depend, in part, on how quickly we utilize the funds we raise in this offering in our business. Since PFIC status depends in part on the composition and value of our assets (which, assuming we are not a controlled foreign corporation for the year being tested, may be determined in large part by reference to the market value of our ordinary shares, which may be volatile) from time to time, there can be no assurance that we will not be considered a PFIC for any taxable year. However, because we currently have no revenue-producing operations, we

expect to be treated as a PFIC for our current taxable year. Unless and until we generate sufficient revenue from active licensing and other non-passive sources and otherwise satisfy the asset test above, we expect to be treated as a PFIC for future taxable years.

A U.S. shareholder may be able to mitigate some of the adverse U.S. federal income tax consequences described above with respect to owning our ordinary shares if we are classified as a PFIC for our taxable year ending December 31, 2016, provided that such U.S. investor is eligible to make, and successfully makes, a "mark-to-market" election. U.S. investors could also mitigate some of the adverse U.S. federal income tax consequences of us being classified as a PFIC by making a Qualified Electing Fund, or QEF, election, provided that we provide the information necessary for a U.S. investor to make such an election. However, we do not currently intend to provide the information necessary for U.S. investors to make QEF elections. Prospective U.S. investors should consult their own tax advisors regarding the potential application of the PFIC rules to them as well as whether any elections would be available and, if so, what the consequences of the alternative treatments would be in their particular circumstances. For more information related to classification as a PFIC, see "Taxation—Material U.S. Federal Income Tax Consequences to U.S. Holders—Passive Foreign Investment Company Considerations."

As a foreign private issuer, we are permitted, and intend, to follow home country corporate governance practices instead of otherwise applicable NASDAQ requirements.

As a foreign private issuer, we will be permitted, and intend, to follow home country corporate governance practices instead of those otherwise required by The NASDAQ Stock Market for domestic U.S. issuers. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the NASDAQ Global Market may provide less protection to you than what is accorded to investors under the NASDAQ Rules applicable to domestic U.S. issuers. See the section titled "Management—Corporate Governance Practices."

As a foreign private issuer, we will not be subject to certain U.S. securities laws including, but not limited to, U.S. proxy rules and the filing of certain Exchange Act reports.

As a foreign private issuer, we will be exempt from the rules and regulations under the Securities Exchange Act of 1934, or the Exchange Act, related to the furnishing and content of proxy statements, including the requirement to disclose the compensation of our Chief Executive Officer, Chief Financial Officer, President of Israel Operations and the other two most highly compensated executive officers on an individual basis. Nevertheless, pursuant to regulations promulgated under the Israeli Companies Law, 5759-1999, or the Israeli Companies Law, we are required to disclose the annual compensation of our five most highly compensated office holders on an individual basis. Such disclosure will not be as extensive as that required of a U.S. domestic issuer. Our officers, directors and principal shareholders will also be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose securities are registered under the Exchange Act and we will be exempt from filing quarterly reports with the SEC under the Exchange Act. Moreover, we will not be required to comply with Regulation FD, which restricts the selective disclosure of material information. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

We would lose our foreign private issuer status if a majority of our shares are owned by U.S. residents and a majority of our directors or executive officers are U.S. citizens or residents or we fail to meet additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we may take advantage of certain exemptions from various requirements that are applicable to other public companies that are not emerging growth companies.

For as long as we remain an emerging growth company we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not “emerging growth companies.” These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited condensed interim financial statements, with correspondingly reduced “Management’s discussion and analysis of financial condition and results of operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenues of at least $1.0 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of this offering; (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (iv) the date on which we are deemed to be a “large accelerated filer” under the Exchange Act. We have opted out of the extended transition period made available to emerging growth companies to comply with newly adopted public company accounting requirements.

When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above. We cannot predict if investors will find our ordinary shares less attractive as a result of our reliance on exemptions under the JOBS Act. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

Risks Related to our Operations in Israel

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

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

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering the reinstatement

value of direct damages that are caused by terrorist attacks or acts of war, there can be no assurance that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition and results of operations.

Further, our operations could be disrupted by the obligations of our employees to perform military service. As of December 31, 2015, we had 27 employees based in Israel. Of these employees, some may be military reservists, and may be called upon to perform military reserve duty of up to 36 days per year (and in some cases more) until they reach the age of 40 (and in some cases, up to the age of 45 or older). Additionally, they may be called to active duty at any time under emergency circumstances. In response to increased tension and hostilities in the region, there have been, at times, call-ups of military reservists, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of these employees due to military service. Such disruption could harm our business and operating results.

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

We have received grants under the Israeli Law for the Encouragement of Industrial Research and Development, 5754-1984, or the R&D Law, from the Office of the Chief Scientist in the Ministry of Economy and Industry in Israel, or OCS, for some of our development programs. As of December 31, 2015, we had received grants in the aggregate amount of $1.9 million. We have applied, and may in the future apply, to receive additional grants from the OCS. However, we cannot predict whether we will be entitled to any future grants, or the amounts of any such grants.

A recipient of a grant from the OCS is obligated to pay royalties generally at a rate of 3% to 5% on revenues from sales of products developed with OCS-funded technology, up to the amount of the grant related to any such products plus accrued interest. Under the R&D Law, a company that received grants from the OCS may not transfer OCS-funded technology or manufacture products developed with OCS-funded technology outside of the State of Israel without first obtaining the approval of the OCS. We may not receive any such approval should we request it, which could prevent us, for example, from out-licensing our product candidates. Even if we do receive such approvals, we may be required to pay increased royalties and significant penalties and other amounts. The OCS may also impose certain conditions on any arrangement under which it permits us to transfer OCS-funded technology outside of the State of Israel. Furthermore, the consideration available to our shareholders in a transaction involving the transfer outside of the State of Israel of OCS-funded technology (such as a merger or similar transaction) may be reduced by any amounts that we are required to pay to OCS. The restrictions under the R&D Law will continue to apply even after we have repaid the full amount of royalties due to the OCS. If we fail to satisfy the conditions of the R&D Law, we may be required to refund the amounts of the grants previously received, together with interest and penalties, and may become subject to criminal charges.

Provisions of Israeli law and our amended and restated 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 this prospectus 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. The majority of our directors and most of our executive officers listed in this prospectus reside outside of the United States, and most of our assets and most of the assets of these persons are located outside of the United States. Therefore, a judgment obtained against us, or any of these persons, 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 these persons 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. Please see the section entitled “Enforcement of Civil Liabilities” for additional information on your ability to enforce a civil claim against us and our executive officers or directors named in this prospectus.

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 amended and restated 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing and conduct of our clinical trials of MitoGel, VesiGel and our other product candidates, including statements regarding the timing, progress and results of current and future preclinical studies and clinical trials, and our research and development programs;
- the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of MitoGel, VesiGel and our other product candidates;
- our plans regarding utilization of regulatory pathways that would allow for accelerated marketing approval in the United States;
- our expectations regarding timing for application for and receipt of regulatory approval for any of our product candidates;
- our ongoing and planned discovery and development of product candidates;
- our expectations regarding future growth, including our ability to develop, and obtain regulatory approval for, new product candidates;
- our ability to obtain and maintain adequate intellectual property rights and adequately protect and enforce such rights;
- our plans to develop and commercialize our product candidates;
- our estimates regarding the market opportunity for our product candidates;
- our estimates regarding expenses, future revenues, capital requirements and the need for additional financing;
- our planned level of capital expenditures and our belief that our existing cash and the net proceeds from this offering will be sufficient to fund our operations for at least the next 12 months;
- the impact of our research and development expenses as we continue developing product candidates;
- our expectations regarding the maintenance of our foreign private issuer status;
- the impact of government laws and regulations; and
- our expectations regarding the use of proceeds from this offering.

Forward-looking statements are based on our management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and our management’s beliefs and assumptions, and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this prospectus may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” and
elsewhere in this prospectus. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements.

The forward-looking statements included in this prospectus speak only as of the date of this prospectus. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See “Where You Can Find More Information.”

USE OF PROCEEDS

We estimate that the net proceeds from the sale of ordinary shares in this offering will be approximately $, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, based on an assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus. If the underwriters exercise their option to purchase additional ordinary shares in full, we estimate that the net proceeds to us from this offering will be approximately $, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per ordinary share would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by $, assuming that the number of ordinary shares offered by us, as set forth on the cover of this prospectus, remains the same. We may also increase or decrease the number of ordinary shares we are offering. An increase (decrease) of 100,000 in the number of ordinary shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, by $, assuming the assumed initial public offering price stays the same.

We expect to use the net proceeds from this offering, together with our existing cash resources, to advance our clinical pipeline, including specifically:

- approximately $ to file an IND for, and initiate and complete our planned single pivotal Phase 3 clinical trial of, MitoGel for the treatment of low-grade UTUC;
- approximately $ to file an IND for, and to initiate our Phase 2b clinical trial of, VesiGel for the treatment of low-grade NMIBC; and
- the remainder to fund continued research and clinical development of our other product candidates, and for working capital and other general corporate purposes.

Due to the uncertainties inherent in the clinical development and regulatory approval process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for any of the above purposes on a stand-alone basis.

Pending our application of the net proceeds from this offering, we plan to invest such proceeds in depositary institutions.

DIVIDEND POLICY

We have never declared or paid cash dividends to our shareholders and we do not intend to pay cash dividends in the foreseeable future. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors in compliance with applicable legal requirements and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

See “Risk Factors—Risks Related to an Investment in 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” and, for an explanation concerning the payment of dividends under Israeli law, see “Description of Share Capital—Dividend and Liquidation Rights.”

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2015 on:

- an actual basis;
- a pro forma basis to reflect the exercise for cash of all outstanding warrants to purchase Series A-1 preferred shares, and the automatic conversion thereafter of all outstanding preferred shares into an aggregate of 1,850,559 ordinary shares; and
- a pro forma as adjusted basis to give further effect to the sale of ordinary shares in this offering at an assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted data included in the table below are also unaudited. You should read this information together with our condensed interim financial statements appearing elsewhere in this prospectus and the information set forth under the headings “Selected Financial Data,” “Use of Proceeds” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	AS OF DECEMBER 31, 2015		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED
		(in thousands)	
Cash and cash equivalents(1)	$ 17,975	$ 23,665	$
Non-current liabilities	$ 872	$ —	$
Shareholders’ equity			
Ordinary shares, NIS 0.01 par value: 5,500,000 and 8,000,000 shares authorized at December 31, 2015 and 2014, respectively, actual; 10,000,000 shares authorized pro forma and pro forma as adjusted; 719,060 issued and outstanding as of December 31, 2015 and 2014, actual; 2,569,619 shares issued and outstanding, pro forma; issued and outstanding, pro forma as adjusted.	2	7	
Series A and A-1 preferred shares, NIS 0.01 par value: 4,500,000 and 2,000,000 shares authorized at December 31, 2015 and 2014, respectively, actual; zero shares authorized pro forma and pro forma as adjusted; 1,622,957 and 270,973 shares issued and outstanding at December 31, 2015 and 2014, respectively, actual; zero shares issued and outstanding, pro forma and pro forma as adjusted	4	—	
Additional paid-in capital	41,548	48,109	
Accumulated deficit	(25,273)	(25,273)	
Total shareholders’ equity(1)	16,281	22,843	
Total capitalization(1)	$ 17,153	$ 22,843	$

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus, would increase or decrease, respectively, the amount of cash and cash equivalents, total equity and total capitalization by $, assuming the number of ordinary shares offered by us, as set forth on the cover of this prospectus, remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. An increase or decrease of 100,000 in the number of ordinary shares we are offering would increase or decrease, respectively, the amount of cash and cash equivalents, total equity and total capitalization by $, assuming the assumed initial public offering price per ordinary share, as set forth on the cover of this prospectus, remains the same. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

The number of ordinary shares in the table above shown as issued and outstanding on a pro forma basis is based on ordinary shares outstanding as of December 31, 2015 and assumes:

- the issuance of Series A-1 preferred shares upon the exercise for cash of all outstanding warrants to purchase Series A-1 preferred shares; and
- the issuance of ordinary shares upon the conversion of all Series A preferred shares and Series A-1 preferred shares into ordinary shares, which will occur automatically upon the closing of this offering;

but excludes:

- ordinary shares reserved for issuance under our 2010 Israeli Share Option Plan, including ordinary shares reserved for issuance upon the exercise of outstanding options at a weighted average exercise price of $ per share, and ordinary shares reserved for issuance upon the vesting of outstanding restricted share units; and
- ordinary shares reserved for issuance upon the achievement of certain milestones under the Vesimune asset purchase agreement with Telormedix SA.

DILUTION

If you invest in our ordinary shares in this offering, your interest will be immediately diluted to the extent of the difference between the initial public offering price per ordinary share in this offering and the net tangible book value per ordinary share after this offering. Dilution results from the fact that the initial public offering price per ordinary share is substantially in excess of the net tangible book value per ordinary share. As of December 31, 2015, we had a historical net tangible book value per ordinary share of $22.64. Our net tangible book value per share represents total tangible assets less total liabilities, all divided by the number of shares outstanding on December 31, 2015.

After giving effect to the sale of ordinary shares in this offering at an assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses, our pro forma net tangible book value at December 31, 2015 would have been $ per share. This represents an immediate increase in pro forma net tangible book value of $ per share to existing shareholders and immediate dilution of $ per ordinary share to new investors. The following table illustrates this dilution per ordinary share:

Assumed initial public offering price per ordinary share		$
Historical net tangible book value per ordinary share as of December 31, 2015	$ 22.64	
Increase in pro forma net tangible book value per ordinary share attributable to new investors	$	
Pro forma net tangible book value per ordinary share after this offering		$
Dilution per ordinary share to new investors participating in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) our pro forma net tangible book value as of December 31, 2015 after this offering by approximately $ per ordinary share, and would increase (decrease) dilution to investors in this offering by $ per ordinary share, assuming that the number of ordinary shares offered by us, as set forth on the cover of this prospectus, remains the same, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of ordinary shares we are offering. An increase (decrease) of 100,000 in the number of ordinary shares we are offering would increase (decrease) our pro forma net tangible book value as of December 31, 2015 after this offering by approximately $ per ordinary share, and would decrease (increase) dilution to investors in this offering by approximately $ per ordinary share, assuming the assumed initial public offering price per ordinary share remains the same, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing. If the underwriters fully exercise their option to purchase additional ordinary shares, the pro forma net tangible book value after this offering would increase to approximately $ per ordinary share, and there would be an immediate dilution of approximately $ per ordinary share to new investors.

If the underwriters exercise in full their option to purchase additional ordinary shares, the pro forma as adjusted net tangible book value will increase to $ per ordinary share, representing an immediate increase in pro forma as adjusted net tangible book value to existing shareholders of $ per ordinary share and an immediate dilution of $ per ordinary share to new investors participating in this offering.

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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our equity holders.

The following table shows, as of December 31, 2015, on a pro forma basis, the number of ordinary shares purchased from us, the total consideration paid to us and the average price paid per share during the last five years by existing shareholders and by new investors purchasing ordinary shares in this offering at an assumed initial public offering price of $ per ordinary share, which is the midpoint of the price range set forth on the cover of this prospectus, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us:

(In thousands, except share and per share amounts and percentages)	SHARES SUBSCRIBED FOR/ PURCHASED		TOTAL CONSIDERATION		AVERAGE PRICE PER SHARE
	NUMBER	PERCENT	AMOUNT	PERCENT	
Existing shareholders		%	$	%	$
Investors participating in this offering		%	$	%	$
Total		100%	$	100%	$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per ordinary share (the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) the total consideration paid by investors participating in this offering, total consideration paid by all shareholders and the average price per share paid by all shareholders by approximately $ million, $ million and $, respectively, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

Similarly, a 100,000 share increase (decrease) in the number of ordinary shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the total consideration paid by investors participating in this offering, total consideration paid by all shareholders and the average price per share paid by all shareholders by approximately $ million, $ million and $, respectively, assuming the assumed initial public offering price of $ per ordinary share (the midpoint of the price range set forth on the cover of this prospectus) remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The number of ordinary shares in the table and discussion above is based on ordinary shares outstanding as of December 31, 2015 and assumes:

- the issuance of Series A-1 preferred shares upon the exercise for cash of all outstanding warrants to purchase Series A-1 preferred shares; and
- the issuance of ordinary shares upon the conversion of all Series A preferred shares and Series A-1 preferred shares into ordinary shares, which will occur automatically upon the closing of this offering;

but excludes:

- ordinary shares reserved for issuance under our 2010 Israeli Share Option Plan, including ordinary shares reserved for issuance upon the exercise of outstanding options at a weighted average exercise price of $ per share, and ordinary shares reserved for issuance upon the vesting of outstanding restricted share units; and
- ordinary shares reserved for issuance upon the achievement of certain milestones under the Vesimune asset purchase agreement with Telormedix SA.

SELECTED FINANCIAL DATA

The following tables present selected financial data for our business. We derived the selected statements of operations data for the years ended December 31, 2015 and 2014 and the balance sheet data as of December 31, 2015 and 2014 from our audited financial statements included elsewhere in this prospectus. 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. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the information under the captions "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results are not necessarily indicative of our future results, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

	YEAR ENDED DECEMBER 31,	
	2015	2014
	(in thousands, except share and per share data)	
Statements of Operations Data:		
Research and development expenses, net	$ 10,515	$ 3,479
General and administrative expenses	1,895	890
Operating loss	12,410	4,369
Finance expenses (income), net	279	107
Net loss for the period	$ 12,689	$ 4,476
Loss per ordinary share, basic and diluted	$ 18.83	$ 6.34
Weighted average number of ordinary shares outstanding used in computing basic and diluted loss per ordinary share	719,060	719,060

	AS OF DECEMBER 31,	
	2015	2014
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 17,975	$ 3,870
Working capital(1)	$ 16,894	$ 3,397
Total assets	$ 19,390	$ 4,359
Total liabilities	$ 3,109	$ 1,196
Total shareholders' equity	$ 16,281	$ 3,163

(1) Working capital is defined as total current assets minus total current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

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

Our lead product candidates, MitoGel and VesiGel, are formulated using our proprietary RTGel technology. We believe that RTGel-based drug formulations, which provide for the sustained release of an active drug, may improve the efficacy of treatment of various types of urothelial cancer without compromising the safety of the patient or interfering with the natural flow of fluids from the urinary tract to the bladder. Our formulations are designed to achieve this by increasing the dwell time as well as the tissue coverage throughout the organ of the active drug. Consequently, we believe that RTGel-based drug formulations may enable us to overcome the anatomical and physiological challenges that have historically contributed to the lack of drug development for the treatment of urothelial cancer. No drugs have been approved by the FDA for UTUC, and no drugs have been approved by the FDA for bladder cancer for more than 15 years.

Our clinical stage pipeline also includes Vesimune, our proprietary immunotherapy product candidate for the treatment of high-grade NMIBC, as well as BotuGel, which we are developing for the treatment of overactive bladder and interstitial cystitis, also known as painful bladder syndrome. We acquired Vesimune from Telormedix SA, a private Swiss-based biotechnology company, in the fourth quarter of 2015.

We have incurred net losses in each year since our formation in 2004. We incurred net losses of $12.7 million and $4.5 million for the years ended December 31, 2015 and 2014, respectively. As of December 31, 2015 and 2014, our accumulated deficit was $25.3 million and $12.6 million, respectively. We expect to continue to incur losses for the foreseeable future, and our losses may fluctuate significantly from year to year. We expect that our expenses will increase substantially in connection with our ongoing activities as we:

- file an IND for MitoGel with the FDA and, if accepted, initiate a single pivotal Phase 3 clinical trial, and file an IND for VesiGel and, if accepted, initiate a Phase 2b clinical trial, each pursuant to the FDA's 505(b)(2) regulatory pathway;
- initiate an additional clinical trial for Vesimune, either as a single agent or in combination with another agent, and initiate a dose-ranging study for BotuGel;
- continue the preclinical development of our other product candidates;
- file an NDA seeking regulatory approval for any product candidates;
- establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development;
- hire additional clinical development, quality control and manufacturing personnel; and

- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization.

Components of Results of Operations

Revenue

We do not currently have any products approved for sale, and we have not recognized any revenue to date. In the future, we may generate revenue from a combination of product sales, reimbursements, up-front payments, milestone payments, and royalties in connection with future collaborations. If we fail to achieve clinical success and/or to obtain regulatory approval of any of our product candidates in a timely manner, our ability to generate future revenue will be impaired.

Research and development expenses, net

The largest component of our total operating expenses has historically been and we expect will continue to be research and development. Research and development expenses consist primarily of:

- salaries and related costs, including share-based compensation expense, for our personnel in research and development functions;
- expenses incurred under agreements with third parties, including CROs, subcontractors, suppliers and consultants, preclinical studies and clinical trials;
- expenses incurred to acquire, develop and manufacture preclinical study and clinical trial materials;
- facility and equipment costs, including depreciation expense, maintenance and allocated direct and indirect overhead costs; and
- in process research and development costs related to intellectual property purchased from others.

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

As of December 31, 2015, we have received grants of $1.9 million in the aggregate from the Office of the Chief Scientist in the Ministry of Economy and Industry in Israel, or OCS, for research and development funding. Pursuant to the terms of the grants, we are required to pay royalties to the Government of Israel on revenues from sales of products for which the research and development was funded, in whole or in part, by the OCS. Pursuant to the terms of the grants, we are obligated to pay the OCS royalties of 3.0% to 4.5% on revenues from sales of products developed from a project financed in whole or in part by OCS grants, up to a limit of 100% of the amount of the grant received, plus annual interest calculated at a rate based on 12-month LIBOR. Based on our communications with the OCS, we believe these royalties would only apply to MitoGel, VesiGel and certain preclinical projects.

In addition to paying any royalties due, we must abide by other restrictions associated with receiving such grants under the R&D Law, which will continue to apply to us following full repayment to the OCS. See “Risk Factors—The Israeli government grants we have received for research and development activities restrict our ability to manufacture products and transfer technologies outside of Israel and require us, in addition to the payment of royalties, to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received and incur financial penalties.”

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

We do not believe that it is possible at this time to accurately project total expenses required for us to reach commercialization of our product candidates. Due to the inherently unpredictable nature of preclinical and clinical development, we are unable to estimate with certainty the costs we will incur and the timelines that will be required in the continued development and approval of our product candidates. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. See “Risk Factors—Risks Related to Our Business and Strategy.” 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.

Under applicable accounting rules, we deduct the OCS grants from research and development expenses as the applicable costs are incurred. We also have a preclinical collaboration for BotuGel with a large pharmaceutical company and we deduct the amounts received from this company from research and development expenses as the applicable costs are incurred. As a result, our research and development expenses are shown on our financial statements net of the OCS grants and amounts received from the preclinical collaboration.

General and administrative expenses

General and administrative expenses consist primarily of personnel costs, including share-based compensation, related to directors, executive, finance, and human resource functions, facility costs and external professional service costs, including legal, accounting and audit services and other consulting fees.

We anticipate that our general and administrative expenses will increase in the future as we increase our administrative headcount and infrastructure to support our continued research and development programs and the potential approval and commercialization of our product candidates. We also anticipate that we will incur increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with NASDAQ and SEC requirements, director and officer insurance premiums, director compensation, and other costs associated with being a public company.

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

Finance expenses, net

Finance expenses, net, consists primarily of bank fees, gain or loss from foreign currency exchange differentials and finance expenses on warrants.

Income taxes

We have yet to generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately $13.9 million as of December 31, 2015. We anticipate that we will continue to generate tax losses for the foreseeable future and that we will be able to carry forward these tax losses indefinitely to future taxable years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses. We have provided a full valuation allowance with respect to the deferred tax assets related to these carry forward losses.

Results of Operations

Comparison of the years ended December 31, 2015 and 2014

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014:

	YEAR ENDED DECEMBER 31,	
	2015	2014
	(In thousands)	
Research and development expenses, net (1)	$ 10,515	$ 3,479
General and administrative expenses (1)	1,895	890
Operating loss	12,410	4,369
Finance expenses, net	279	107
Net loss	$ 12,689	$ 4,476

(1) Includes share-based compensation expense as follows:

	YEAR ENDED DECEMBER 31,	
	2015	2014
	(In thousands)	
Research and development, net	$ 170	$ 108
General and administrative expenses	279	185
Total share-based compensation	$ 449	$ 293

Research and development expenses

Research and development expenses increased by $7.0 million, or 200%, to $10.5 million in the year ended December 31, 2015 from $3.5 million in the year ended December 31, 2014. Approximately $4.1 million of expenses relates to in-process research and development costs in connection with intellectual property related to Vesimune that we purchased from Telormedix SA. The remaining increase in research and development expenses resulted primarily from an increase in our activity in preclinical studies and other payments to subcontractors related to the development activity in preparation for our single pivotal Phase 3 clinical trial of MitoGel for the treatment of low-grade UTUC.

General and administrative expenses

General and administrative expenses increased by $1.0 million, or 112%, to $1.9 million in the year ended December 31, 2015 from $890,000 in the year ended December 31, 2014. The increase in general and administrative expenses resulted primarily from an increase in payroll expenses of $389,000 and an increase in professional audit and accounting service expenses of $353,000. The increase was primarily related to our strengthening of our senior management team and payments to consultants hired by us in preparation for this offering.

Finance expenses

Finance expenses, net, increased by $172,000, or 161%, to $279,000 in the year ended December 31, 2015 from $107,000 in the year ended December 31, 2014. The increase was primarily due to an increase of $254,000 in the fair value of the warrants converted to Series A-1 preferred shares. This was partially offset by a decrease of $94,000 in the loss from foreign currency exchange.

Liquidity and Capital Resources

Liquidity

Since our inception, we have incurred losses and negative cash flows from our operations. For the year ended December 31, 2015, we incurred a net loss of $12.7 million and used $7.2 million in our operating activities. As of December 31, 2015, we had working capital of $16.9 million, and an accumulated deficit of $25.3 million. Our principal source of liquidity as of December 31, 2015 consisted of cash and cash equivalents of $18.0 million. We believe that the net proceeds of this offering, together with our existing cash and cash equivalents, will enable us to fund our operations for at least the next 12 months.

Our independent registered public accounting firm has issued a going concern opinion on our December 31, 2015 financial statements, expressing substantial doubt that we can continue as an ongoing business after issuance of their report based on our having incurred cumulative losses and negative cash flows from operating activities since inception and having an accumulated deficit at December 31, 2015 of $25.3 million, as discussed in Note 1 of our accompanying financial statements that appear elsewhere in this prospectus. Our financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Capital resources

Overview

To date, we have financed our operations primarily through private placements of equity securities and convertible notes. Total invested capital as of December 31, 2015 was $36.3 million, which included ordinary shares and Series A preferred shares and warrants to purchase Series A-1 preferred shares, as well as convertible notes. The convertible notes were issued during the first half of 2014 and converted in their entirety into Series A preferred shares and warrants to purchase Series A-1 preferred shares on October 20, 2014.

Such preferred shares will be converted into ordinary shares of the same number upon the closing of this offering, in accordance with our articles of association. The warrants to purchase preferred shares expire upon the closing of this offering. We expect that all of the warrants will be exercised for cash prior to the closing of this offering and the preferred shares issuable upon exercise of the warrants will automatically convert into ordinary shares.

Cash flows

The following table summarizes our statement of cash flows for the years ended December 31, 2015 and 2014:

	YEAR ENDED DECEMBER 31,	
	2015	2014
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (7,175)	$ (4,117)
Investing activities	(301)	(1)
Financing activities	$ 21,581	$ 4,951

Net cash used in operating activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net loss for non-cash items mainly include depreciation and amortization, fair value adjustment of the preferred A-1 warrants and convertible loan and share-based compensation.

Net cash used in operating activities was $7.2 million in the year ended December 31, 2015, compared to $4.1 million in the year ended December 31, 2014. The $3.1 million increase was attributable primarily to the increase of $8.2 million in the loss for the period, partly offset by an increase of non-cash charges of $4.1 million in in-process research and development costs related to the intellectual property related to Vesimune that we purchased from Telormedix SA, $254,000 fair value adjustment of the preferred A-1 warrants and $156,000 in share-based compensation expense offset by a net increase in operating assets and liabilities of $456,000.

Net cash used in investing activities

The use of cash in investing activities relates primarily to the purchase of property and equipment and changes in restricted deposits.

Net cash used in investing activities was $301,000 in the year ended December 31, 2015, compared to $1,000 in the year ended December 31, 2014.

Net cash provided by financing activities

Net cash provided by financing activities was $21.6 million in the year ended December 31, 2015, an increase of $16.6 million from $5.0 million in the year ended December 31, 2014. In October 2015, we entered into a share purchase agreement, to which we refer as the 2015 Share Purchase Agreement. In September 2014, we entered into a share purchase agreement, to which we refer as the 2014 Share Purchase Agreement. During 2014, we issued convertible notes, which were converted to Series A preferred shares upon the closing of the 2014 Share Purchase Agreement. During 2015, we raised $18.1 million from the 2015 Share Purchase Agreement and $3.6 million from the 2014 Share Purchase Agreement. During 2014 we raised $4.4 million from the 2014 Share Purchase Agreement and $647,000 from issuance of the convertible notes.

Funding Requirements

We believe that the net proceeds of this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

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

- the progress, timing and completion of clinical trials for MitoGel and VesiGel;
- and preclinical studies and clinical trials for Vesimune or any of our other product candidates;
- the potential costs of further developing BotuGel in connection with our pharmaceutical partner or alone;
- the costs related to obtaining regulatory approval for MitoGel, VesiGel and Vesimune 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 MitoGel and VesiGel 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 MitoGel, VesiGel, Vesimune, BotuGel and any other product candidates.

For more information as to the risks associated with our future funding needs, see "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

Our known contractual obligations as of December 31, 2015 are summarized in the following table. The obligations detailed below do not include grants received from the OCS pursuant to which we will owe royalties upon commercialization of our product candidates. As of December 31, 2015, the maximum royalty amount payable by us under these funding arrangements is $1.9 million, excluding interest.

	PAYMENTS DUE BY PERIOD			
	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS	TOTAL
	(In thousands)			
Operating lease obligations (1)	$ 184	$ 423	$ 158	$ 765

(1) Operating lease obligations consist of payments pursuant to a lease agreement for our Israeli offices and laboratory facility. In November 2014, we entered into a new 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 April 2016, we entered into a new lease agreement for our U.S. offices for a period of seven years, which period commences on May 1, 2016.

Off-balance Sheet Arrangements

As of the date of this prospectus and during the periods presented, we do not and did not, respectively, have any off-balance sheet arrangements.

Quantitative and Qualitative Disclosure about Market Risk

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows.

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 2011, the rate of devaluation of the dollar against the NIS was 0.3% and 12% in 2015 and 2014, respectively, which was compounded by inflation in Israel at a rate of (1.0)% and (0.2)%, respectively. 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.

Liquidity risk

We monitor forecasts of our liquidity reserve (comprising cash and cash equivalents and deposits). We generally carry this out based on our expected cash flows in accordance with practice and limits set by our management. We are in the research and development stage and have not yet generated any revenue from sales of our product candidates; we are therefore exposed to liquidity risk. However, we believe that the net proceeds of this offering, together with our existing cash and cash equivalents and deposits, will enable us to fund our operating expenses and capital expenditure requirements for the next 12 months.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. GAAP, as issued by the FASB. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this prospectus, we believe that the accounting policies discussed below are critical to our financial results and to the understanding of our past and future performance, as these policies relate to the more significant areas involving management's estimates and assumptions. We consider an accounting estimate to be critical if: (i) it requires us to make assumptions because information was not available at the time or it included matters that were highly uncertain at the time we were making our estimate and (ii) changes in the estimate could have a material impact on our financial condition or results of operations.

Share-Based Compensation

We account for our share-based compensation for employees and directors in accordance with the provisions of ASC 718, Compensation—Stock Compensation, U.S. GAAP "Stock-based Payment," which requires us to measure the cost of share-based compensation based on the fair value of the award on the grant date.

We re-measure equity awards granted to non-employees at each reporting period at fair value until they have vested. The fair value of equity awards is charged to the statement of operations over the service period using the straight-line method.

Option Valuations

We selected the Black-Scholes option pricing model as the most appropriate method for determining the estimated fair value of our share-based awards. The resulting cost of a share incentive award is recognized as an expense over the requisite service period of the award, which is usually the vesting period. We recognize compensation expense over the vesting period using the straight-line method, and classify these amounts in the financial statements based on the department to which the related employee reports.

The determination of the grant date fair value of options using an option pricing model is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our share price over the expected term of the options, share option exercise and cancellation behaviors, risk-free interest rates and expected dividends, which are estimated as follows:

- *Fair value of our ordinary shares*. Because our shares are not publicly traded, we must estimate the fair value of ordinary shares, as discussed below in "—Valuation of our ordinary shares."
- *Volatility*. The expected share price volatility was based on the historical volatility of the ordinary shares of comparable companies that are publicly traded.

- *Expected term*. The expected term of options granted represents the period of time that options granted are expected to be outstanding. Since adequate historical experience is not available to provide a reasonable estimate, the expected term for grants to employees for at the money options (except senior management) is determined based on the midpoint between the available exercise dates (the end of the vesting periods) and the last available exercise date (the contracted expiry date). The expected term for grants to non-employees, senior management, directors, and out of the money options granted to employees, is determined based on the contractual life of the options.
- *Risk-free rate*. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with a term equivalent to the expected term of the options.
- *Expected dividend yield*. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

If any of the assumptions used in the Black-Scholes option pricing model change significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

The following table presents the weighted-average assumptions used to estimate the fair value of options granted on the dates indicated below.

	YEAR ENDED DECEMBER 31, 2015	YEAR ENDED DECEMBER 31, 2014
Expected volatility (%)	69.78 - 76.68	68.45 - 74.78
Expected term (years)	1 - 7	3.9 - 7.3
Risk-free rate (%)	0.38 - 2.08	1.3 - 2.27
Expected dividend yield (%)	—	—

The following table presents the grant dates, number of underlying shares and related exercise prices of options granted to employees and non-employees since January 1, 2014, as well as the estimated fair value of the underlying ordinary shares on the grant date.

DATE OF GRANT	NUMBER OF SHARES SUBJECT TO AWARDS GRANTED	CLASS OF SHARES SUBJECT TO THE AWARDS GRANTED	TYPE OF EQUITY INSTRUMENT AWARDED	EXERCISE PRICE PER SHARE	ESTIMATED FAIR VALUE PER ORDINARY SHARE AT GRANT DATE
July - September 2014	60,732	ordinary	Options	$16	$ 5.06
August - September 2015	91,065 (1)	ordinary	Options and RSUs(*)	$0-16	$ 9.64
October - December 2015	316,000(2)	ordinary	Options	$ 5.7-19	$ 9.54

(1) Includes 9,000 ordinary shares issuable upon the vesting of restricted share units, which were granted contingent upon the consummation of the completed purchase of intellectual property from Telormedix SA, and excludes 9,000 ordinary shares issuable upon the vesting of restricted share units, the grant of which is contingent upon the closing of this offering.

(2) Excludes 3,000 ordinary shares issuable upon the vesting of options, the grant of which is contingent upon the closing of this offering.

After December 31, 2015, we granted additional options to purchase a total of 104,768 ordinary shares at an with exercise prices per share of $0.01 to $19.00.

Based on the assumed initial public offering price of $ per share, the midpoint of the range set forth on the cover page of this prospectus, the intrinsic value of the awards outstanding as of December 31, 2015 was $ million, of which $ million related to vested options and $ million related to unvested options.

Valuation of our ordinary shares

Due to the absence of an active market for our ordinary shares, the fair value of our ordinary shares for purposes of determining the exercise price for award grants was determined in good faith by our management during the fourth quarter of 2015 in relation to grants up to September 30, 2015 and during the first quarter of 2016. In connection with preparing our financial statements, our management considered the fair value of our ordinary shares based on a number of objective and subjective factors, consistent with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held- Company Equity Securities Issued as Compensation, referred to as the AICPA Practice Aid.

2010-2013 Awards

The ordinary share price was estimated based on the price at which the most recent financing (from external investors) took place, based on our assumption that no significant changes have occurred between the financing closing date and the grant date.

2014 Awards

The ordinary share price was derived from the price used in the financing round on October 20, 2014, based on our assumption that no significant changes have occurred between grant date and the financing round closing date. The derivation of ordinary share price was performed under the option pricing method, or OPM, valuation framework, as described below.

2015 Awards

The ordinary share price was estimated based on valuations performed as of September 30, 2015, November 15, 2015 and December 31, 2015, as described below, and based on our assumption that no significant changes have occurred between grant date and the valuation date.

Fair value of our ordinary shares for 2014 Awards – Methodology

The valuation of the ordinary shares as of October 20, 2014 was performed under the OPM framework and using the Backsolve method, which infers the equity value consistent with the financing round on October 20, 2014. The OPM method is regarded as a common framework for allocating the equity value between the different share classes and other securities. Under this approach, the financial instruments issued by the company (preferred shares, warrants, employee options and ordinary shares) are deemed as contingent claims whose future payoffs depends on our (future) equity value. The OPM was implemented by using the Monte Carlo simulation technique, which generates different scenarios of the equity value and the resulting payoff to the holders of our financial instruments.

The underlying asset, or the equity value, was estimated by implementing the Backsolve method,

Following the above allocation process, we applied a discount of lack of marketability, or DLOM, to the price of an ordinary share. Specifically, we applied the average strike put option in order to estimate the DLOM.

Fair value of our ordinary shares for 2015 Awards—Methodology

As a 15% possibility for IPO event in the near future was estimated, the valuation was conducted through the use of the Hybrid model. The Hybrid approach combines two probability-weighted scenarios:

- Scenario I – IPO Event. The probability of this scenario was estimated at 15%.

  The valuation of our financial instruments was based on the estimated range of equity value upon an IPO and the resulting payoff per each financial instrument.

- Scenario II – Liquidation Event. The probability of this scenario was estimated at 85%.

  The valuation of the ordinary share price under this scenario was performed under the OPM framework using the Monte Carlo simulation technique, in similar fashion to the approach used for the 2014 valuation, as described above.

The equity value used in the OPM method was derived from the financing round in October 2015 (the Backsolve method). As of September 30, 2015, this financing round was highly expected to be closed. The closing date of this round was November 15, 2015.

We applied a DLOM to the ordinary share price, using the average strike put option.

The fair value of an ordinary share was calculated as the weighted average of the ordinary share prices, derived from the calculations made under the two scenarios described above.

Future option awards

Following the completion of our initial public offering and the listing of our shares on the NASDAQ Global Market, the determination of the fair market value of our ordinary shares for purposes of setting the exercise price of future option awards or other share-based compensation to employees and other grantees will no longer require good faith estimates by our board of directors based on various comparisons or benchmarks.

Accounting treatment of the convertible notes

During 2014, we issued a series of convertible notes, or the Convertible Notes, in the aggregate amount of approximately $647,000. The Convertible Notes are to be automatically converted into ordinary shares at a conversion price of $16.00 in December 2017, or to the most senior preferred shares or ordinary shares upon the occurrence of certain events, such as an IPO, merger, acquisition or a financing round in an amount of at least $5.0 million in a single transaction or a series of related transactions, or collectively, the Qualifying Events. The Convertible Notes will convert upon a Qualifying Event into a number of shares, based on the then applicable conversion price that reflects a fixed discount on the price per share reflected in the respective Qualifying Event.

In September 2014, we signed the 2014 Share Purchase Agreement with shareholders and new investors for an aggregate amount of $8.0 million. In October 2014, June 2015 and July 2015, we issued 421,122 Series A preferred shares at a price per share of $19.00 and warrants to purchase an additional 210,571 shares of Series A-1 preferred shares at an exercise price of $25.00 per share. The initial closing under the 2014 Share Purchase Agreement occurred in October 2014. Pursuant to the 2014 Share Purchase Agreement, each investor who invested more than $500,000 transferred 50% of the investment at the initial closing and an additional 50% was invested upon the occurrence of certain milestones as agreed on in the 2014 Share Purchase Agreement, or the Milestone Closing. Investors that invested less than $500,000 transferred their entire investment amount in the initial closing, or at a deferred closing six months after the initial closing. The Milestone Closing occurred in June 2015.

We offered the Convertible Note holders an option to convert the notes according the terms of the 2014 Share Purchase Agreement, in lieu of the conversion for discount. At the initial closing, all of the holders of the Convertible Notes elected to convert the notes according to the terms of the 2014 Share Purchase Agreement, and we issued 34,061 shares of Series A preferred shares to them and granted warrants to purchase an additional 17,031 shares of Series A-1 preferred shares.

The Convertible Notes are accounted for at fair value through profit and loss at each reporting period and until final conversion pursuant to the above mentioned 2014 Share Purchase Agreement, in accordance with ASC 480. Under ASC 480, a financial instrument that embodies a conditional obligation, which the issuer may settle by issuing a variable number of its equity shares, shall be classified as a liability if, at inception, the monetary value of the obligation is based solely or predominantly on a fixed monetary amount known at inception. We analyzed the terms of the Convertible Notes at inception and determined that they should be classified as a liability under ASC 480 since the Convertible Notes will be converted into variable numbers of shares based predominantly on a fix monetary amount.

Accounting treatment of the warrants to purchase preferred shares

Our warrants to purchase preferred shares are exercisable into Series A-1 preferred shares of the company, nominal value NIS 0.01 per share, for an exercise price of $25.00 per share commencing on the date of the issuance and expiring at the earlier of a qualified IPO, certain M&A events, or four years from the date of issuance.

In the event that the warrants are exercised in connection with a qualified IPO or certain M&A events, the holder may elect to convert the warrants on a net share basis.

The warrants are classified as liabilities in accordance with ASC 480, as they are freestanding instruments, exercisable into Series A-1 preferred shares, which are redeemable upon certain events that represent “Deemed Liquidation” events. Accordingly, the warrants are measured at fair value at the end of every reporting period, and changes in their fair value are recognized in earnings.

Accounting treatment of the Series A Preferred Shares

The Series A preferred shares are classified within permanent equity because they are not subject to liability classification under the scope of ASC 480, and because they meet all of the requirements for equity classification under ASC 480-10S99.

Accounting treatment of intellectual property assets purchased from Telormedix SA

In October 2015, we entered into an asset purchase agreement with Telormedix SA pursuant to which we purchased all of the intellectual property assets of Telormedix in consideration of 216,000 shares of our Series A preferred shares at a price per share of $19.00. Upon the occurrence of any one of three specified regulatory milestones, we are required to issue an additional 29,000 Series A preferred shares, or 29,000 ordinary shares in the event any milestone is achieved following the completion of this offering. If all three milestones are achieved, we would be required to issue in total an aggregate of 87,000 Series A preferred shares, or 87,000 ordinary shares in the event the milestones are achieved after the completion of this offering.

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.

Deferred taxes

Income 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. We have provided a full valuation allowance with respect to its deferred tax assets.

Recent Accounting Pronouncements

There are no U.S. GAAP standards as issued by the FASB that are effective for the first time for the financial year beginning on or after January 1, 2015 that would be expected to have a material impact on our financial position. See Note 2q to our annual financial statements.

Internal Control Over Financial Reporting

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of our ordinary shares. Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, starting with the second annual report that we file with the SEC after the consummation of this offering, our management will be required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an “emerging growth company” under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above, our independent registered public accounting firm will also need to attest to the effectiveness of our internal control over financial reporting under Section 404. We have not yet commenced the process of determining whether our existing internal controls over financial reporting systems are compliant with Section 404 and whether there are any material weaknesses or significant deficiencies in our existing internal controls. This process will require the investment of substantial time and resources, including by our Chief Financial Officer and other members of our senior management. In addition, we cannot predict the outcome of this determination and whether we will need to implement remedial actions in order to implement effective control over financial reporting. The determination and any remedial actions required could result in us incurring additional costs that we did not anticipate. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may

experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors.

JOBS Act

As an “emerging growth company,” as defined in the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them. We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

The JOBS Act additionally permits emerging growth companies such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected not to avail ourselves of this provision and, as a result, we will comply with new or revised accounting standards as other public companies that are not emerging growth companies.

BUSINESS

Overview

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

Our lead product candidates, MitoGel and VesiGel, are formulated using our proprietary reverse thermally triggered hydrogel, or RTGel, technology. We believe that RTGel-based drug formulations, which provide for the sustained release of an active drug, may improve the efficacy of treatment of various types of urothelial cancer without compromising the safety of the patient or interfering with the natural flow of fluids from the urinary tract to the bladder. Our formulations are designed to achieve this by increasing the dwell time as well as the tissue coverage throughout the organ of the active drug. Consequently, we believe that RTGel-based drug formulations may enable us to overcome the anatomical and physiological challenges that have historically contributed to the lack of drug development for the treatment of urothelial cancer. No drugs have been approved by the U.S. Food and Drug Administration, or the FDA, for the treatment of UTUC, and no drugs have been approved by the FDA for the treatment of bladder cancer for more than 15 years.

We are currently evaluating the safety and efficacy of MitoGel, our novel sustained-release formulation of MMC, in UTUC patients pursuant to an ongoing "Compassionate Use" program. "Compassionate Use" is the use outside of a clinical trial of an investigational, or not approved, medical product when patient enrollment in a clinical trial is not possible, typically due to patient ineligibility or a lack of ongoing clinical trials. Of the seven low-grade UTUC patients with confirmed low-grade UTUC evaluated in the program to date, four achieved a complete response and three achieved a partial response. Thus far, MitoGel has been observed to be well-tolerated. We have obtained Orphan Drug Designation for MitoGel for the treatment of UTUC. We expect to file an investigational new drug, or IND, application for MitoGel with the FDA in the second half of 2016 and, if accepted, to commence a single pivotal, open-label, single-arm Phase 3 clinical trial for the treatment of low-grade UTUC also in the second half of 2016. We intend to pursue the FDA's 505(b)(2) regulatory pathway for MitoGel, which is a streamlined, lower-cost and more well-defined pathway to drug approval when compared to traditional drug development. We believe that MitoGel has the potential to become the first FDA-approved drug for the treatment of low-grade UTUC and to serve as a first-line chemoablation agent, sparing patients from repeated tumor resection surgeries and potentially reducing the need for kidney and upper urothelial tract removal.

In addition, we are currently evaluating the safety and efficacy of VesiGel, our novel sustained-release high dose formulation of MMC, for the treatment of low-grade non-muscle invasive bladder cancer, or NMIBC. To date, 18 of 20, or approximately 90%, of the patients with confirmed low-grade NMIBC evaluated in our ongoing Phase 2a clinical trial who were treated in the VesiGel high dose group (80mg MMC) achieved a complete response. Moreover, in the clinical program to date, comprised of the Phase 2a and Phase 1 clinical trials, over 80% of the patients who achieved a complete response and who have been followed for 12 months thereafter remained recurrence free and were able to sustain a durable complete response during those 12 months. This compares to approximately 40% of patients who historically have been able to sustain a 12-month durable complete response following transurethral resection of bladder tumor, or TURBT, as first-line treatment. We plan to file an IND for

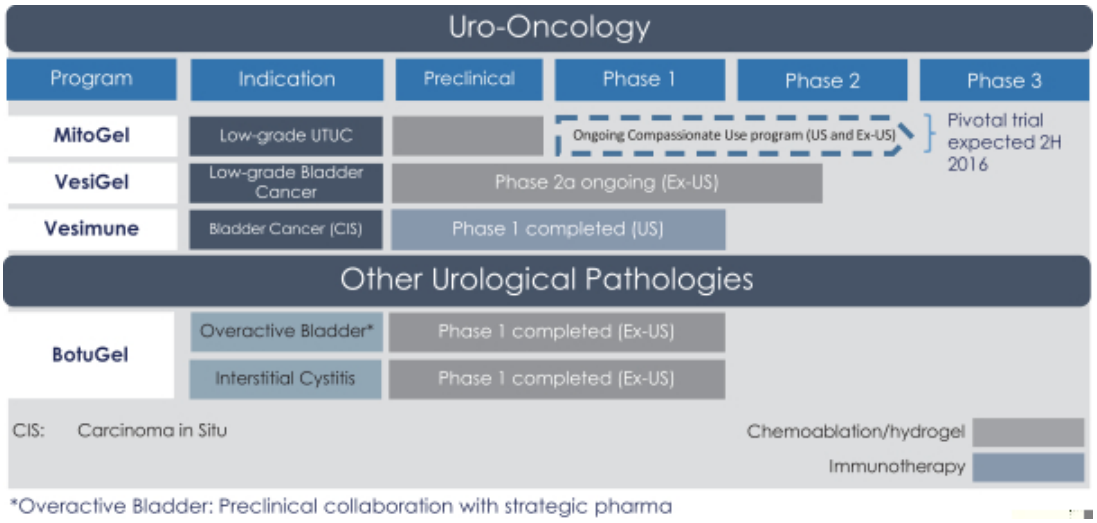
VesiGel in the first half of 2017 and, if accepted, to commence a Phase 2b clinical trial for VesiGel, also in the first half of 2017. We also intend to pursue a 505(b)(2) regulatory pathway for VesiGel. We believe that VesiGel has the potential to replace tumor resection surgery and become the new first-line standard of care for the treatment of low-grade NMIBC to replace tumor resection surgery as first-line treatment.

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 be at least $4 billion in 2010 and are projected to be at least $5 billion in 2020. The majority of the historical expenditures was spent on tumor resection surgeries such as TURBT and bladder, kidney and upper urothelial tract removal. In 2012, the estimated prevalence of urothelial cancer in the United States was 625,000 with an annual incidence of approximately 80,000. The 2012 prevalence of each of low-grade NMIBC and low-grade UTUC in the United States was approximately 325,000 and 14,500, respectively.

Our clinical stage pipeline also includes Vesimune, our proprietary immunotherapy product candidate for the treatment of high-grade NMIBC, as well as BotuGel, which we are developing for the treatment of overactive bladder and interstitial cystitis, also known as painful bladder syndrome. Vesimune is a novel, liquid formulation of Imiquimod, a generic toll-like receptor 7, or TLR7, agonist. Toll-like receptor agonists play a key role in initiating the innate immune response system. We believe that Vesimune could represent a valid alternative to the current standard of care for the adjuvant treatment following TURBT of high-grade NMIBC. BotuGel is our proprietary novel RTGel-based formulation of botulinum toxin, a branded drug, that we believe can potentially serve as an effective treatment option for patients suffering from overactive bladder and interstitial cystitis.

Our Product Candidate Pipeline

The following chart summarizes the current status of our clinical stage product candidate pipeline.



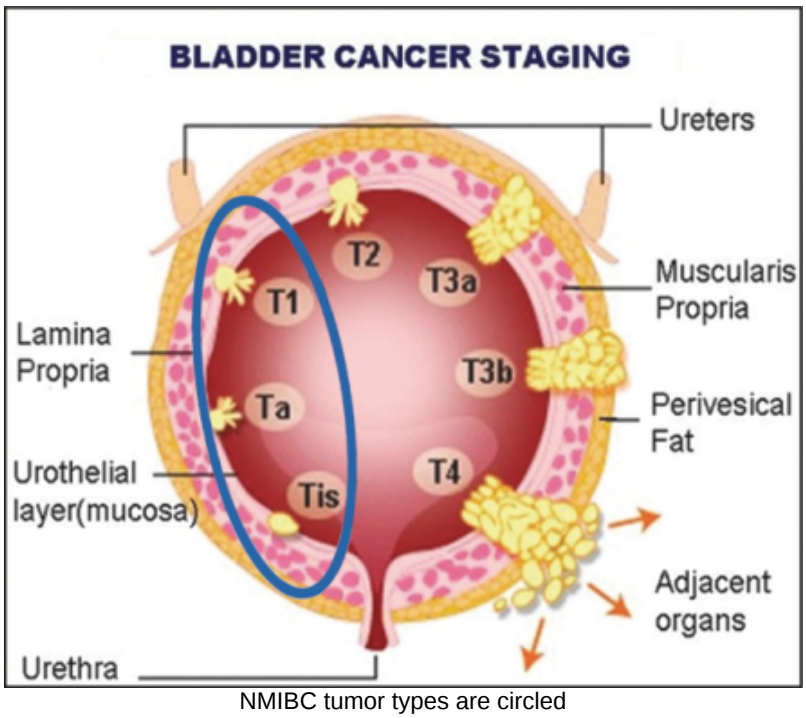
Uro-Oncological Indications Targeted by Our Product Candidates

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

Table of Contents

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 urothelial tract tubes, called ureters. The bladder wall has four main layers. The innermost lining is comprised of cells called urothelial or transitional cells, and this inner layer is called the urothelium or transitional epithelium. Beneath the urothelium, there is a layer called the lamina propria. Next is a thick layer of muscle called the muscularis propria followed by a layer of perivesical fat.

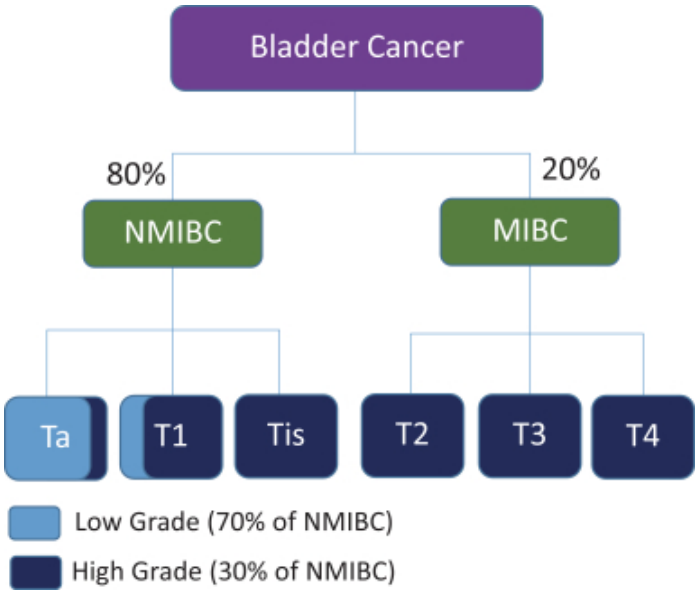


NMIBC tumor types are circled

Bladder cancer accounts for approximately 90% to 95% of all new cases of urothelial cancer in the United States, with a prevalence of approximately 580,000. Bladder cancer is nearly three to four times more common in men than women, and, with an average age at diagnosis of 73, mostly affects the elderly. Bladder cancers are described as non-muscle invasive or muscle-invasive based on how far into the wall of the bladder they have invaded. The magnitude and rate of the spreading of the cancer is called “staging,” which ranges from Ta to T1 for NMIBC, and T2 to T4 for muscle-invasive bladder cancers, as defined by the American Joint Committee on Cancer TNM System. In addition, Carcinoma in Situ, or CIS, a form of NMIBC, has a staging designation of Tis. Muscle-invasive bladder cancer, or MIBC, has an average five-year survival rate of 15% to 63%, depending on severity. MIBC represents a worse prognosis than NMIBC, which has a five-year survival rate of approximately 90%. NMIBC accounts for approximately 80% of all new cases of bladder cancer diagnosed in the United States each year, which corresponds to an estimated annual incidence and prevalence of approximately 60,000 and 465,000 cases, respectively.

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

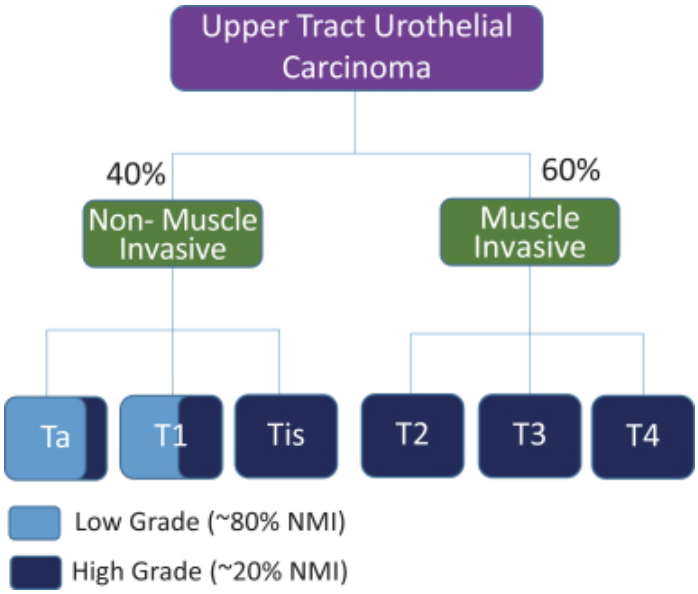
The chart below indicates the prevalence of stage and grade of bladder cancer in the United States.



Upper Tract Urothelial Carcinoma

UTUC refers to malignant changes of the transitional urothelial cells lining the upper urothelial tract of the renal pelvis and ureter. UTUC typically exhibits high local recurrence and development of metastases. Similar to NMIBC, the prognosis of patients with UTUC correlates with the stage and grade of disease at the time of initial diagnosis. The key prognostic factor at the time of diagnosis of UTUC is whether the tumor is in the muscle-invasive or non-muscle invasive stage. The number, size and location of tumors presented also represent important prognostic factors for UTUC. Approximately 40% of the patients diagnosed annually with UTUC in the United States present with non-muscle invasive UTUC. Non-muscle invasive UTUC is also divided into two grades, low and high. In two studies conducted in 1997 and 2003 of 30 and 20 patients with non-muscle invasive UTUC, 87% and 75% of patients were diagnosed with low-grade non-muscle UTUC, respectively.

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



UTUC accounts for approximately 5% to 10% of all new cases of urothelial cancer, which corresponds to an estimated annual incidence in the United States of up to 7,500 cases. In 2012, the estimated prevalence of UTUC in the United States was approximately 45,000, of which approximately 14,500 had low-grade disease. UTUC is nearly three times more common in men than women and affects mostly the elderly.

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

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

We believe that because tumor resection procedures followed by adjuvant chemotherapy therapy are sub-optimal, nephroureterectomy is often used even in patients that may be otherwise candidates for organ sparing treatments.

Non-Muscle Invasive Bladder Cancer

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

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

Other Urological Indications Targeted by Our Product Candidates

Overactive Bladder

Overactive bladder is characterized by urinary urgency, with or without urgency-associated urinary incontinence. Overactive bladder is often associated with urinary frequency and nocturia, or excessive urination during the night, in the absence of pathologic or metabolic conditions that may cause or mimic overactive bladder, such as urinary tract infections, polyuria, which is excessive or abnormally large production or passage of urine, transitional cell carcinoma of the bladder, and underlying neurologic abnormalities. Urgency, the hallmark of overactive bladder, is defined as the sudden compelling desire to urinate, a sensation that is difficult to defer. Urinary frequency is defined as voiding eight or more times in a 24-hour period. Nocturia is defined as the need to wake one or more times per night in order to void the bladder. Approximately 33 million Americans have overactive bladder. The overall prevalence of overactive bladder in 2012 in the United States ranges from 26% to 33% for men and from 27% to 46% for women. Behavioral therapy is considered to be the first recommended therapy. The most common drug treatment option for overactive bladder is anticholinergics, which are neurotransmitters that act in the central and peripheral nervous system. In a 2008 study of 1,117 overactive bladder patients, 73.5% reported that they stopped taking their anticholinergic therapy within one year. According to two separate surveys, the top reasons for discontinuing anticholinergics were the side effects and lack of efficacy. Reconstructive surgery exists as a last resort.

Botulinum toxin is often used as a second-line drug treatment for patients with overactive bladder who do not respond to or tolerate anticholinergics. When administered into the bladder wall, botulinum toxin has been shown to lead to significant improvement in urge and incontinence. However, the current mode of administration of botulinum toxin into the bladder wall has several disadvantages, including the fact that the procedure is conducted under general anesthesia, the requirement of cystoscopy, which is a video guide inserted through the urethra into the bladder, a need to inject the botulinum toxin into the bladder muscle and the non-uniformity of the distribution of such injections, and the occurrence of urinary retention.

Interstitial Cystitis

Interstitial cystitis, also referred to as painful bladder syndrome, is a condition of recurring pressure, pain or discomfort in the bladder and pelvic region, combined with urinary frequency and urgency. It is estimated that at least three million women and one million men in the United States have interstitial cystitis.

There is no cure for interstitial cystitis. However, certain treatment options are available to help relieve symptoms. There are several lines of recommended therapy for interstitial cystitis, including behavioral modification techniques, antidepressants such as Prozac, antihistamines such as Claritin, pentosan polysulfate sodium such as Elmiron, bladder instillations, such as heparin and immunosuppresants such as Cyclosporine. When these treatments have failed, a fourth-line treatment is botulinum toxin injections into the bladder muscle. Bladder removal, enlargement or urinary diversion surgery exist as last resorts. Elmiron is the only FDA-approved drug indicated for the relief of pain for patients with chronic interstitial cystitis. However, since 1996, no treatments have been approved for interstitial cystitis. We therefore believe there remains a significant unmet medical need for the treatment of interstitial cystitis.

Our Competitive Strengths

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

Potential ability to develop non-surgical, first-line drug therapies for uro-oncology. Leveraging our innovative formulation technology, we are developing two lead product candidates, MitoGel and VesiGel, as potential replacements to first-line treatment for low-grade UTUC and NMIBC, respectively. Both MitoGel and VesiGel 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 MMC. Clinical data generated to date supports our belief that our lead product candidates may be able to replace the current first-line tumor surgical procedures, providing a chemoablation treatment that has the potential to better eradicate tumors irrespective of their detectability and location within the urinary tract. To date, of the seven low-grade UTUC patients treated with MitoGel in an ongoing Compassionate Use program and evaluated for efficacy, four have achieved a complete response and the remaining three have achieved a partial response. In the case of VesiGel, to date, 18 of 21, or approximately 86%, of the patients treated with the high dose of VesiGel in the ongoing Phase 2a trial, which is evaluating the efficacy and safety of VesiGel's chemoablation properties, achieved a complete response.

Expertise in developing proprietary formulations of drugs for clinical benefit. We focus on developing proprietary RTGel formulations of previously approved drugs whose efficacy for a particular indication is limited by current formulations or routes of administration. While we have not yet brought a drug to market, our expertise has enabled us to develop proprietary RTGel-based formulations for several previously approved drugs to date, including clinical stage proprietary formulations of MMC 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. With 10 Ph.D. or medical doctors on our staff, we have a strong research and development team to advance our product candidates.

Lower development risks and costs for our pipeline product candidates. We expect the approval process for each of our current uro-oncology product candidates to be conducted according to the FDA's 505(b)(2) regulatory pathway, a streamlined, lower-cost and more well-defined pathway to drug approval when compared to traditional drug development. Furthermore, two of our product candidates, MitoGel and Vesimune, have received Orphan Drug Designation from the FDA for the treatment of UTUC and CIS, respectively, which we expect will provide seven years of marketing exclusivity following FDA approval, if received. We expect to submit our IND for MitoGel in the second half of 2016 and, if accepted by the FDA, we expect to commence a single pivotal Phase 3 clinical trial for the treatment of low-grade UTUC also in the second half of 2016. Based on multiple discussions with the FDA, our current expectation is that our single pivotal Phase 3 clinical trial for MitoGel will be an open-label, single-arm study, evaluating between 50 and 70 patients with low-grade UTUC in the United States, Europe and Israel. Additionally, we expect that our product candidates will be safe and well-tolerated because they are novel formulations of previously approved drugs.

***Leverageable proprietary formulation technology*.** We believe that RTGel has multiple potential applications beyond urology. Our formulation know-how may enable us to develop different drug formulations to facilitate the delivery, retention and sustained release of active drugs to a variety of targeted body cavities. We believe that our proprietary formulation technology can improve the efficacy of locally administered drugs in body cavities such as the stomach, uterus and rectum that present anatomical and physiological challenges related to frequent wash out, rapid excretion and bodily secretions.

Strong intellectual property position. We have a robust intellectual property portfolio that includes four issued patents in the United States and several patent applications worldwide related to methods, systems and compositions for treating bladder cancer related to our lead product candidates, MitoGel and VesiGel, as well as RTGel, both on its own and formulated with other drugs. The four issued patents are expected to expire between 2024 and 2030. We also have 11 granted patents worldwide related to our other product candidates, which are expected to expire between 2030 and 2031. We also have approximately 60 pending patent applications worldwide covering all of our product candidates. Additionally, the FDA has granted Orphan Drug Designation to

MitoGel for the treatment of UTUC, which potentially entitles us to marketing exclusivity for MitoGel for seven years following approval, if granted, by the FDA.

***Experienced and accomplished leadership team with proven track record*.** We have an experienced management team, with each member possessing more than 15 years of biopharmaceutical and related industry experience. Our Chief Executive Officer, Ron Bentsur, successfully navigated Auryxia (ferric citrate) through the 505(b)(2) streamlined regulatory pathway to FDA approval. In addition, our Chairman, Arie Belldegrun, M.D., is a seasoned biotech executive and is currently the Chairman, Chief Executive Officer and President of Kite Pharma, as well as a director of Teva Pharmaceutical Industries. We believe that our leadership team is well-positioned to lead us through clinical development, regulatory approval and commercialization for our product candidates.

Our Growth Strategy

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

Establish each of our lead product candidates, MitoGel and VesiGel, as the first-line treatment in its target indication. We believe that data from treatments in an ongoing Compassionate Use program currently being conducted in the United States, Europe and Israel provide evidence of the potential safety and efficacy of MitoGel for the treatment of low-grade UTUC. We expect to file an IND for MitoGel with the FDA in the second half of 2016 and, if accepted, to commence a single pivotal Phase 3 clinical trial also in the second half of 2016 pursuant to the FDA's 505(b)(2) regulatory pathway. We are currently performing a Phase 2a randomized, open-label, single-arm, active-controlled clinical trial of VesiGel for the treatment of low-grade NMIBC outside the United States. We expect to file an IND for VesiGel in the first half of 2017 and, if accepted, to commence a Phase 2b clinical trial also in the first half of 2017. We also expect to pursue a 505(b)(2) regulatory pathway for VesiGel. We believe that these local drug treatments have the potential to replace the costly, sub-optimal and burdensome tumor resection and kidney removal surgeries to become the first-line standard of care.

Expand our uro-oncology product pipeline. A Phase 1 clinical trial of Vesimune was completed under an IND in 12 patients with CIS, an aggressive type of high-grade urinary bladder cancer. In the study, 10 patients were evaluated for response and a 40% complete response rate with Vesimune as a single-agent treatment was observed. We believe that Vesimune has the potential to serve as a treatment option for high-grade urothelial tumors. We are also pursuing preclinical oncology programs that take advantage of our RTGel technology. Our preclinical programs are being developed for high-grade bladder cancer and high-grade UTUC. We may also evaluate in-licensing or acquiring additional product candidates for the treatment of urological cancers.

Develop our non-oncology product candidates. We are developing additional product candidates designed to take advantage of our proprietary RTGel formulation technology to better adapt to the specific anatomical and physiological constraints of the urological system. The most notable of these product candidates is BotuGel, our proprietary novel RTGel-based formulation of botulinum toxin for the treatment of overactive bladder and interstitial cystitis. BotuGel was evaluated in a 39 patient Phase 1b proof-of-concept, investigator-initiated study in Europe in patients with overactive bladder. It is also the subject of a preclinical, IND-enabling collaboration with a large pharmaceutical company and in a preliminary 15 patient Phase 1 proof-of-concept study in Israel in patients with interstitial cystitis.

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 and sustained release of active drugs to a variety of targeted body cavities. Beyond the urinary tract, we may target the gastrointestinal tract and the female reproductive system. In the future, we may also choose to develop our RTGel technology in combination with other drugs to treat cancer and other indications endemic to such body cavities.

Evaluate and selectively pursue potential collaborations to develop improved formulations and product life-cycle management strategies. We intend to evaluate and selectively pursue collaborations with pharmaceutical companies through a combination of in-licensing, out-licensing, joint venture and partnership transactions in order to formulate additional drugs using such companies' products or product candidates in combination with RTGel. 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 Thermally Triggered 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 urothelial tract, by conforming to the anatomy of the target organ while preventing rapid excretion of the drug. The following images show the progression of four stages of RTGel at different temperatures.

LT: Liquid at low temperature
BT: Converts into gel form at body temperature

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: MMC in the case of MitoGel and VesiGel, and botulinum toxin in the case of BotuGel. The resulting formulations are instilled intravesically in liquid form directly into the bladder or upper urothelial 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 urothelial tract by significantly extending the dwell time of the active drug while conforming to the anatomy of the bladder and the upper urothelial tract, which allows for enhanced drug tissue coverage. For example, the average dwell time of the standard MMC water formulation, currently used as adjuvant treatment, in the upper urothelial tract is approximately five minutes, compared to approximately six hours when MMC 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 MMC in 1 ml of water while it is possible to formulate up to 8 mg of MMC 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 MMC in the urinary tract for both MitoGel and VesiGel, and of botulinum toxin in the case of BotuGel. Further, RTGel may be particularly effective in the bladder and upper urothelial 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 urothelial tract.

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

MMC is a generic drug currently utilized off-label as the standard adjuvant chemotherapy for the treatment of low-grade UTUC and NMIBC after tumor resection, such as TURBT. MMC is typically administered using a water-based

formulation, which has a relatively short dwell time in the bladder limited to first voiding. MMC often causes temporary irritation of the bladder, including the need to urinate frequently and urgently. This often results in first voiding occurring shortly after instillation. In the upper urothelial 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 MMC in the bladder results in more efficacious treatment of bladder cancer. In one such study, it was shown that MMC 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.

MMC'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 MMC in the bladder. Thus, because our RTGel-based MMC sustained-release formulations, MitoGel and VesiGel, provide for a significantly longer dwell time of MMC in the upper urothelial tract and in the bladder as compared to standard MMC water formulations, there is a greater chance that tumor cells will go through their S-phase while the instilled MMC is still present using MitoGel or VesiGel, potentially resulting in a higher percentage of tumor cells being affected by the instilled MMC.

MitoGel: Our Product Candidate for the Treatment of Low-Grade Upper Tract Urothelial Carcinoma

We are developing MitoGel, our novel sustained-release formulation of MMC, for the treatment of low-grade UTUC. We have observed preliminary evidence of the efficacy of MitoGel in an ongoing investigator-initiated Compassionate Use program for the treatment of severe, non-resectable UTUC. Based on multiple discussions with the FDA, we do not believe that we will need to perform additional clinical trials prior to initiating a single pivotal Phase 3 clinical trial with MitoGel. Additionally, the FDA granted MitoGel Orphan Drug Designation for the treatment of UTUC. We plan to develop MitoGel through the FDA's 505(b)(2) regulatory pathway. We intend to submit an IND for MitoGel in the second half of 2016 and, if accepted, to commence the single pivotal Phase 3 clinical trial also in the second half of 2016.

Limitations of Current Therapies for Upper Tract Urothelial Carcinoma

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

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

Our Solution: MitoGel

MitoGel is our novel sustained-release RTGel-based formulation of MMC that we are developing for the treatment of low-grade UTUC. RTGel is liquid at lower temperatures and converts into gel form at body temperature. This temperature-dependent viscosity characteristic allows the simple and convenient instillation of the cooled MitoGel in its liquid form to the upper urothelial tract via standard catheters. Once instilled, MitoGel converts into gel form in less than 10 minutes at body temperature. Subsequently, upon contact with urine, MitoGel gradually dissolves and releases the active drug, MMC, over a period of several hours versus several minutes for MMC in its current water-based formulation. We believe that this substantial increase in dwell time of MMC positions MitoGel as a potential

first-line chemoablation treatment for low-grade UTUC, sparing patients from repeated tumor resection surgeries and potentially reducing the need for kidney and upper urothelial tract removal.

The Orphan Drug Designation granted to MitoGel for the treatment of UTUC potentially entitles us to marketing exclusivity for MitoGel for seven years following approval by the FDA, if granted, as well as priority review of our New Drug Application, or NDA.

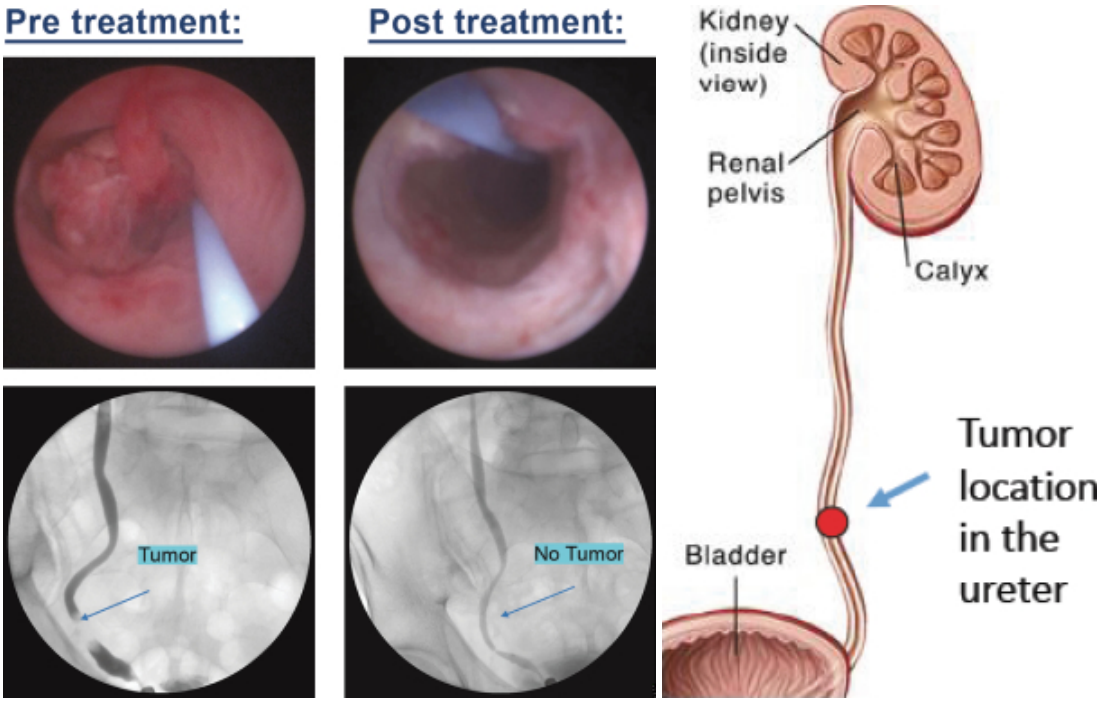
Initial Clinical Results for MitoGel

MitoGel is being evaluated in an ongoing investigator-initiated Compassionate Use program for the treatment of severe, non-resectable UTUC, which commenced in November 2014 and is ongoing. The Compassionate Use program, which is being conducted in the United States, Europe and Israel, includes patients diagnosed with unilateral and bilateral UTUC, low- and high-grade UTUC, as well as patients with a solitary kidney. Patients in the Compassionate Use program receive six weekly instillations of MitoGel administered directly to the upper urothelial tract via catheter. Consistent with the nature of Compassionate Use programs, which are investigator-initiated clinical trials, no statistical plan or primary endpoint is being used. Approximately four weeks following the completion of the treatment course, the patients are evaluated for response. Safety and feasibility of treatment with MitoGel are also being evaluated. To date, we have treated 18 patients, with more than 90 instillations of MitoGel performed. Of the 18 treated patients, 12 were assessed as having low-grade disease. Of these 12 patients, seven have reached the primary evaluation time point to date and have been evaluated for response, with four achieving a complete response and the remaining three achieving a partial response.

Thus far in the study, MitoGel has been observed to be well-tolerated. The main observed adverse events, or AEs, related to MitoGel have been fatigue, allergic reaction, nausea, fever, and dysuria, which is pain or difficulty while urinating. All of the AEs that have been observed to date are known side effects associated with the use of MMC and appear on the MMC label as potential side effects. Various serious adverse events, or SAEs, were also reported and were determined to be unrelated to treatment with MitoGel. These SAEs include acute pyelonephritis, a kidney infection caused by bacteria; hydronephrosis, which is the swelling of a kidney due to a build-up of urine; severe arrhythmia, which is a severe abnormal heart rhythm; cardiac asthma, which is a medical diagnosis of wheezing, coughing or shortness of breath due to congestive heart failure; aggravation of renal function; pancytopenia, which is a deficiency of red cells, white cells and platelets in the blood; and death. There was one drug-related SAE, upper tract chemical irritation, which was resolved.

This Compassionate Use program was allowed by the FDA to accumulate safety and efficacy data. Based on our recent discussions with the FDA, we do not expect that we will need to perform any additional clinical trials prior to initiating a single pivotal Phase 3 open-label, single-arm clinical trial with MitoGel.

The following images show pre-treatment and post-MitoGel treatment results from one low-grade UTUC patient in the Compassionate Use program.



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

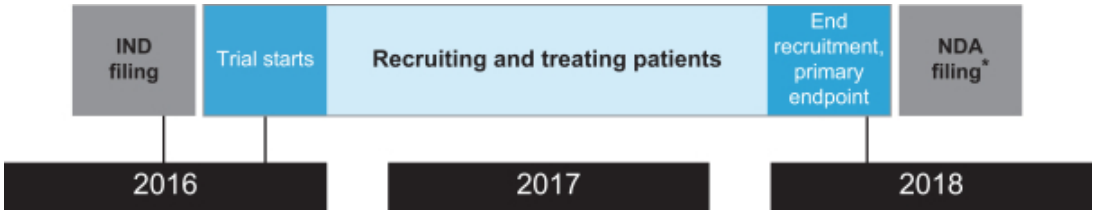
The top left image is a pre-treatment ureteroscopic view of a tumor located in the ureter. The bottom left image is a pre-treatment x-ray revealing an obstruction within the ureter in which no contrast (black) can be visualized in the distal ureter (denoted by arrow). The top right image is a post-treatment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

IND-Enabling Studies for MitoGel

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

Next Steps in the Clinical Development of MitoGel

Based on discussions with the FDA, we intend to develop MitoGel through the FDA's 505(b)(2) regulatory pathway. We plan to submit an IND for MitoGel in the second half of 2016 and, if accepted, to commence a single pivotal Phase 3 clinical trial also in the second half of 2016.



* Only if clinical trial is successfully completed

We have had several face-to-face, pre-IND meetings with the FDA to discuss the MitoGel development program for low-grade UTUC. Currently, the proposed design for the planned single pivotal Phase 3 clinical trial is an open-label, single-arm study evaluating 50 to 70 patients with low-grade UTUC. We expect this clinical trial, if successfully completed, to support an NDA for low-grade UTUC for MitoGel. The patients will initially receive six weekly instillations of MitoGel. The primary efficacy endpoint is expected to be the complete response rate, defined as the percentage of patients with a complete response at the primary disease evaluation visit, which occurs approximately four weeks following the sixth weekly instillation. In addition, patients who achieve a complete response at the primary disease evaluation visit will be followed for durability of response. Such patients will also receive monthly MitoGel maintenance instillations for up to 12 months. If this clinical trial is successfully completed, we currently anticipate submitting an NDA for MitoGel in 2018.

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

VesiGel is our novel sustained-release formulation of high dose MMC that we are developing for the treatment of low-grade NMIBC as a first-line non-surgical chemoablation alternative to TURBT. We are currently conducting a Phase 2a randomized, open-label, single-arm active-controlled clinical trial in Europe and Israel to evaluate the safety and efficacy of VesiGel (40mg and 80mg MMC) in low-grade NMIBC. We commenced the trial in September 2013 and the last patient was enrolled in March 2016. To date, 18 of 20, or approximately 90%, of the patients with confirmed low-grade NMIBC treated in this trial have been observed to achieve complete responses in the 80mg MMC dose group of VesiGel, and therefore did not need surgical intervention. In the clinical program to date, comprised of the Phase 2a and earlier Phase 1 clinical trials, over 80% of the patients who achieved a complete response with VesiGel treatment and who have been followed for 12 months thereafter remained recurrence free and were able to sustain a durable complete response during those 12 months after treatment. This compares to approximately 40% of patients who historically have been able to sustain a 12-month durable complete response following TURBT as first-line treatment.

We plan to complete the ongoing Phase 2a clinical trial in the first half of 2016. We plan to meet with the FDA in mid-2016 to discuss the next steps in the clinical development plan for VesiGel and timing for IND submission. We expect to file an IND for VesiGel in the first half of 2017 and, if accepted, to commence a Phase 2b clinical trial for VesiGel also in the first half of 2017.

Limitations of Current Therapies for Non-Muscle Invasive Bladder Cancer

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

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

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

- bleeding at the time of surgery that requires clot irrigation and mild burning;
- infection of the bladder;
- injured urethra and bladder perforation with potential intra-abdominal leakage;
- re-seeding 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 re-seeding of the cancerous cells, consist primarily of chemotherapy in the case of low-grade tumors and immunotherapy in the case of high-grade tumors, and are administered intravesically via catheter. Adjuvant intravesical chemotherapy is used primarily in low-grade tumors following TURBT in order to try to delay tumor recurrence, but is not used as a chemoablation agent. The rationale is to expose tumors to high local drug concentrations while minimizing the systemic exposure, thereby enhancing the treatment effect and reducing the drug toxicity. However, these traditional adjuvant treatments to treating bladder cancer have been limited because, after instillation, the drug concentration is reduced and the drug is washed out due to urine voiding. As a result, the cancerous tissue is not exposed to the chemotherapy drug for the optimal length of time.

No drugs have been approved by the FDA as first-line treatment for NMIBC and only three drugs have been approved for NMIBC, all used as adjuvant treatment: Thiotepa, which was approved in 1959; bacille Calmette-Guerin, or BCG, which was approved in 1989; and Valstar, which was approved in 1998. MMC is the drug used most often for intravesical chemotherapy. It is used off-label as an adjuvant treatment in the post-operative setting for low-grade tumors with high risk of recurrence. Other drugs that can be used include docetaxe 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 Black Box 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: VesiGel

VesiGel, an RTGel-based formulation of high dose MMC, is our product candidate for the treatment of low-grade NMIBC. VesiGel 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, VesiGel converts into gel form within approximately 15 minutes at body temperature. Subsequently, upon contact with urine, VesiGel gradually dissolves and releases the active drug, MMC, over a period of several hours versus the time until first voiding, often less than an hour, for MMC 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 MMC in the bladder prolongs exposure of MMC to the tissue and therefore has the potential to chemoablate visible and unseen tumors. As a result of these properties, our goal is to develop VesiGel as a first-line chemoablation non-surgical alternative to TURBT for the treatment of low-grade NMIBC.

Ongoing Phase 2a Clinical Trial

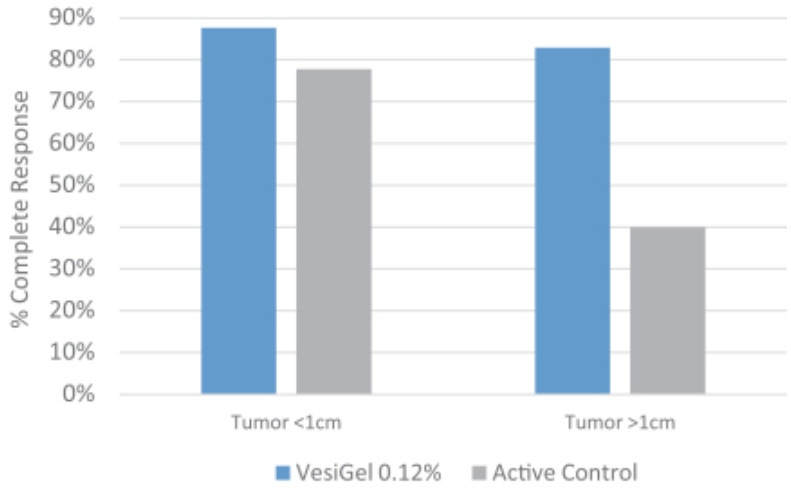
We are currently conducting a Phase 2a randomized, open-label, single-arm, active-controlled clinical trial in Europe and Israel to evaluate the safety and efficacy of VesiGel 0.06% (40 mg MMC in 64 ml gel) and VesiGel 0.12% (80 mg MMC in 64 ml gel) in low-grade NMIBC compared to the intravesical instillation of 40 mg of MMC in water (MMC 0.1%). We commenced the trial in September 2013 and the last patient was enrolled in March 2016. In this trial, patients undergo six weekly instillations according to their assigned treatment arm. The primary endpoint of the trial used for observational purposes only is the complete response rate at the primary disease endpoint, which is evaluated approximately four weeks after the sixth weekly installation. Safety, feasibility of local treatment with VesiGel and durability of response are also being evaluated. To date, we have enrolled 79 patients, 63 of whom have been evaluated for response. Of the 63 patients evaluable to date, 20, 20 and 23 patients are in the VesiGel 0.06%, VesiGel 0.12% and MMC 0.10% groups, respectively. The results to date indicate complete response rates of 45%, 90% and 69.6% for VesiGel 0.06%, VesiGel 0.12% and MMC 0.10%, respectively.

In treating low-grade NMIBC, resection of small tumors is primarily conducted in the outpatient setting, typically without anesthesia using fulguration, a procedure that destroys the diseased area in the lining of the bladder by burning using electric current. The effectiveness of tumor resection in these cases is high and the one year recurrence rate is estimated to be only 10%. However, larger, multiple tumors are surgically removed using TURBT,

a procedure conducted in the operating room in a hospital setting under general anesthesia, which often requires at least an overnight stay. TURBT is associated with increased risks and costs and higher recurrence rates that can reach up to 60%.

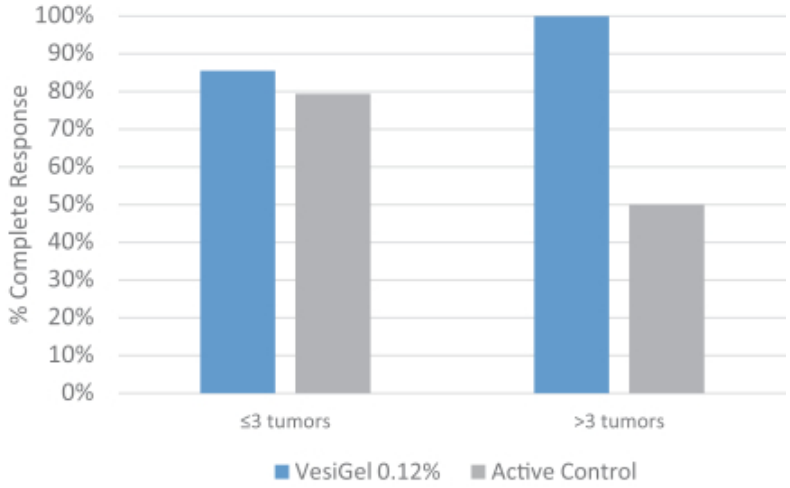
When evaluating the effect of chemoablation on large tumors that would typically be treated with TURBT, we observed a more profound difference in the complete response rate between the VesiGel 0.12% arm compared to the MMC 0.10% control arm. In tumors less than 1 cm in diameter, the complete response rate was 78% and 87% in the MMC 0.10% control group and the VesiGel 0.12% group, respectively. However, in tumors greater than or equal to 1 cm in diameter, the complete response rate was 40% and 83% in the control group and VesiGel 0.12% group, respectively.

The graph below illustrates the complete response rates by tumor size for the VesiGel 0.12% and MMC 0.10% control treatment arms.



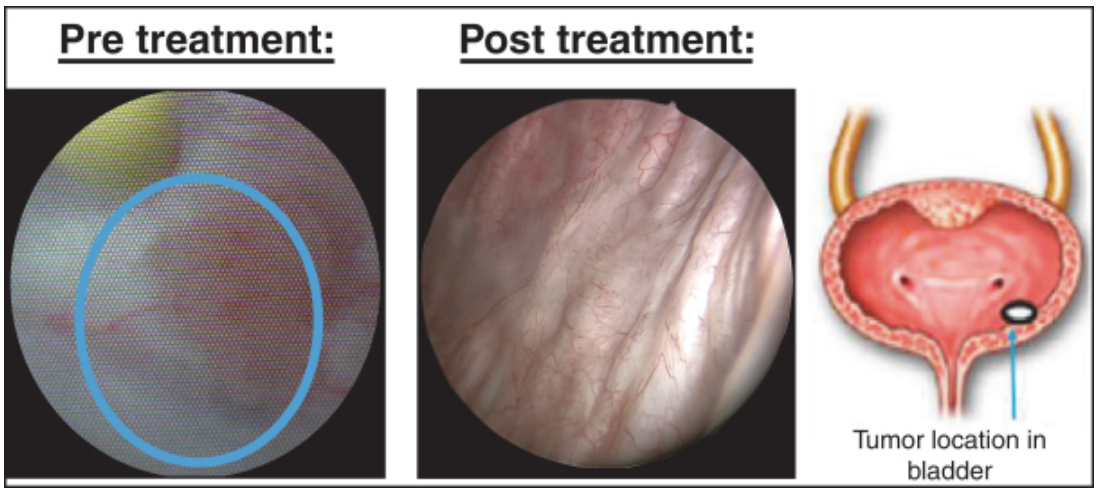
We also observed a difference in the complete response rate between the VesiGel 0.12% arm compared to the MMC 0.10% control arm when evaluating the effect of chemoablation on the number of tumors. In cases of three or fewer tumors, the complete response rate was 80% and 87% in the MMC 0.10% control group and the VesiGel 0.12% group, respectively. However, in cases of more than three tumors, the complete response rate was 50% and 100% in the MMC 0.10% control group and the VesiGel 0.12% group, respectively.

The graph below illustrates the complete response rates by tumor volume for the VesiGel 0.12% and MMC 0.10% control treatment arms.



To date, the incidence of AEs reported for both VesiGel groups in the study has been low and appear similar to that of the active control group, with the majority of the AEs having occurred in the VesiGel 0.2% group. The main observed AEs related to VesiGel have been dysuria, allergy, lower urinary tract symptoms, and hematuria, or the presence of blood in the urine. The AEs that have occurred were associated with the use of MMC, MMC intravesical instillation or the cystoscopy procedure itself. The MMC-related AEs were primarily burning sensation, rash, urgency, and dysuria, which is painful or difficult urination. These AEs appear on the MMC label as potential side effects. SAEs were also reported, including allergy, weakness, hematuria, difficult or labored breathing, lower urinary tract symptoms other than dysuria, and death. None were determined to be related to VesiGel, except for two allergy cases that were resolved.

The following images show cytoscopic views of complete responses in a low-grade NMIBC patient treated with VesiGel.



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

Dose Escalation Study for VesiGel

In parallel to the ongoing Phase 2a clinical trial, in the first half of 2015, we initiated a dose escalation study for patients with NMIBC in Europe and Israel to evaluate the safety and efficacy of VesiGel at dose levels higher than 80 mg MMC. To date, we have enrolled 14 patients. All patients to date have been treated with the 120 mg MMC in 60 ml gel dose, or 0.2% concentration. Of the 13 low-grade NMIBC patients evaluated to date, 10 have achieved a complete response. However, at the 120 mg MMC dose level, we also observed a higher rate of MMC-related AEs than in patients treated with the 80 mg MMC dose. Five of 13 patients did not complete six weekly instillations due to their non-compliance. As a result, we have determined to focus our development efforts going forward on the 80 mg MMC dose level.

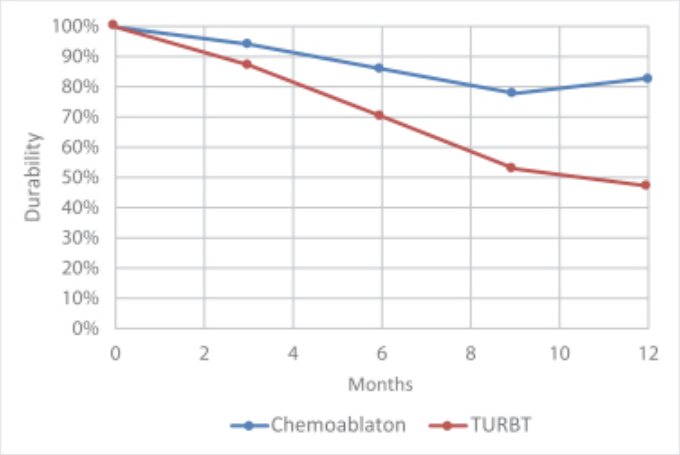
Phase 1 Clinical Trial for VesiGel

In early 2014, we completed a Phase 1 clinical trial in India evaluating two earlier formulations of VesiGel. Patients underwent six weekly instillations according to their assigned treatment of RTGel (40 ml) formulated with either 40 mg MMC or 80 mg MMC. Following completion of the six instillations, patients were evaluated for safety and efficacy. We enrolled 18 patients, 14 of whom were evaluated for response to treatment. Of the 14 evaluable patients, seven achieved a complete response, with two out of five from the 40 mg MMC arm and five out of nine from the 80 mg MMC arm. Patients were followed for one year after treatment. The results of this study led to the initiation of the ongoing Phase 2a clinical trial, in which we are using a higher volume of RTGel, 64 ml compared to 40 ml, in an attempt to further enhance the efficacy of the 40 mg and 80 mg MMC VesiGel dose groups, by increasing the dwell time of the drug.

Durability of Response

All of the patients in our Phase 2a and Phase 1 clinical trials were followed for 12 months after the primary disease evaluation time point. Those who achieved a complete response (*i.e.*, the chemoablation group) did not undergo any additional treatments. Those who had a partial response or no response underwent TURBT followed by adjuvant therapy according to the standard of care (*i.e.*, the TURBT group). 54, 49, 46 and 43 patients completed 3, 6, 9 and 12 month follow-up meetings, respectively. In the chemoablation group, 94% 86% 78% and 83% had durable complete responses at 3, 6, 9 and 12 months, respectively. In the TURBT group, 87%, 70%, 53% and 47% had durable complete responses at 3, 6, 9 and 12 months, respectively.

The graph below demonstrates the durability data for the two groups.



We believe that these results support our belief that VesiGel, acting as a chemoablation agent, can replace TURBT, with the possibility of improving durability of response.

Next Steps in the Clinical Development of VesiGel

We plan to complete the ongoing Phase 2a clinical trial in the first half of 2016. We plan to meet with the FDA in mid-2016 to discuss next steps in the clinical development program for VesiGel and timing for IND submission. We expect to file an IND for VesiGel in the first half of 2017 and to commence a Phase 2b clinical trial for VesiGel following the IND submission, if accepted, also in the first half of 2017.

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

We are developing Vesimune, our immune-modulation product candidate, for the treatment of high-grade NMIBC. A Phase 1 dose escalation study was conducted in 23 NMIBC patients and Vesimune appeared to be well-tolerated in the study. This was followed by a Phase 1 pilot study under an IND in 12 patients with CIS bladder cancer in the United States. 40% of the 10 evaluable patients achieved a complete response, and Vesimune was observed to be well-tolerated in the trial. We intend to further investigate the use of Vesimune for the treatment of high-grade NMIBC, as a single agent or possibly combining it with VesiGel or MitoGel.

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 Black Box warning on the label.

Our Solution: Vesimune

We believe that Vesimune, 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. Vesimune's active ingredient is Imiquimod, an imidazoquinoline, synthetic immune modulator, which specifically targets TLR7, which is expressed in bladder cancer cells. Toll-like receptors are pattern recognition receptors whose importance in stimulating innate and adaptive immunity has been established by recent studies and approval by the FDA of various cancer immunotherapies. 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. Vesimune is a liquid formulation of Imiquimod for intravesical administration that has been optimized for delivery in the urinary tract. Vesimune does not use our RTGel technology. We believe that Vesimune may elicit an adaptive immune response in the presence of released bladder cancer antigens, which may translate into a long lasting acquired immune response. Vesimune could as a result represent a viable alternative to BCG for the adjuvant treatment of high-grade NMIBC.

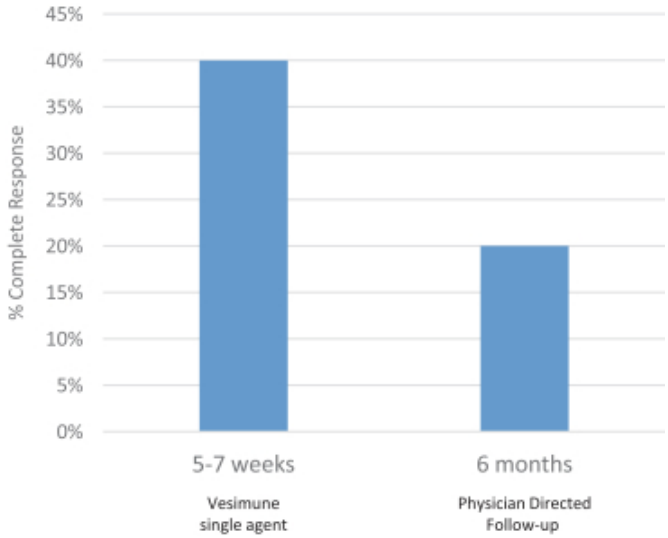
We have obtained Orphan Drug Designation for Vesimune for the treatment of CIS in the bladder. We have an active IND for Vesimune, which has been effective since 2013.

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

Vesimune Clinical Results and Post-Study Follow-Up

Vesimune was evaluated in a Phase 1 dose escalation study that enrolled 23 patients diagnosed with NMIBC. Vesimune was well-tolerated at the doses used. Subsequently, a Phase 1b study of Vesimune was conducted under an IND in patients with CIS bladder cancer in the United States. The Phase 1b study was commenced in April 2013 and completed in February 2014. Patients were dosed with Vesimune 0.4% weekly for six weeks. The study was designed to evaluate the safety and preliminary efficacy of Vesimune in CIS patients. The primary efficacy endpoint for observational purposes only was the rate of complete response at five to seven weeks after the sixth weekly instillation. Twelve patients were enrolled into the pilot study, of which 10 patients were evaluable for response. Four of the 10 patients, or 40%, achieved a complete response. Vesimune was observed to be well tolerated in this trial. The most common AEs related to Vesimune were urination urgency, dysuria, fatigue, urinary tract infections and hematuria. One SAE, a urinary tract infection, was observed and was resolved. For observational purposes, patients were followed for an additional six month period beyond the completion of the study, referred to as the Post-Study Follow Up. Of the four patients who had achieved a complete response with Vesimune in the study, two patients remained disease free at the end of the Post-Study Follow Up while receiving no additional therapy. The two other patients who had achieved a complete response with Vesimune in the study also remained disease free at the end of the Post-Study Follow Up while receiving BCG therapy during this period.

The chart below represents the complete response rates for patients receiving only Vesimune:



Next Steps in the Clinical Development of Vesimune

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

BotuGel: Our Product Candidate for the Treatment of Overactive Bladder and Interstitial Cystitis

Overactive Bladder

We are developing BotuGel, a novel formulation of botulinum toxin and RTGel, for the treatment of overactive bladder. Overactive bladder is a common condition that occurs mostly in adults, affecting an estimated 33 million people in the United States. Overactive bladder is defined by the International Continence Society as severe urgency and frequency of urination or urinary incontinence. Urgency is defined as a sudden compelling desire to pass urine, which is difficult to defer. Frequency is associated with small volumes of urine voided, and patients suffering from frequency are usually awoken at night to urinate. These urological symptoms can have a considerable negative impact on an individual's physical quality of life and the psychological effects of suffering from overactive bladder can negatively affect relationships, intimacy and self-image.

The safety and efficacy of BotuGel in overactive bladder patients was evaluated in an investigator-initiated, Phase 2, double-blind, randomized study conducted in the Czech Republic. In this study, which enrolled 39 patients, it was observed that longer contact time of botulinum toxin with bladder tissue may have a positive effect on the symptoms of overactive bladder.

Limitations of Current Therapies for Overactive Bladder

The pathophysiology of overactive bladder is not fully understood. Behavioral therapy, including fluid intake regulation, weight loss, caffeine reduction and bladder re-training, is often the first recommended therapy. The most common drug treatment option for overactive bladder is treatment with anticholinergics, which are neurotransmitters that act in the central and peripheral nervous system. However, 50% of patients receiving anticholinergics do not respond to the treatment. Where treatment with anticholinergics fails, physicians may rely on invasive interventions such as botulinum toxin injections into the bladder muscle, and neuromodulation, which is the alteration of nerve activity through application of electrical or drug agents directly to a brain area. Reconstructive surgery exists as a last resort.

Treatment with botulinum toxin is FDA-approved as a therapeutic option for overactive bladder. A Phase 3 clinical trial conducted to support the approval has shown that botulinum toxin administered by intramural injection into the bladder wall in patients with overactive bladder leads to improvement in urge and incontinence. However, we believe the current mode of administration has several disadvantages, including the fact that the procedure is conducted under general anesthesia, the requirement of cystoscopy, which is a video guide inserted through the urethra into the bladder, a need to inject the botulinum toxin into the muscle and the non-uniformity of the distribution of such injections, and the occurrence of urinary retention.

In addition, the bladder wall is believed to play an important role in bladder sensation and the pathophysiology of overactive bladder. As a result, we believe intravesical instillation of botulinum toxin is a potential alternative to injection into the bladder wall. To date, however, we believe the potential efficacy of intravesical instillation of botulinum toxin has been limited by insufficient duration of exposure of the active drug to the bladder, resulting, we believe, from formulation of the botulinum toxin with saline solution.

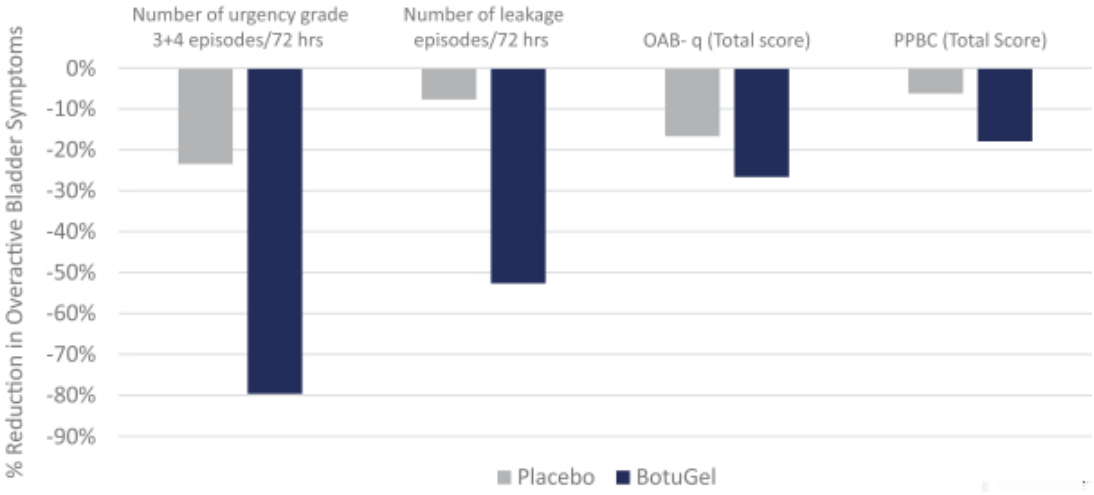
Our Solution: BotuGel

Using our proprietary RTGel technology, we have developed BotuGel, a novel formulation of botulinum toxin and RTGel for the treatment of overactive bladder.

We believe instillation of BotuGel to treat overactive bladder may be superior to instillation of a botulinum toxin-saline mixture because our RTGel-based formulation has the ability to significantly increase the dwell time of botulinum toxin in the bladder to several hours, without preventing the patient from urinating. Prolongation of treatment duration may increase botulinum toxin bioavailability and thus increase treatment efficacy. In addition, we believe that providing a potentially more effective instillation treatment option may increase patient compliance compared to patients treated with the current injection administration procedure for botulinum toxin.

Initial Clinical Results of BotuGel for the Treatment of Overactive Bladder

The safety and efficacy of BotuGel in overactive bladder patients was evaluated in an investigator-initiated, double-blind, randomized study conducted at the University Hospital Ostrava Czech Republic. The study was commenced in August 2013 and was completed in September 2014. The study, which enrolled 39 female patients ages 18 to 65 who had experienced overactive bladder symptoms for longer than three months, was designed to evaluate urge to urinate, incontinence and certain quality of life measures at one month. Patients were assigned to each of two primary treatment arms. Nine patients were administered BotuGel containing 200 units of botulinum toxin and 11 patients were administered saline as placebo. Each received a single instillation per their respective treatment assignment. Only one AE, urinary tract infection, was reported, which was determined to be treatment/procedure-related and not related to treatment with BotuGel. No SAEs were reported. The chart below summarizes the results observed at one month.



Next Steps in the Clinical Development of BotuGel for Overactive Bladder

Based on the data from the investigator-initiated study of BotuGel, we intend to conduct a dose-ranging study of BotuGel outside of the United States in 2017.

In addition, we have a preclinical collaboration for BotuGel with a large pharmaceutical partner. We anticipate the submission of an IND filing for BotuGel in the first half of 2017, which, if accepted, may be followed by clinical trials conducted by our partner.

Interstitial Cystitis

We are also developing BotuGel for the treatment of interstitial cystitis. Interstitial cystitis affects at least an estimated four million people in the United States. Interstitial cystitis is characterized by chronic (*i.e.*, extending over more than six months) pelvic pain of unknown etiology during urination, coupled with frequent urination. This pelvic pain often changes as the bladder fills and empties. We conducted an open-label, single-arm pilot trial in Israel evaluating the safety and efficacy of intravesical instillation of BotuGel 200 units in 15 patients with interstitial cystitis. The trial was commenced in November 2013 and was completed in August 2014. The primary endpoint for observational purposes only was to evaluate the effect of BotuGel 200 units on pain symptoms of patients with interstitial cystitis at two, six and 12 weeks after a single instillation. Patients were evaluated using the visual analogue scale, or VAS. A reduction from baseline in the VAS score was observed at the first follow-up visit at week two. This reduction was also observed at week 12. In this trial, we did not observe any discomfort or pain associated with the procedure and no lasting adverse effects associated with the treatment were reported. Short-term AEs, consisting primarily of constipation, were reported, but were resolved after 24 hours of being reported.

Limitations of Current Therapies for Interstitial Cystitis

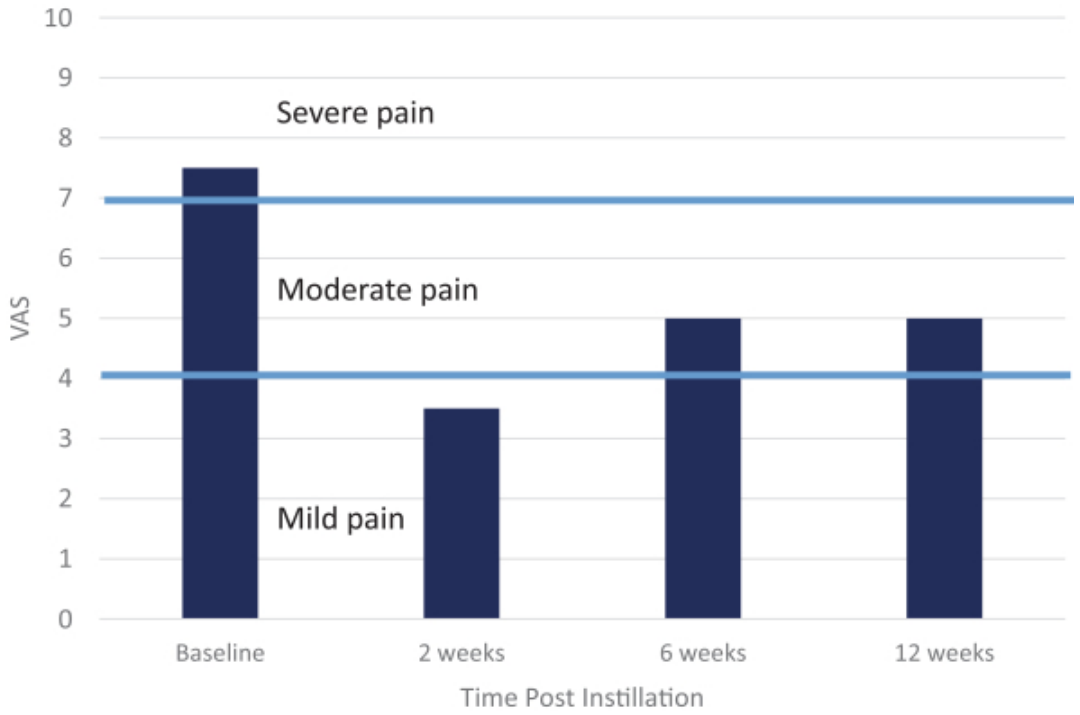
According to the American Urology Association guidelines, there are several lines of recommended therapy for interstitial cystitis including behavioral modification techniques and symptom control treatments. Symptom control treatments include local and systemic pain management drugs, ablation of lesions by fulguration, which is a procedure that uses heat from an electric current to destroy abnormal tissue, neurostimulation, botulinum toxin injections to the muscle and surgery. There is currently only one drug approved by the FDA for the treatment of interstitial cystitis, Elmiron (Janssen Pharmaceuticals).

There have been several open-label studies that have tested the efficacy of instillations of botulinum toxin for the treatment of interstitial cystitis. One such study reported short-lived (*i.e.*, one week) improvement of symptoms after a single intravesical instillation of 200 units of botulinum toxin diluted in 50 ml of saline. Inadequate dose, insufficient instillation time and/or absence of pre-instillation administration of substances to increase urothelial permeability were believed to account for the lack of efficacy in this study.

Initial Clinical Results of BotuGel for Interstitial Cystitis

We conducted an open-label, single-arm pilot trial evaluating the safety and efficacy of intravesical instillation of BotuGel 200 units in patients with interstitial cystitis. This pilot trial was conducted in Israel and enrolled 15 patients. The patients underwent a single intravesical instillation of BotuGel and were followed at two, six and 12 weeks post instillation. We did not observe any severe discomfort or pain associated with the procedure. The primary end-point was the pain score, per the VAS. No lasting adverse effects associated with the treatment were reported.

The following chart illustrates the average VAS scores during the pilot trial.



Next Steps in the Clinical Development of BotuGel for Interstitial Cystitis

Based on the reduction in pain score we observed in the interstitial cystitis pilot trial, we intend to conduct a dose-ranging trial of BotuGel outside of the United States in 2017.

Preclinical Programs

Using our proprietary RTGel formulation technology, we are pursuing additional preclinical programs to expand and enhance our uro-oncology product portfolio. In particular, we are pursuing preclinical programs for high-grade bladder cancer and high-grade UTUC.

Intellectual Property

We seek patent protection for all of our product candidates, and we have established several patents families comprised of issued patents and pending patent applications covering our proprietary RTGel formulation technology and the formulations, methods of use and manufacturing aspects of our product candidates. In the United States, we currently have four issued patents in the United States and several patent applications worldwide related to methods, systems and compositions for treating bladder cancer related to our lead product candidates, MitoGel and VesiGel, as well as RTGel, both on its own and formulated with other drugs. The four issued patents are expected to remain in effect until between 2024 and 2030. We also have five pending patent applications relating to MitoGel and VesiGel in Europe, the United States and Israel, and five pending patent applications relating to BotuGel in the United States and the European Union, as well as in each of Russia, China, and Israel. In addition, we have two granted patents related to Vesimune in the United States as well as granted patents in the European Union, Japan, Australia, Mexico and China, each of which are expected to remain in effect until 2031. In addition to the issued patents mentioned above, our portfolio includes pending patent applications relating to Vesimune in the United States, the European Union, Canada, Korea, Brazil, Israel, Hong Kong and Japan.

Our patents and patent applications mainly relate to hydrogel-based pharmaceutical compositions for optimal delivery of any drug to the internal cavity such as a bladder and/or urinary tract; the method for treating urothelial

cancer using hydrogel based composition; the method for treating overactive bladder and interstitial cystitis topically without a need for injections; special catheters and in-dwelling ureter-catheter systems for optimal delivery of a drug into the renal cavity; pharmaceutical compositions comprising an imidazoquinolin-amine (specifically imiquimod) and lactic acid for treating bladder cancer diseases, and novel phospholipid drug analogs for treating cancer or infections.

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.

We submit applications directly to the United States Patent and Trademark Office, or USPTO, as provisional patent applications. Then usually we continue filing under the Patent Cooperation Treaty, or PCT, which is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in any one of the designated member states. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

Competition

The standard of care for treating NMIBC patients is the TURBT procedure for tumor resection, followed by post-operative adjuvant chemotherapy or immunotherapy instillations, administered to prevent re-seeding of the cancerous cells. The adjuvant agents used are predominately generic treatments and regimens. Only three drugs have been approved for bladder cancer: Thiotepa, which was approved by the FDA in 1959, BCG, which was approved by the FDA in 1989 and Valstar, which was approved by the FDA in 1998. Even though there remain high unmet needs in the bladder cancer market, nothing has replaced these drugs in recent years. BCG has been used to treat patients with CIS and high-grade T1 since 1990. Thiotepa and Valstar are rarely used, and MMC is used off-label as the standard adjuvant treatment in the post-TURBT setting for low-grade NMIBC patients. Off-label means that while the FDA has not approved MMC as adjuvant treatment in the post-TURBT setting for low-grade NMIBC patients, physicians are permitted to utilize it as standard of care for this indication as part of medical practice. However, off-label usage as a standard of care does not change the FDA's approval criteria and does not suggest that FDA approval is more likely than for other investigational drugs. In the UTUC space, there are no approved drugs used to treat the disease. Tumor resection surgeries are conducted in some cases of low-grade UTUC; however, partial or complete kidney and upper urothelial tract removal is the standard of care for frequently recurring UTUC.

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

We are aware that other companies, such as Merck Sharp & Dohme Corp., Viventia Bio Inc., Telesta Therapeutics Inc., Heat Biologics, Inc., Viralytics Limited, AADi, LLC, Biocancell Ltd., Halozyme Therapeutics, Inc., Astellas Pharma Inc., Cold Genesys, Inc., Altor BioScience Corporation, FKD Therapies Oy, Nippon Kayaku Co., Ltd, Spectrum Pharmaceuticals, Inc., Taris Biomedical LLC and Handok Inc., are conducting or have recently conducted clinical trials for product candidates for the treatment of low-grade and high-grade NMIBC, including CIS. In addition, we are aware of several pharmaceutical companies that are developing drug candidates for muscle-invasive bladder cancer. We do not know whether these potential competitors are already developing, or plan to develop, low-grade UTUC or high-grade UTUC treatments or other indications that we are pursuing.

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

We are not aware of any company developing a sustained release formulation of botulinum toxin for intravesical bladder instillations for the treatment of overactive bladder. The standard of care for treating patients with overactive bladder is anticholinergic drugs, which are medications that relax the bladder and are helpful for relieving symptoms and reducing episodes of urge incontinence. The following anticholinergic drugs are FDA-approved: Tolterodine (Detrol), Oxybutynin (Ditropan; Oxytrol), Trospium (Sanctura), Solifenacin (Vesicare), Darifenacin (Enablex), Mirabegron (Myrbetriq), Flavoxate (Urispas) and Fesoterodine (Toviaz). Even though there are several drugs approved for overactive bladder, we believe a high unmet medical need remains as these drugs are associated with side effects such as dry mouth, dry eyes and constipation occurring in up to 50% of patients. Botulinum toxin A, or Botox, injections into the bladder muscle are another option for these patients. Botox, an acetylcholine release inhibitor and a neuromuscular blocking agent, is indicated for the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency in adults who have an inadequate response to or are intolerant of an anticholinergic medication. Botox is also indicated for the treatment of urinary incontinence due to overactive or uncontrolled contraction of the bladder wall associated with a neurological condition, such as a spinal cord injury or multiple sclerosis, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

We are not aware of any company developing sustained release formulations of botulinum toxin for intravesical bladder administration for the treatment of interstitial cystitis. The only oral medicine that is FDA-approved for the treatment of interstitial cystitis is Pentosan (Elmiron), which was approved in 1996 and is indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. Another drug that is also used for the treatment of interstitial cystitis is dimethyl sulfoxide (Rimso-50), which is administered intravesically and was approved in 1978 to treat symptoms of chronic inflammatory bladder disease. At this time, we believe there remains a high unmet medical need for treatments for interstitial cystitis.

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 licensing on an exclusive basis products that are more effective, easier to administer or less costly than our product candidates.

Government Regulation

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

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

- nonclinical laboratory and animal tests that must be conducted in accordance with good laboratory practices, or GLPs;
- submission of an IND, which must become effective before clinical trials may begin;
- approval by an independent institutional review board, or IRB, for each clinical site or centrally before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended use, performed in accordance with good clinical practices, or GCPs;

- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMP and GCPs; and
- FDA approval of an NDA to permit commercial marketing for particular indications for use.

Prior to the commencement of marketing of controlled substances, the DEA must also determine the controlled substance schedule, taking into account the recommendation of the FDA.

The testing and approval process requires substantial time, effort and financial resources. Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a product candidate, we must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial by imposing a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each study site proposing to conduct the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans. Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, if the drug has been associated with unexpected serious harm to subjects, or based on evolving business objectives or competitive climate. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise us to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

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

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

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

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

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

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

505(b)(2) Regulatory Approval Process

Section 505(b)(2) of the FDCA, or 505(b)(2), provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The applicant may rely upon the FDA's prior findings of safety and efficacy for an approved product that acts as the reference listed drug for purposes of a 505(b)(2) NDA. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support any changes from the reference listed drug. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

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

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

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

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

Exclusivity

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

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

an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Abbreviated Licensure Pathway of Biologics as Biosimilar or Interchangeable under 351(k)

The Biologics Price Competition and Innovation Act, or BPCIA, amended the Public Health Service Act by adding Section 351(k), which created an abbreviated approval pathway for biologics shown to be highly similar to an FDA-licensed reference biologic. Biosimilarity is demonstrated through extensive analytical studies, animal studies (when deemed necessary), and clinical trials. An application submitted under the 351(k) pathway must include information demonstrating that the proposed biosimilar product and reference product have the same route of administration, dosage form and the strength and the biosimilar product utilizes the same mechanism of action for the condition(s) of use approved in the proposed labeling to the extent the mechanism(s) of action are known for the reference product.

The BPCIA provides for a designation of “interchangeability” between the reference and biosimilar products, whereby the biosimilar may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. After the assessment of biosimilarity, the higher standard of interchangeability must be demonstrated by information sufficient to show that the proposed product is expected to produce the same clinical result as the reference product in any given patient and for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the reference product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving, or accepting applications for, any product candidates that are purportedly biosimilar to the reference product. The FDA cannot approve a biosimilar application for 12 years from the date of first licensure of the reference product. Additionally, a biosimilar product sponsor may not submit an application under the 351(k) pathway for four years from the date of first licensure of the reference product. The first biosimilar product determined to be interchangeable with a reference product for any condition of use is also entitled to a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the reference product for any condition of use. This exclusivity period extends until the earlier of: (i) one year after the first commercial marketing of the first interchangeable product; (ii) 18 months after resolution of a patent infringement suit against the applicant that submitted the application for the first approved interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (iii) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted against the applicant that submitted the application for the first interchangeable product is still ongoing; or (iv) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued for patent infringement.

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.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. These user fees must be filed 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 must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients, that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary of the reasons for not referring it to an advisory committee. The FDA may also refer drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

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

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter, or CRL, or approval letter. A CRL indicates that the review cycle of the application is complete and the application is not

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

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

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling, which has resulted in a Black Box 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 user fee requirements for any approved products and the establishments at which such products are manufactured, 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.

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

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

Other Healthcare Regulations

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for, or purchasing, leasing, ordering, or arranging for the purchase, lease or order of, any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. 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, and other healthcare criminal fraud statutes, 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 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 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 or to avoid, decrease or conceal an obligation to pay money to the federal government.

We, and our business activities, are subject to the civil monetary penalties statute which 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 False Claims Act liability.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program 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. Additionally, the ACA amended the intent requirement of some of these criminal statutes 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 committed a violation.

Additionally, the federal Open Payments program pursuant to the Physician Payments Sunshine Act, created under Section 6002 of the ACA and its implementing regulations, require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1.0 million per year for "knowing failures."

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. 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 and may not have the same effect, thus complicating compliance efforts.

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 third-party payor, including commercial insurers. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Enforcement actions can be brought by federal or state governments or 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 penalties, including criminal, civil and/or administrative criminal penalties, damages, fines, disgorgement, debarment from government contracts, exclusion of products from reimbursement under 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 government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. 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.

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 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 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, what the level of reimbursement will be. 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 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 is changing health care financing by both governmental and private insurers and significantly affecting 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 utilization of prescriptions of individuals enrolled in 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. We continue to evaluate the effect that the ACA has on our business. There have been judicial and U.S. Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future.

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, following passage of the Bipartisan Budget Act of 2015, and will remain in effect through 2025 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 bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Additional health reform measures may continue and affect our business in unknown ways.

The Foreign Corrupt Practices Act

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

Foreign Regulation

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

Manufacturing, Supply and Production

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on third-party contract manufacturers for all of our required raw materials, active ingredients and finished products for our preclinical research and clinical trials, including the proposed single pivotal Phase 3 clinical trial for MitoGel. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of our product candidates if they are approved. If product candidates are approved by any regulatory agency, we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of those products.

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

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

Marketing, Sales and Distribution

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

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

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

Employees

As of December 31, 2015, we had 24 full-time employees and four part-time employees, 27 based in Israel and one based in the United States. Of these employees, 19 are primarily engaged in research and development activities and nine are primarily engaged in general and administrative matters. A total of 10 employees have an M.D. or Ph.D. degree. None of our employees is represented by a labor union. We have never experienced any employment-related work stoppages and believe 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.

Facilities

Our principal executive offices are located at 9 HaTa'asiya St., Ra'anana 4365007, Israel, where we lease an approximately 617 square meter facility. This Israeli facility houses our administrative headquarters and our research and development laboratories. Our wholly owned subsidiary's office is located at 689 Fifth Avenue, New York, New York, where we lease an approximately 694 square meter space. The New York facility houses our subsidiary's headquarters. 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.

Environmental, Health and Safety Matters

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, primarily Israel, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage. Our operations use chemicals and produce waste materials and sewage and require permits from various governmental authorities including, local municipal authorities, the Ministry of Environmental Protection and the Ministry of Health. The Ministry of Environmental Protection and the Ministry of Health, local authorities and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with the various regulations. These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If we fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations. In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities which were previously permitted.

Legal and Corporate Structure

Our legal and commercial name is UroGen Pharma Ltd. We were formed as a company in the State of Israel in April 2004. Urogen Pharma, Inc., our wholly owned subsidiary, was incorporated under the laws of the State of Delaware in October 2015.

Legal Proceedings

From time to time, we may become party to litigation or other legal proceedings that we consider to be a part of the ordinary course of our business. We are not currently involved in any legal proceedings that could reasonably be expected to have a material adverse effect on our business, financial condition or results of operations.

MANAGEMENT

Executive Officers, Key Personnel and Directors

The following table sets forth information relating to our executive officers, key personnel and directors as of December 31, 2015. Unless otherwise stated, the address for our executive officers, key personnel and directors is c/o UroGen Pharma Ltd., 9 Ha'Ta'asiya Street, Ra'anana 4365007, Israel.

NAME	AGE	POSITION
Executive Officers		
Ron Bentsur	50	Chief Executive Officer and Director
Gil Hakim	46	President, Israeli Operation
Gary Titus	56	Chief Financial Officer
Key Personnel		
Mark Schoenberg, M.D.	58	Medical Director
Non-Employee Directors		
Arie Belldegrun, M.D.	66	Chairman of the Board of Directors
Stuart Holden, M.D.	73	Director
Chaim Hurvitz	55	Director
Ran Nussbaum	40	Director
Pini Orbach, Ph.D.	51	Director

Our Executive Officers

Ron Bentsur has served as our Chief Executive Officer since August 2015, and as a member of our board of directors since October 2015. Mr. Bentsur has served as a member of the board of directors of Stemline Therapeutics, Inc. since 2009 and as Executive Chairman of Advanced Inhalation Technologies, Ltd. since August 2015. Mr. Bentsur has more than 15 years of experience in the biotech industry. Until 2015, Mr. Bentsur served for more than five years as the Chief Executive Officer of Keryx Biopharmaceuticals, Inc., and during his tenure, Keryx received FDA approval pursuant to the FDA's 505(b)(2) regulatory pathway for Auryxia (ferric citrate) and launched it commercially in the United States. Prior to that Mr. Bentsur served as Chief Executive Officer of XTL Biopharmaceuticals Ltd., a position he held from January 2006 until April 2009. From October 2000 Mr. Bentsur was with Keryx and served as its Chief Financial Officer from June 2003 until his departure in January 2006. From July 1998 to October 2000, Mr. Bentsur served as Director of Technology Investment Banking at Leumi Underwriters, where he was responsible for all technology/biotechnology private placement and advisory transactions. From June 1994 to July 1998, Mr. Bentsur worked as an investment banker in New York City, spending most of this period at ING Barings Furman Selz. Mr. Bentsur is a Director of Stemline Therapeutics, Inc. and Executive Chairman of Advanced Inhalation Therapies (AIT) Ltd. Mr. Bentsur holds a B.A. in Economics and Business Administration with distinction from the Hebrew University of Jerusalem, Israel and an M.B.A. (Magna Cum Laude), from New York University's Stern School of Business.

Gil Hakim has served as our President, Israeli Operation since August 2015 and, prior to that, served as our Chief Executive Officer since August 2010. Mr. Hakim has more than 20 years of experience in the biotech industry. Prior to joining us, Mr. Hakim served as Director of New Product Development at Medispec Ltd. from 2004 to 2010, and was in charge of product development in fields such as cardiology, urology and dermatology. Prior to Medispec, from 2002 to 2004, Mr. Hakim was Director of Marketing and Clinical Research at MTRE Advanced Technologies Ltd., a wholly owned subsidiary of Mennen Medical Ltd. that develops thermoregulation devices. Prior to that, from 2000 to 2002, he was Business Development Manager at Omrix Biopharmaceuticals, Inc. (acquired by Johnson & Johnson in 2008), which develops biological glue and blood derivative products. Before that, from 1998 to 2000, he served as European Product Manager at Biosense-Webster (Johnson & Johnson) in Belgium, following Johnson & Johnson's acquisition of Biosense Israel, where he was also part of the Research and Development team. Mr. Hakim holds a B.Sc. in Life Sciences from Ben-Gurion University, Israel.

Gary Titus has served as our Chief Financial Officer since July 2015. Mr. Titus has been a member of the board of directors of ImmunoCellular Therapeutics, Ltd. since January 2013. Mr. Titus has more than 20 years of business experience in the healthcare and biopharmaceutical industries, primarily in senior management roles. Prior to his appointment as our Chief Financial Officer, from 2014 to 2015, Mr. Titus held the position of Chief Financial Officer of BioCardia, Inc. Prior to that, from 2008 to 2013, Mr. Titus was Senior Vice President and Chief Financial Officer at SciClone Pharmaceuticals, Inc. From 2006 to 2008, Mr. Titus was Senior Vice President of Finance and Chief Financial Officer at Kosan Biosciences, Inc. From 2003 to 2006, he was Chief Financial Officer and Vice President at Nuvelo, Inc. Earlier in his career, Mr. Titus held a variety of positions at other companies, including Metabolex, Inc., Intrabiotics Pharmaceuticals, Inc. and Johnson & Johnson. Mr. Titus holds a B.Sc. in Accounting from University of South Florida and a B.Sc. in Finance from University of Florida. Mr. Titus also completed the Global BioExecutive Program at the University of California Berkeley's Haas School of Business.

Our Key Personnel

Mark Schoenberg, M.D. has served as our Medical Director since February 2016. Dr. Schoenberg has over 20 years of experience in clinical practice and research focused on the care of patients with all forms of bladder cancer. Since April 2014, Dr. Schoenberg has been Professor and University Chair at The Montefiore Medical Center and The Albert Einstein College of Medicine of Yeshiva University. Prior to joining Montefiore, from 2005 to 2014, Dr. Schoenberg served as Director of Urologic Oncology and Bernard L. Schwartz Distinguished Professor of Urology at Johns Hopkins Hospital. Dr. Schoenberg is also the past chair of the Medical Advisory Board of the Bladder Cancer Advocacy Network, the author of The Guide to Living with Bladder Cancer, co-editor of The Textbook of Bladder Cancer, a contributor to Campbell's Urology and a seminars editor of the journal Urologic Oncology. Dr. Schoenberg received his M.D. (Alpha Omega Alpha) from the University of Texas Health Sciences Center and completed his residency in General Surgery and Urology at the Hospital of The University of Pennsylvania, where he served as chief resident and urology instructor, before completing basic research and clinical urologic oncology fellowships at Johns Hopkins under the auspices of The American Cancer Society. Dr. Schoenberg is a fellow of the American College of Surgeons, as well as a member of the American Association of Cancer Research, the Society of Urologic Oncology and the American Urological Association.

Our Directors

Arie Belldegrun, M.D. has served as our Chairman since December 2012. Dr. Belldegrun is Professor of Urology, holds the Roy and Carol Doumani Chair in Urologic Oncology, and Director of the UCLA Institute of Urologic Oncology at the David Geffen School of Medicine at UCLA. Prior to joining UCLA, he was a research fellow at the National Cancer Institute/National Institute of Health in surgical oncology and immunotherapy under Dr. Steven A. Rosenberg. Dr. Belldegrun has more than 20 years of experience in the life science and biotech industry. In 1996 he founded Agensys, Inc., a biotechnology company, and served as its founding Chairman of the board of directors and as a board member until 2007, when it was acquired by Astellas Pharma Inc. Dr. Belldegrun was also a founder and the Vice-Chairman of the board of directors and Chairman of the scientific advisory board of Cougar Biotechnology, Inc., a biotechnology company, from 2003 to 2009, when it was acquired by Johnson & Johnson. He currently serves as Chairman and Chief Executive Officer of Kite Pharma, Inc. (NASDAQ: KITE), Chairman of Arno Therapeutics, Inc., and Two River Group and as a board member of Teva Pharmaceutical Industries Ltd. Dr. Belldegrun completed his M.D. at the Hebrew University Hadassah Medical School in Jerusalem, Israel, his post graduate studies in Immunology at the Weizmann Institute of Science, Israel, and his residency in Urologic Surgery at Harvard Medical School. Dr. Belldegrun has authored several books in oncology and more than 500 scientific and medical papers related to urological cancers, immunotherapy, gene therapy, and cancer vaccines. Dr. Belldegrun is certified by the American Board of Urology and is a Fellow of the American College of Surgeons and the American Association of Genitourinary Surgeons.

Stuart Holden, M.D. has served as our director since December 2015. Dr. Holden has been the Chairman of ProQuest Investments' Scientific Advisory Board since it was founded in 1998. Since May 2014, Dr. Holden has served as a member of the UCLA faculty as a Health Sciences Clinical Professor of Urology, Spielberg Family Chair in Urologic Oncology, in the Department of Urology at the UCLA David Geffen School of Medicine and Associate Director of the UCLA Institute of Urologic Oncology. Dr. Holden has worked in the field of prostate cancer for more than 36 years. Dr. Holden also serves as Medical Director of the Prostate Cancer Foundation since the foundation's inception in 1993. Dr. Holden was the director of the Louis Warschaw Prostate Cancer Center at Cedars-Sinai

Medical Center and the first holder of the Warschaw, Robertson, Law Families Chair in Prostate Cancer. Dr. Holden has served as a member of the board of directors of Telormedix SA since 2008, and served as a member of the board of directors of Acurian, Inc. from 1999 through 2014. In addition, he was a founding partner at Tower Urology in Los Angeles. Dr. Holden received a B.A. degree from the University of Wisconsin-Madison and completed his medical degree and received his surgical training at Weill Cornell Medical College and the New York Hospital—Cornell University Medical College. He completed his urology residency at Emory University School of Medicine and fellowships in urology and developmental genetics at Memorial Sloan-Kettering Cancer Center. He also was awarded a clinical fellowship from the American Cancer Society. Dr. Holden was appointed to serve on our board by ProQuest Investments IV, L.P., one of our shareholders, pursuant to rights granted to such shareholder under our articles of association as in effect prior to this offering.

Chaim Hurvitz has served as our director since May 2013. Mr. Hurvitz has 31 years of experience in the life sciences industry. Mr. Hurvitz currently serves as Chief Executive Officer of CH Health, a private venture capital firm, a position he has held since May 2011. Prior to that, Mr. Hurvitz was a member of the senior management of Teva Pharmaceutical Industries Ltd., serving as the President of Teva International Group from 2002 until 2010, as President and Chief Executive Officer of Teva Pharmaceuticals Europe from 1992 to 1999 and as Vice President Israeli Pharmaceutical Sales from 1999 until 2002. Mr. Hurvitz served as a director of Teva Pharmaceutical Industries Ltd. from 2010 to 2014. Mr. Hurvitz served as a director of Aposense Ltd. from 2010 to 2014. Mr. Hurvitz currently serves as Chairman of Galmed Pharmaceuticals Ltd. Mr. Hurvitz has been Chairman of the pharmaceuticals branch of the Manufacturer's Association of Israel since 2001 and is a member of its board. Mr. Hurvitz received a B.A. in Political Science and Economics from Tel Aviv University, Israel. Mr. Hurvitz was appointed to serve on our board by Shirat HaChaim Ltd., one of our shareholders, pursuant to rights granted to such shareholder under our articles of association as in effect prior to this offering.

Ran Nussbaum has served as our director since May 2013. Mr. Nussbaum is a managing partner and the co-founder of The Pontifax Group, a group of Israeli-based life sciences venture funds focusing on investments in development stage bio-pharmaceutical and med-tech technologies and a shareholder of our company. He also serves as a board member on many of Pontifax's portfolio companies, including Kite Pharma, Inc., BioBlast Pharma Ltd., Eloxx Pharmaceuticals Ltd., Nutrina Ltd., OCON Medical Ltd and Quiet Therapeutics Ltd. Mr. Nussbaum was appointed to serve on our board by Pontifax (Israel) III Limited Partnership and Pontifax (Cayman) III Limited, two of our shareholders, pursuant to rights granted to such shareholders under our articles of association as in effect prior to this offering.

Pini Orbach, Ph.D. has served as our director since October 2014. Dr. Orbach has served as a director of Quiet Therapeutics Ltd. since January 2013. Dr. Orbach has 10 years of experience in executive positions. Since February 2010, Dr. Orbach has been the head of Pharma and Life Science at Arkin Holdings. Dr. Orbach was the Chief Executive Officer of NanoDoc Technology, Inc. from 2010 to 2015, Chairman of the board of directors of cCAM Biotherapeutics Ltd. from 2014 to 2015, and served as a Director of Quiet Therapeutics Ltd. since January 2013, FusiMab Ltd. from 2011 to 2014, HealOr Ltd. from 2010 to 2013, Metallo-Therapy Ltd. from 2011 to 2015, Insuline Medical Ltd. from December 2013 to January 2015, and CollPlant Holdings Ltd. from May 2013 to August 2014. Prior to joining Arkin Holdings, Dr. Orbach served as Chief Executive Officer of several healthcare companies in Israel. Dr. Orbach received his Ph.D. from the Department of Physiology and Functional Genomics at the University of Florida, and was a postdoctoral fellow at the Cardiovascular Research Center at Harvard Medical School. Dr. Orbach was appointed to serve on our board by Arkin Communications Ltd., one of our shareholders, pursuant to rights granted to such shareholder under our articles of association as in effect prior to this offering.

Arrangements Concerning Election of Directors; Family Relationships

Our board of directors consists of six directors. Currently serving directors will continue to serve pursuant to their appointment until the first annual general meeting of shareholders held after this offering. We are not a party to, and are not aware of, any voting agreements among our shareholders. In addition, there are no family relationships among our executive officers and directors.

Corporate Governance Practices

After completion of this offering, we will have an audit committee comprised of members, of whom will meet The NASDAQ Stock Market independence requirements, and one of these members will also possess

the requisite financial expertise. In addition, under Israeli law we are required to have an audit committee which includes all of the external directors and consists of a majority of "unaffiliated directors" as defined under the Israeli Companies Law, 5759-1999, or the Israeli Companies Law. See "Board Committees—Audit Committee—Israeli Companies Law Requirements." Furthermore, under the Israeli Companies Law, we are required to have a compensation committee consisting of at least three members, including all of the external directors, who must constitute a majority of the members of the compensation committee. See "Board Committees—Compensation Committee and Compensation Policy—Israeli Companies Law Requirements." Subject to certain conditions in the Israeli Companies Law, our audit committee may also serve as our compensation committee.

Companies incorporated under the laws of the State of Israel, whose shares are publicly traded, including companies with shares listed on the NASDAQ Global Market, are considered public companies under Israeli law and are required to comply with various corporate governance requirements under Israeli law relating to such matters as external directors, the audit committee, the compensation committee and an internal auditor. This is the case even if our shares are not listed on the Tel Aviv Stock Exchange, or TASE, which our shares are not expected to be. These requirements are in addition to the corporate governance requirements imposed by the NASDAQ Rules and other applicable provisions of U.S. securities laws to which we will become subject (as a foreign private issuer) upon the closing of this offering and the listing of our ordinary shares on the NASDAQ Global Market. Under the NASDAQ Rules, a foreign private issuer may generally follow its home country rules of corporate governance in lieu of the comparable requirements of the NASDAQ Rules, except for certain matters including the composition and responsibilities of the audit committee and the independence of its members within the meaning of the rules and regulations of the SEC.

We intend to rely on this "home country practice exemption" with respect to the following NASDAQ requirements:

- *Quorum*. As permitted under the Israeli Companies Law and pursuant to our amended and restated articles of association to be effective upon the closing of this offering, the quorum required for an ordinary meeting of shareholders will consist of at least two shareholders present in person, by proxy or by other voting instrument in accordance with the Israeli Companies Law, who hold at least 25% of the voting power of our shares (and in an adjourned meeting, with some exceptions, at least two shareholders), instead of 33 1/3% of the issued share capital required under the NASDAQ Rules.
- *Nomination of Directors*. With the exception of external directors and directors elected by our board of directors due to a vacancy, our directors are elected at an annual general meeting of our shareholders to hold office until the next annual general meeting following his or her election. See "Board Practices—Board of Directors." The nominations for directors, which are presented to our shareholders by our board of directors, are generally made by the board of directors itself or a duly authorized committee thereof, in accordance with the provisions of our amended and restated articles of association and the Israeli Companies Law. Nominations need not be made by a nominating committee of our board of directors consisting solely of independent directors or otherwise, as required under the NASDAQ Rules.
- *Select Board and Compensation Committee Requirements*. We will not be required to and, in reliance on home country practice, we do not intend to comply with certain NASDAQ Rules applicable to domestic companies listed on the NASDAQ Global Market, which require a listed company's board of directors to be comprised of a majority of directors deemed to be independent under the NASDAQ Rules, and a listed company to maintain a compensation committee subject to specific requirements of the NASDAQ Rules, including membership consisting solely of directors deemed to be independent under the NASDAQ Rules (subject to IPO transition requirements). In accordance with Israeli corporate governance requirements, we intend to maintain a compensation committee, whose responsibilities would overlap with those required by the NASDAQ Rules, and our board of directors, or a committee thereof, will oversee the tasks that would otherwise be required of independent directors or a nominating committee under the NASDAQ Rules.
- *Proxy Statements.* We will not be required to and, in reliance on home country practice, we do not intend to comply with certain NASDAQ Rules regarding the provision of proxy statements for general meetings of shareholders. Israeli corporate law does not have a regulatory regime for the solicitation of proxies. We intend to provide notice convening an annual general meeting, including an agenda and other relevant documents.

- *Shareholder Approval.* We will not be required to and, in reliance on home country practice, we do not intend to comply with certain NASDAQ Rules regarding shareholder approval for certain issuances of securities under NASDAQ Rule 5635. In accordance with the provisions of our amended and restated articles of association and the Israeli Companies Law, our board of directors is authorized to issue securities, including shares, warrants and convertible notes.

We currently intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and the NASDAQ Global Market's listing standards.

Board Practices

Board of Directors

Under the Israeli Companies Law, our board of directors is responsible for setting our general policies and supervising the performance of management. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our board of directors, subject to the terms of the employment agreement that we have entered into with him. All other executive officers are also appointed by our board of directors, and are subject to the terms of any applicable employment agreements that we may enter into with them.

Under our amended and restated articles of association, to be effective upon the closing of this offering, our board of directors must consist of at least directors and not more than directors, including at least two external directors required to be appointed under the Israeli Companies Law. Our board of directors will consist of directors upon the closing of this offering, including two new directors who are our nominees to serve as external directors and whose appointment will be effective upon the closing of this offering. The appointment of the external director nominees will be effective upon the closing of this offering, but their appointment as external directors is subject to approval at a general meeting of our shareholders to be held no later than three months following the closing of this offering. Other than external directors, for whom special election requirements apply under the Israeli Companies Law, as detailed below, the Israeli Companies Law and our amended and restated articles of association provide that directors are elected annually at the general meeting of our shareholders by a vote of the holders of a majority of the voting power represented present and voting in person, by proxy or by other voting instrument at that meeting. We have only one class of directors.

Under the Israeli Companies Law, our board of directors is required to employ independent judgment and discretion when voting, and is prohibited from entering into any voting arrangements with respect to actions taken at meetings of the board. Further, the Israeli Companies Law provides that in the event a director learns about an alleged breach of law or improper conduct of business relating to a company matter, said director must promptly take action to summon a meeting of the board of directors to address any such breach.

In accordance with the exemptions available to foreign private issuers under NASDAQ rules, we do not intend to follow the requirements of the NASDAQ rules with regard to the process of nominating directors. Instead, we intend to follow Israeli law and practice, in accordance with which our board of directors (or a committee thereof) is authorized to recommend to our shareholders director nominees for election.

Under the Israeli Companies Law and our amended and restated articles of association, nominees to serve as directors may also be proposed by any shareholder holding at least 1% of our outstanding voting power. However, any such shareholder may propose a nominee only if a written notice of such shareholder's intent to propose a nominee has been given to the company. Any such notice must include certain information, including, among other things, a description of all arrangements between the nominating shareholder and the proposed director nominee and any other person pursuant to which the nomination is to be made by the nominating shareholder, the consent of the proposed director nominee to serve as our director if elected and a declaration signed by the nominee declaring that there is no limitation under the Israeli Companies Law preventing his or her election, and that all of the information that is required under the Israeli Companies Law to be provided to us in connection with such election has been provided.

In addition, our amended and restated articles of association allow our board of directors to appoint directors to fill vacancies on our board of directors, including filling empty board seats up to the maximum number of directors permitted under our articles of association, for a term of office equal to the remaining period of the term of office of each director whose office has been vacated. Vacancies on our board of directors, other than vacancies created by an external director, may be filled by a vote of a simple majority of the directors then in office. A director so appointed will hold office until the next annual general meeting of our shareholders in which the other directors then in office are proposed to be replaced or reappointed. External directors are elected for an initial term of three years and may be elected for additional three-year terms under the circumstances described below. External directors may be removed from office only under the limited circumstances set forth in the Israeli Companies Law. See “External Directors.”

Under the Israeli Companies Law, our board of directors must determine the minimum number of directors who are required to have accounting and financial expertise. See “External Directors.” In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors of our company who are required to have accounting and financial expertise is one.

External Directors

Under the Israeli Companies Law, we are required to include on our board of directors at least two members who qualify as external directors. and have agreed to serve as our external directors, subject to ratification at a meeting of our shareholders to be held no later than three months following the closing of this offering. Upon their approval by the shareholders, we expect that both external directors will also serve on our audit committee and compensation committee.

The provisions of the Israeli Companies Law set forth special approval requirements for the election of external directors. External directors must be elected by a majority vote of the shares present and voting at a meeting of shareholders, provided that either:

- 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 the election of the external director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding abstentions, to which we refer as a disinterested majority; or
- the total number of shares voted by non-controlling shareholders and by shareholders who do not have a personal interest in the election of the external director against the election of the external director does not exceed 2% of the aggregate voting rights in the company.

The term “controlling shareholder” is defined in the Israeli Companies Law as a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. The term “office holder” is defined under the Israeli Companies Law as a general manager, chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of these positions regardless of that person’s title, a director and any other manager directly subordinate to the general manager. A shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in a company or has the right to appoint the majority of the directors of the company or its chief executive officer (referred to in the Israeli Companies Law as the general manager). With respect to certain matters, a controlling shareholder is deemed to include a shareholder that holds 25% or more of the voting rights in a public company if no other shareholder holds more than 50% of the voting rights in the company, but excludes a shareholder whose power derives solely from his or her position as a director of the company or from any other position with the company.

The initial term of an external director is three years. Thereafter, an external director may be reelected by shareholders to serve in that capacity for up to two additional three-year terms, provided that either:

- his or her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company’s voting rights or by the external director himself or herself and is approved at a shareholders meeting by a disinterested majority, where the total number of shares held by non-controlling,

disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the company, provided that the external director and certain of his or her related parties meet additional independence requirements; or

- his or her service for each such additional term is recommended by the board of directors and is approved at a meeting of shareholders by the same majority required for the initial election of an external director (as described above).

The term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the NASDAQ Global Market, may be extended indefinitely in increments of additional three-year terms, in each case provided that the audit committee and the board of directors of the company confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for each such additional period is beneficial to the company, and provided that the external director is reelected subject to the same shareholder vote requirements as if elected for the first time (as described above). Prior to the reelection of the external director at a general meeting of shareholders, the company's shareholders must be informed of the term previously served by him or her and of the reasons why the board of directors and audit committee recommended the extension of his or her term.

External directors may be removed from office by a special general meeting of shareholders called by the board of directors, which approves such dismissal by the same shareholder vote percentage required for their election or by a court, in each case, only under limited circumstances, including ceasing to meet the statutory qualifications for appointment, or violating their duty of loyalty to the company.

If an external directorship becomes vacant and there are fewer than two external directors on the board of directors at the time, then the board of directors is required under the Israeli Companies Law to call a shareholders' meeting as soon as practicable to appoint a replacement external director.

Each committee of the board of directors that exercises any of the powers of the board of directors must include at least one external director, except that the audit committee and the compensation committee must include all external directors then serving on the board of directors. Under the Israeli Companies Law, external directors of a company are prohibited from receiving, directly or indirectly, any compensation from the company other than for their services as external directors pursuant to the Israeli Companies Law and the regulations promulgated thereunder. Compensation of an external director is determined prior to his or her appointment and may not be changed during his or her term subject to certain exceptions.

The Israeli Companies Law provides that a person is not qualified to serve as an external director if (i) the person is a relative of a controlling shareholder of the company, or (ii) if that person or his or her relative, partner, employer, another person to whom he or she was directly or indirectly subordinate, or any entity under the person's control, has or had, during the two years preceding the date of appointment as an external director: (a) any affiliation or other disqualifying relationship with the company, with any person or entity controlling the company or a relative of such person, or with any entity controlled by or under common control with the company; or (b) in the case of a company with no controlling shareholder, had at the date of appointment as an external director, any affiliation or other disqualifying relationship with a person then serving as chairman of the board or chief executive officer, or a holder of 5% or more of the issued share capital or voting power in the company or the most senior financial officer.

The term "relative" is defined under the Israeli Companies Law as a spouse, sibling, parent, grandparent or descendant; spouse's sibling, parent or descendant; and the spouse of each of the foregoing persons.

Under the Israeli Companies Law, the term "affiliation" and the similar types of disqualifying relationships include (subject to certain exceptions):

- an employment relationship;
- a business or professional relationship even if not maintained on a regular basis (excluding insignificant relationships);
- control; and

- service as an office holder, excluding service as a director in a private company prior to the initial public offering of its shares if such director was appointed as a director of the private company in order to serve as an external director following the initial public offering.

In addition, no person may serve as an external director if that person's position or professional or other activities create, or may create, a conflict of interest with that person's responsibilities as a director or otherwise interfere with that person's ability to serve as an external director or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. Furthermore, a person may not continue to serve as an external director if he or she received direct or indirect compensation from the company including amounts paid pursuant to indemnification or exculpation contracts or commitments and insurance coverage for his or her service as an external director, other than as permitted by the Israeli Companies Law and the regulations promulgated thereunder.

Following the termination of an external director's service on a board of directors, such former external director and his or her spouse and children may not be provided a direct or indirect benefit by the company, its controlling shareholder or any entity under its controlling shareholder's control. This includes engagement as an office holder or director of the company or a company controlled by its controlling shareholder or employment by, or provision of services to, any such company for consideration, either directly or indirectly, including through a corporation controlled by the former external director. This restriction extends for a period of two years with regard to the former external director and his or her spouse or child and for one year with respect to other relatives of the former external director.

If at the time at which an external director is appointed all members of the board of directors who are not controlling shareholders or relatives of controlling shareholders of the company are of the same gender, the external director to be appointed must be of the other gender. A director of one company may not be appointed as an external director of another company if a director of the other company is acting as an external director of the first company at such time.

According to the Israeli Companies Law and the regulations promulgated thereunder, a person may be appointed as an external director only if he or she has professional qualifications or if he or she has accounting and financial expertise (each, as defined below). In addition, at least one of the external directors must be determined by our board of directors to have accounting and financial expertise. However, if at least one of our other directors (i) meets the independence requirements under the Exchange Act, (ii) meets the standards of the NASDAQ Rules for membership on the audit committee, and (iii) has accounting and financial expertise as defined under the Israeli Companies Law, then neither of our external directors is required to possess accounting and financial expertise as long as each possesses the requisite professional qualifications.

A director with accounting and financial expertise is a director who, due to his or her education, experience and skills, is proficient in, and possesses an understanding of, business – accounting matters and financial statements, such that he or she is able to understand the financial statements of the company, in depth, and initiate a discussion about the manner of presentation of financial data. A director is deemed to have professional qualifications if he or she has any of (i) an academic degree in economics, business management, accounting, law or public administration, (ii) an academic degree or has completed another form of higher education in the primary field of business of the company or in a field which is relevant to his or her position in the company, or (iii) at least five years of experience serving in one of the following capacities, or at least five years of cumulative experience serving in two or more of the following capacities: (a) a senior business management position in a company with a significant volume of business; (b) a senior position in the company's primary field of business; or (c) a senior position in public administration or service. The board of directors is charged with determining whether a director possesses financial and accounting expertise or professional qualifications.

Our board of directors has determined that has accounting and financial expertise and possesses professional qualifications as required under the Israeli Companies Law.

Under recently enacted amendments to regulations promulgated under the Israeli Companies Law, Israeli companies whose shares are traded on stock exchanges such as the NASDAQ Global Market that do not have a controlling shareholder and which comply with the requirements of the jurisdiction where the company's shares are traded with respect to the appointment of independent directors and the composition of an audit committee and compensation

committee, may elect not to follow the Israeli Companies Law requirements with respect to the composition of its audit committee and compensation committee and the appointment of external directors.

Leadership Structure of the Board

In accordance with the Israeli Companies Law and our amended and restated articles of association, our board of directors is required to appoint one of its members to serve as chairman of the board of directors. Our board of directors has appointed Arie Belldegrun, M.D. to serve as chairman of the board of directors.

Board Committees

Under the Israeli Companies Law and our amended and restated articles of association, our board of directors is permitted to form committees, and to delegate to any such committee powers allotted to the board of directors, subject to certain exceptions. In general, the board of directors may overturn a resolution adopted by a committee it has formed; provided, however, that the board's decision shall not affect the ability of third parties, who were not aware of such decision, to rely on the committee's resolution prior to the time it is overturned. Only members of the board of directors can be members of a board committee, unless the committee is solely advisory.

Audit Committee

Following the listing of our ordinary shares on the NASDAQ Global Market, our audit committee will consist of , and . will serve as chairman of the audit committee.

Israeli Companies Law Requirements

Under the Israeli Companies Law, we will be required to appoint an audit committee following the closing of this offering. The audit committee must be comprised of at least three directors, including all of the external directors, one of whom must serve as chairman of the committee. The audit committee may not include the chairman of the board, a controlling shareholder of the company, a relative of a controlling shareholder, a director employed by or providing services on a regular basis to the company, to a controlling shareholder or to an entity controlled by a controlling shareholder, or a director who derives most of his or her income from a controlling shareholder. In addition, under the Israeli Companies Law, the audit committee of a publicly traded company must consist of a majority of unaffiliated directors.

In general, an "unaffiliated director" is defined under the Israeli Companies Law either as an external director or as a director who meets the following criteria:

- he or she meets the qualifications for being appointed as an external director, except for the requirements that the director (i) be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed for trading outside of Israel) and (ii) possess accounting and financial expertise or professional qualifications; and
- he or she has not served as a director of the company for a period exceeding nine consecutive years. For this purpose, an interruption in service of less than two years shall not be deemed to interrupt the continuation of the service.

Our audit committee may not approve any actions requiring its approval (see "Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers"), unless at the time of the approval a majority of the committee's members are present, and a majority of those members present, consists of unaffiliated directors including at least one external director.

Under recently enacted amendments to regulations promulgated under the Israeli Companies Law, Israeli companies whose shares are traded on stock exchanges such as the NASDAQ Global Market that do not have a controlling shareholder and which comply with the requirements of the jurisdiction where the company's shares are traded with respect to the appointment of independent directors and the composition of an audit committee and compensation committee, may elect not to follow the Israeli Companies Law requirements with respect to the composition of its audit committee and compensation committee and the appointment of external directors.

NASDAQ Listing Requirements

Under the NASDAQ Rules, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NASDAQ Stock Market. Our board of directors has determined that is an audit committee financial expert as such term is defined by the SEC rules and has the requisite financial experience as defined by the NASDAQ Rules. Each of the members of our audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act and satisfies the independent director requirements under the NASDAQ Rules.

Audit Committee Role

Our audit committee charter, to be effective upon the listing of our shares on the NASDAQ Global Market, sets forth the responsibilities of the audit committee consistent with the rules and regulations of the SEC and the NASDAQ Rules, as well as the requirements for such committee under the Israeli Companies Law, including the following:

- oversight of our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination of the person filling the office of our internal auditor; and
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the auditors are independent of management.

Under the Israeli Companies Law, our audit committee is responsible for:

(i) determining whether there are deficiencies in the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;

(ii) determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest and whether such transaction is extraordinary or material under the Israeli Companies Law) (see "Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers");

(iii) establishing the approval process for certain transactions with a controlling shareholder or in which a controlling shareholder has a personal interest;

(iv) where the board of directors approves the working plan of the internal auditor, examining such working plan before its submission to the board of directors and proposing amendments thereto;

(v) examining our internal audit controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to fulfill his responsibilities;

(vi) examining the scope of our auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors or shareholders, depending on which of them is considering the appointment of our auditor; and

(vii) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Compensation Committee and Compensation Policy

Upon the listing of our ordinary shares on the NASDAQ Global Market, we intend to establish a compensation committee. The members of the compensation committee will be , and , and will serve as chairman of the compensation committee.

Israeli Companies Law Requirements

Under the Israeli Companies Law, the board of directors of a public company must appoint a compensation committee. The compensation committee must be comprised of at least three directors, including all of the external

directors, who must constitute a majority of the members of the compensation committee. However, subject to certain exceptions, Israeli companies whose securities are traded on stock exchanges such as the NASDAQ Global Market, and who do not have a controlling shareholder, do not have to meet this majority requirement; provided, however, that the compensation committee meets other Israeli Companies Law composition requirements, as well as the requirements of the jurisdiction where the company's securities are traded. Each compensation committee member who is not an external director must be a director whose compensation does not exceed an amount that may be paid to an external director. The compensation committee is subject to the same Israeli Companies Law restrictions as the audit committee as to who may not be a member of the committee.

Under recently enacted amendments to regulations promulgated under the Israeli Companies Law, Israeli companies whose shares are traded on stock exchanges such as the NASDAQ Global Market that do not have a controlling shareholder and which comply with the requirements of the jurisdiction where the company's shares are traded with respect to the appointment of independent directors and the composition of an audit committee and compensation committee, may elect not to follow the Israeli Companies Law requirements with respect to the composition of its audit committee and compensation committee and the appointment of external directors.

The duties of the compensation committee include the recommendation to the company's board of directors of a policy regarding the terms of engagement of office holders, to which we refer as a compensation policy. That policy must be adopted by the company's board of directors, after considering the recommendations of the compensation committee, and will need to be approved by the company's shareholders, which approval requires what 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. We will be required to adopt a compensation policy within nine months following our listing on the NASDAQ Global Market.

Even if the company's shareholders do not approve the compensation policy, the 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.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's long-term objectives, business plan and policies, and creation of appropriate incentives for office holders. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must furthermore consider the following additional factors:

- the education, skills, expertise and accomplishments of the relevant office holder;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the relationship between the terms offered and the average compensation of the company's personnel;
- the impact of disparities in salary upon work relationships in the company;
- the possibility of reducing variable compensation at the discretion of the board of directors;
- the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include the following principles:

- the link between variable compensation and long-term performance and measurable criteria;

- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;
- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

Compensation Committee Roles

The compensation committee is responsible for (i) recommending the compensation policy to our board of directors for its approval (and subsequent approval by our shareholders) and (ii) duties related to the compensation policy and to the compensation of our office holders, including:

- recommending whether a compensation policy should continue in effect, if the then-current policy has a term of greater than five years from a company's initial public offering, or otherwise three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur five years from a company's initial public offering, or otherwise every three years);
- recommending to the board of directors periodic updates to the compensation policy;
- assessing implementation of the compensation policy;
- determining whether to approve the terms of compensation of certain office holders which, according to the Israeli Companies Law, require the committee's approval; and
- determining whether the compensation terms of a candidate for the position of the chief executive officer of the company needs to be brought to approval of the shareholders.

Our board of directors intends to adopt a compensation committee charter setting forth the responsibilities of the compensation committee, which include:

- the responsibilities set forth in the compensation policy;
- reviewing and approving the granting of options and other incentive awards to the extent such authority is delegated by our board of directors; and
- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors.

Disclosure of Compensation of Executive Officers

For so long as we qualify as a foreign private issuer, we are not required to comply with the proxy rules applicable to U.S. domestic companies, including the requirement applicable to emerging growth companies to disclose the compensation of our Chief Executive Officer, Chief Financial Officer, President, Israeli Operation and other two most highly compensated executive officers on an individual, rather than on an aggregate, basis. Nevertheless, under regulations promulgated under the Israeli Companies Law, we are required to disclose the annual compensation of our five most highly compensated office holders (as defined under the Israeli Companies Law) on an individual basis, rather than on an aggregate basis, as was previously permitted for Israeli public companies listed overseas. This disclosure will not be as extensive as that required of a U.S. domestic issuer. We intend to commence providing such disclosure, at the latest, in the notice (which is generally part of the proxy statement) for our 2017 annual general meeting of shareholders, which will be filed under cover of a Report of Foreign Private Issuer on Form 6-K and we may elect to provide such information at an earlier date.

Internal Auditor

Under the Israeli Companies Law, the board of directors of an Israeli public company must appoint an internal auditor recommended by the audit committee. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;

- an office holder (including a director) of the company (or a relative thereof); or
- a member of the company's independent accounting firm, or anyone on its behalf.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures, and to report to the chief executive officer, the chairman of the board and the chairman of the audit committee. The internal auditor is entitled to receive notice of audit committee meetings and to participate in them. In addition, the internal auditor may request that the chairman of the audit committee convene a meeting within a reasonable time to discuss an issue raised by the internal auditor. The internal auditor is responsible for preparing a proposal for an annual or periodical audit plan and submit such plan to the board of directors or the audit committee for their approval. We intend to appoint an internal auditor following the closing of this offering.

Approval of Related Party Transactions under Israeli Law

Fiduciary Duties of Directors and Executive Officers

The Israeli Companies Law codifies the fiduciary duties that office holders owe to a company. Each person listed in the table under "Executive Officers and Directors" is an office holder under the Israeli Companies Law.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of loyalty includes an obligation that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to any such action.

The duty of loyalty includes a duty to:

- refrain from any conflict of interest between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions

The Israeli Companies Law requires that an office holder promptly disclose to the 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 general manager or in which he or she has the right to appoint at least one director or the general manager, 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 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.

Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions

Pursuant to Israeli law, the disclosure requirements regarding personal interests that apply to directors and executive officers also apply to a controlling shareholder of a public company. In the context of a transaction involving a shareholder of the company, a controlling shareholder also includes a shareholder who holds 25% or more of the voting rights in the company if no other shareholder holds more than 50% of the voting rights in the company. For this purpose, the holdings of all shareholders who have a personal interest in the same transaction will be aggregated.

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.

Shareholder Duties

Pursuant to the Israeli Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting and at shareholder class meetings with respect to the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;
- a merger; or
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

In addition, certain shareholders have a duty of fairness toward the company. These shareholders include a controlling shareholder, a shareholder who knows that he or she has the power to determine the outcome of a shareholder vote and a shareholder who has the power to appoint or to prevent the appointment of an office holder of the company or other power towards the company. The Israeli Companies Law does not define the substance of the duty of fairness, except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Israeli Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our amended and restated articles of association which will be effective upon the closing of this offering include such a provision. A company may not exculpate in advance a director from liability arising out of a breach of the duty of care with respect to a distribution.

Under the Israeli Companies Law, a company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such

investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding, and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction; and

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Israeli Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder, if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of the duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- a financial liability imposed on the office holder in favor of a third party.

Under the Israeli Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, civil fine, monetary sanction or forfeit levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders. See "Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers."

Our amended and restated articles of association to be effective upon the closing of this offering will permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Israeli Companies Law.

We have obtained directors and officers liability insurance for the benefit of our office holders and intend to increase such coverage in an amount standard for a company of our size prior to the closing of this offering. We intend to maintain such increased coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law. In addition, prior to the closing of this offering, we intend to enter into agreements with each of our directors and executive officers exculpating them from liability to us for damages caused to us as a result of a breach of duty of care and undertaking to indemnify them, in each case, to the fullest extent permitted by our amended and restated articles of association to be effective upon the closing of this offering and Israeli law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance. In the opinion of the SEC, however, indemnification of directors and office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

Code of Business Conduct and Ethics

We intend to adopt a Code of Business Conduct and Ethics applicable to all of our directors and employees, including our Chief Executive Officer, Chief Financial Officer, controller or principal accounting officer, or other

persons performing similar functions, which is a “code of ethics” as defined in Item 16B of Form 20-F promulgated by the SEC. Upon the effectiveness of the registration statement of which this prospectus forms a part, the full text of the Code of Business Conduct and Ethics will be posted on our website at www.urogen.com. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus and is not incorporated by reference herein. If we make any amendment to the Code of Business Conduct and Ethics or grant any waivers, including any implicit waiver, from a provision of the code of ethics, we will disclose the nature of such amendment or waiver on our website to the extent required by the rules and regulations of the SEC. Under Item 16B of Form 20-F, if a waiver or amendment of the Code of Business Conduct and Ethics applies to our principal executive officer, principal financial officer, principal accounting officer or controller and relates to standards promoting any of the values described in Item 16B(b) of Form 20-F, we are required to disclose such waiver or amendment on our website in accordance with the requirements of Instruction 4 to such Item 16B.

Compensation of Executive Officers and Directors

The aggregate compensation paid and equity-based compensation and other payments expensed by us to our directors and executive officers with respect to the year ended December 31, 2015 was $1.0 million. This amount does not include business travel, relocation, professional and business association dues and expenses reimbursed to office holders, and other benefits commonly reimbursed or paid by companies in our industry.

As of December 31, 2015, options to purchase 269,277 ordinary shares granted to our directors and executive officers were outstanding under our 2010 Israeli Share Option Plan at a weighted average exercise price of $15.00 per share and 86,000 restricted share units were granted to our directors and executive officers under our 2010 Israeli Share Option Plan. Such number excludes options to purchase up to 3,000 ordinary shares and 9,000 restricted share units, which are contingent upon the closing of this offering.

We do not have any written agreements with any director providing for benefits upon the termination of such director’s relationship with our company, other than our employment agreement with our Chief Executive Officer.

Agreements with Executive Officers; Consulting and Directorship Services Provided by Directors

Upon the closing of this offering, we will have entered into written employment agreements with all of our executive officers. These agreements contain standard provisions for a company in our industry regarding non-solicitation, confidentiality of information, non-competition and assignment of inventions. Our executive officers will not receive benefits upon the termination of their respective employment with us, other than payment of salary and benefits (and limited accrual of vacation days) during the required notice period for termination of their employment, which varies for each individual. In addition, we have entered into an agreement for management services with the chairman of our board of directors. See “Certain Relationships and Related Party Transactions—Agreements and Arrangements with, and Compensation of, Directors and Executive Officers” for additional information.

2010 Israeli Share Option Plan

In September 2010, we adopted our 2010 Israeli Share Option Plan, or the 2010 Plan. The 2010 Plan provides for the grant of share options and restricted share units to our company’s employees, non-employee directors and consultants. The reserved pool of shares under the 2010 Plan is shares. Generally, shares that are forfeited, cancelled, terminated or expire unexercised under the 2010 Plan shall be available for issuance under new awards.

The 2010 Plan provides for the grant by us of awards pursuant to Sections 102 and 3(i) of Israeli Income Tax Ordinance [New Version] 5721 - 1961, or the Ordinance, and the rules and regulations promulgated thereunder. The 2010 Plan is effective with respect to awards granted as of 30 days from the date we submitted it to the Israeli Tax Authority, or the ITA. Section 102 of the Ordinance allows employees, directors and officers who are not controlling shareholders and who are Israeli residents, to receive favorable tax treatment for compensation in the form of shares or options. Section 102 of the Ordinance includes two alternatives for tax treatment involving the issuance of options or shares to a trustee for the benefit of the grantees and also includes an additional alternative for the issuance of options or shares directly to the grantee. Section 102(b)(2) of the Ordinance, which provides the most favorable tax treatment for grantees, permits the issuance to a trustee under the “capital gains track.” In order to comply with the terms of the capital gains track, all options granted under a specific plan and subject to the

provisions of Section 102 of the Ordinance, as well as the shares issued upon exercise of such options and other shares received following any realization of rights with respect to such options, such as share dividends and share splits, must be registered in the name of a trustee selected by the board of directors and held in trust for the benefit of the relevant employee, director or officer. The trustee may not release these options or shares to the relevant grantee before the second anniversary of the registration of the options in the name of the trustee. However, under this track, we are not allowed to deduct an expense with respect to the issuance of the options or shares.

The 2010 Plan provides for awards to be granted to our employees or those of our affiliates, directors and officers who are not controlling shareholders, as defined in the Ordinance, and who are considered Israeli residents, to the extent that such awards either are (i) intended to qualify for special tax treatment under the "capital gains track" provisions of Section 102(b)(2) of the Ordinance or (ii) not intended to qualify for such special tax treatment. The 2010 Plan also provides for the grant of awards under Section 3(i) of the Ordinance to our Israeli non-employee service providers and controlling shareholders, who are not eligible for such special tax treatment.

The 2010 Plan is administered by our board of directors. Awards under the 2010 Plan may be granted until 10 years after the effective date of the 2010 Plan.

The terms of options granted under the 2010 Plan, including the exercise price, vesting provisions and the duration of an option, will be determined by our board of directors and set forth in an award agreement. Except as provided in the applicable award agreement, or in the discretion of the compensation committee, an option may be exercised only to the extent that it is then exercisable and, generally, shall expire for employees 90 days following termination of the service of the grantee.

Restricted share units are awards covering a number of hypothetical units with respect to shares that are granted subject to such vesting and transfer restrictions and conditions of payment as our board of directors may determine in an award agreement. Restricted share units are payable in cash, ordinary shares of equivalent value or a combination thereof.

In the event of any dividend (excluding any ordinary dividend) or other distribution, recapitalization, share split, reverse share split, reorganization, merger, consolidation, split-up, split-off, combination, repurchase or exchange of shares or similar event (including a change in control) that affects the ordinary shares, the board of directors will make any such adjustments in such manner as it may deem equitable, including any or all of the following: (i) adjusting the number of shares available for grant under the 2010 Plan, and (ii) providing for a substitution or assumption of awards.

PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of December 31, 2015 by:

- each person or entity known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each of our directors and executive officers individually; and
- all of our executive officers and directors as a group.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, or the right to receive the economic benefit of ownership. For purposes of the table below, we deem ordinary shares issuable pursuant to options that are currently exercisable or exercisable within 60 days of December 31, 2015 to be outstanding and to be beneficially owned by the person holding the options for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person.

The percentage of shares beneficially owned has been computed on the basis of 2,569,619 ordinary shares outstanding as of December 31, 2015, which reflects the assumed exercise of all of our warrants to purchase preferred shares and the subsequent conversion of all of our preferred shares into ordinary shares. For purposes of calculating the number of ordinary shares into which each preferred share will convert immediately prior to the consummation of this offering, we have assumed an initial public offering price of $ per ordinary share, the midpoint of the range set forth on the cover page of this prospectus.

As of December 31, 2015 and based on their reported registered office, 42 of our shareholders were U.S. persons, holding in aggregate approximately 25.0% of our outstanding ordinary shares immediately prior to this offering. We have also set forth below information known to us regarding any significant change in the percentage ownership of our ordinary shares by any major shareholders during the past three years. Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such shares.

Following the closing of this offering, all of our shareholders, including the shareholders listed below, will have the same voting rights attached to their ordinary shares, and neither our principal shareholders nor our directors and executive officers will have different or special voting rights with respect to their ordinary shares. See “Description of Share Capital—Voting Rights.” A description of any material relationship that our principal shareholders have had with us or any of our predecessors or affiliates within the past three years is included under “Certain Relationships and Related Party Transactions.”

Unless otherwise noted below, the address of each shareholder, director and executive officer is c/o UroGen Pharma Ltd., 9 Ha'Ta'asiya St., Ra'anana 4365007, Israel.

	NUMBER AND PERCENTAGE OF ORDINARY SHARES BENEFICIALLY OWNED PRIOR TO OFFERING		PERCENTAGE OF ORDINARY SHARES BENEFICIALLY OWNED AFTER THE OFFERING	
NAME OF BENEFICIAL OWNER	NUMBER	PERCENT	ASSUMING NO EXERCISE OF OPTION (15) PERCENT	ASSUMING FULL EXERCISE OF OPTION (15) PERCENT
5% or Greater Shareholders				
Arkin Communication Ltd. (1)	539,475	21.0%		
Pontifax (Israel) III Limited Partnership (2)	289,322	11.3%		
Pontifax Cayman III Limited Partnership (3)	135,072	5.2%		
ProQuest Investments IV, L.P. (4)	263,158	10.2%		
Telormedix SA (5)	216,000	8.4%		
Tatham Investments Ltd. (6)	130,025	5.1%		
Directors and Executive Officers				
Arie Belldegrun, M.D. (7)	68,342	2.6%		
Ron Bentsur (8)	10,526	*		
Chaim Hurvitz (9)	126,395	4.9%		
Pini Orbach, Ph.D. (10)	1,013	*		
Stuart Holden, M.D. (11)	216,000	8.4%		
Gil Hakim (12)	47,926	1.8%		
Gary Titus (13)	5,263	*		
Ran Nussbaum (14)	424,394	16.5%		
All directors and executive officers as a group	899,859	33.9%		

* Indicates beneficial ownership of less than 1% of the total ordinary shares outstanding.

(1) Consists of (i) 421,053 ordinary shares issuable upon conversion of preferred shares and (ii) 118,422 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and conversion thereof into ordinary shares. Mr. Moshe Arkin is the sole beneficial owner of Arkin Communication Ltd. The percentage ownership of Arkin Communication Ltd. increased from 15.8% as of December 31, 2014, in connection with its initial investment, to 21.0% as of December 31, 2015, in connection with its additional investment. The address of Arkin Communication Ltd. is 6 HaChoshlim St., Bldg. C, Herzliya 46724, Israel.

(2) Consists of (i) 85,216 ordinary shares; (ii) 175,814 ordinary shares issuable upon conversion of preferred shares; (iii) 26,910 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and conversion thereof into ordinary shares and (iv) 1,382 ordinary shares issuable upon exercise of outstanding options. Does not include 10,232 ordinary shares issuable upon exercise of outstanding options which have not vested. Pontifax Management Fund III L.P. is the general partner of Pontifax (Israel) III Limited Partnership, and Pontifax Management III G.P. (2011) Ltd. is the general partner of Pontifax Management Fund III L.P. Tomer Kariv and Ran Nussbaum are directors of Pontifax Management GP and, as such, hold voting and/or dispositive power over the shares held by Pontifax (Israel) III Limited Partnership. The address of Pontifax (Israel) III Limited Partnership is 14 Shenkar St., Herzliya 4672514, Israel.

(3) Consists of (i) 39,784 ordinary shares; (ii) 82,080 ordinary shares issuable upon conversion of preferred shares; (iii) 12,564 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and conversion thereof into ordinary shares and (iv) 644 ordinary shares issuable upon exercise of outstanding options. Does not include 4,768 ordinary shares issuable upon exercise of outstanding options which have not vested. Pontifax Management Fund III L.P. is the general partner of Pontifax Cayman III Limited Partnership, and Pontifax Management III G.P. (2011) Ltd. is the general partner of Pontifax Management Fund III L.P. Tomer Kariv and Ran Nussbaum are directors of Pontifax Management GP and, as such, hold voting and/or dispositive power over the shares held by Pontifax Cayman III Limited Partnership. The address of Pontifax Cayman III Limited Partnership is 14 Shenkar St., Herzliya 4672514, Israel.

(4) Consists of 263,158 ordinary shares issuable upon conversion of preferred shares. ProQuest Associates IV LLC is the managing member and sole general partner of ProQuest Investments VI, L.P. Jay Moorin and Alain Schreiber are the managing members of ProQuest Associates IV LLC and, as such, hold voting and/or dispositive power over the shares held by ProQuest Investments IV, L.P. The percentage ownership of ProQuest Associates IV LLC increased from 0% to 10.2% during 2015 in connection with its initial investments. The address of ProQuest Investments IV, L.P. is 2430 Vanderbilt Beach Road, 108-190, Naples, FL 34109, USA.

(5) Consists of 216,000 ordinary shares issuable upon conversion of preferred shares. Does not include up to 87,000 ordinary shares that may be issued in the future upon the achievement of certain milestones under the Vesimune asset purchase agreement with Telormedix SA. 62.6% of the beneficial ownership of these securities is held by ProQuest Investments IV, L.P., and 37.4% of the beneficial ownership of these securities is held by Aravis SA. Alain Schreiber, Stuart Holden, Johanna Holldack and Jean-Philippe Tripet, through these entities, share voting and dispositive power over the shares held by Telormedix. The percentage ownership of Telormedix SA increased from 0% to 8.4% during 2015 in connection with its initial investments. The address of Telormedix SA is Via della Posta 10, H-6934 Bioggio, Switzerland.

(6) Consists of (i) 35,500 ordinary shares; (ii) 81,372 ordinary shares issuable upon conversion of preferred shares and (iii) 13,153 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and conversion thereof into ordinary shares. Tatham Investments Ltd. is beneficially owned by Shimon Elkabetz. The address of Tatham Investments Ltd. is 2-4 Arch, Makarios III Ave, Capital Center, 703 Nicosia, Cyprus.

(7) Consists of (i) 26,316 ordinary shares issuable upon conversion of preferred shares held by Bellco Capital, LLC through several entities controlled by it, a company beneficially owned by Arie Belldegrun, M.D. and his spouse Rebecka Belldegrun, M.D. and (ii) 42,026 ordinary shares issuable upon exercise of outstanding options. Does not include 50,000 ordinary shares issuable upon exercise of outstanding options which have not vested.

(8) Consists of 10,526 ordinary shares issuable upon conversion of preferred shares. Does not include 86,000 ordinary shares issuable upon outstanding restricted share units which have not vested, and 9,000 ordinary shares issuable upon the vesting of restricted share units, the grant of which is contingent upon the closing of this offering.

(9) Consists of (i) 31,250 ordinary shares, 78,948 ordinary shares issuable upon conversion of preferred shares and 13,158 ordinary shares issuable upon exercise of outstanding warrants to purchase preferred shares and conversion thereof into ordinary shares beneficially held by Shirat HaChaim Ltd., a company beneficially owned by Chaim Hurvitz, and (ii) 3,039 ordinary shares issuable upon exercise of outstanding options. Does not include 15,000 ordinary shares issuable upon exercise of outstanding options which have not vested.

(10) Consists of 1,013 ordinary shares issuable upon exercise of outstanding options. Does not include 15,000 ordinary shares issuable upon exercise of outstanding options which have not vested.

(11) Consists of beneficial ownership of securities held by Telormedix SA described in note 5 above. Does not include 15,000 ordinary shares issuable upon exercise of outstanding options which have not vested.

(12) Consists of (i) 5,882 ordinary shares; (ii) 1,316 ordinary shares issuable upon conversion of preferred shares and (iii) 40,728 ordinary shares issuable upon exercise of outstanding options. Does not include 39,554 ordinary shares issuable upon exercise of outstanding options which have not vested, of which 15,000 were granted in January 2016.

(13) Consists of 5,263 ordinary shares issuable upon conversion of preferred shares. Does not include 32,000 ordinary shares issuable upon exercise of outstanding options which have not vested, of which 15,000 were granted in January 2016. Does not include 3,000 ordinary shares issuable upon exercise of options, the grant of which is contingent upon the closing of this offering.

(14) Consists of beneficial ownership of securities held by Pontifax (Israel) III Limited Partnership and Pontifax Cayman III Limited Partnership described in notes 2 and 3 above.

(15) Underwriters' option to purchase additional ordinary shares, as set out on the cover page of this prospectus.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Agreements with Shareholders

Registration rights agreement

We have entered into an investors' rights agreement dated September 18, 2014, as amended on October 1, 2015 and on April 12, 2016, or the Registration Rights Agreement, with certain of our shareholders. The Registration Rights Agreement provides that certain holders of our ordinary shares have the right to demand that we file a registration statement or request that their ordinary shares be covered by a registration statement that we are otherwise filing. Any registration rights with respect to this offering have been waived. The registration rights are described in more detail under "Description of Share Capital—Registration Rights." All rights under the Registration Rights Agreement, other than the registration rights, will terminate upon the closing of this offering.

Telormedix SA agreement

We have entered into an asset purchase agreement, or the agreement, dated as of October 1, 2015, with Telormedix SA. Also on October 1, 2015, we entered into the 2015 Share Purchase Agreement, as further described below, pursuant to which ProQuest, which beneficially owns 62.6% of Telormedix, became a 10% beneficial owner of the company. Pursuant to the 2015 Share Purchase Agreement, ProQuest appointed Stuart Holden, M.D., who is a member of the board of directors of Telormedix, to our board of directors. Pursuant to the agreement, we purchased all of the intellectual property assets of Telormedix in consideration for an aggregate amount of 216,000 shares of our Series A preferred shares with a liquidation preference of $19.00 per share. This includes 54,000 of our Series A preferred shares, which are being held in escrow and will be automatically released to Telormedix on the earlier of (i) 12 months from the date of initial closing and (ii) the consummation of this offering, unless we have raised a valid claim prior to the expiration of this period. Upon the occurrence of three specified regulatory milestones, we will issue an additional 29,000 Series A preferred shares, or 29,000 ordinary shares in the event the milestone is achieved following the completion of this offering, to Telormedix upon the occurrence of each milestone, for an aggregate potential maximum amount of 87,000 Series A preferred shares, or 87,000 ordinary shares in the event the milestone is achieved following the completion of this offering.

Agreements and Arrangements with, and Compensation of, Directors and Executive Officers

Employment agreements

We have entered into written employment agreements with each of our executive officers. These agreements contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the executive officers. However, the enforceability of the non-competition provisions may be limited under applicable law. The agreements are terminable by us at will, subject to prior notice, which varies for each individual. Our executive officers will not receive benefits upon termination of their respective employment with us, other than payment of salary and benefits (and limited accrual of vacation days) during the required notice period for termination of their employment. However, Ron Bentsur, our Chief Executive Officer, and Gary Titus, our Chief Financial Officer, will be entitled to accelerated vesting of their stock options in the event of termination without cause.

Consulting and option agreements

We have entered into an agreement with our chairman of the board of directors, Arie Belldegrun, M.D., for management services pertaining to the development of our business. These services include serving as chairman of the board of directors, assisting us in our financing activities and overseeing our clinical development activities. In consideration of these services, as of December 31, 2015, we have issued Dr. Belldegrun options under our 2010 Israeli Share Option Plan to purchase 40,000 ordinary shares at $12.85 per share and 52,026 ordinary shares at $16.00 per share. The agreement has no fixed term and is terminable at will (i) by Dr. Belldegrun upon 30 days' prior written notice and (ii) by us at any time pursuant to the directions of our board of directors or shareholders. The agreement contains customary provisions and representations, including confidentiality and inventions assignment undertakings by Dr. Belldegrun.

We have also entered into an option agreement with our other non-executive directors, Pini Orbach, Chaim Hurvitz and Stuart Holden and option agreements with Pontifax (Israel) III Limited Partnership and Pontifax (Cayman) III

Limited Partnership, which are represented by our non-executive director Ran Nussbaum, according to which each was granted options under our 2010 Israeli Share Option Plan in the number and on the terms set out in the section above titled “Principal Shareholders.”

Financing agreements

Between 2012 and 2015, Arkin Communications Ltd. or Arkin, which appointed Pini Orbach, Ph.D., to our board of directors, Pontifax (Israel) III Limited Partnership, or Pontifax IL, and Pontifax (Cayman) III Limited Partnership, or Pontifax CM, which appointed Ran Nussbaum to our board of directors, Shirat HaChaim Ltd., or Shirat HaChaim, a company controlled by our director Chaim Hurvitz, Bellco Capital LLC, or Bellco, through several entities controlled by it (the beneficial owners of Bellco Capital are Rebecka Belldegrun, M.D. and our chairman Arie Belldegrun, M.D.) and ProQuest Investments IV, L.P., or ProQuest, which appointed Stuart Holden, M.D. to our board of directors, invested in the company an aggregate amount of approximately $22.4 million in consideration of the securities described below:

From January 2012 through April 2013, we entered into share purchase agreements with Pontifax IL, Pontifax CM, Shirat HaChaim and other investors, pursuant to which the company issued to the investors 429,764 ordinary shares at $16.00 per share, of which 85,216, 39,784 and 31,250 ordinary shares were issued to Pontifax IL, Pontifax CM and Shirat HaChaim, respectively.

On September 18, 2014, we entered into the 2014 Share Purchase Agreement with Arkin, Pontifax IL, Pontifax CM, Shirat HaChaim and other investors, pursuant to which the company issued to the investors 455,183 shares of Series A preferred shares at $19.00 per share and 227,592 warrants exercisable to shares of Series A-1 preferred shares at $25.00 per share, of which 236,842, 53,820, 25,126 and 26,316 shares and 118,422, 26,910, 12,564 and 13,158 warrants were issued to Arkin, Pontifax IL, Pontifax CM and Shirat HaChaim, respectively.

On October 1, 2015, we entered into the 2015 Share Purchase Agreement with ProQuest, Arkin, Pontifax IL, Pontifax CM, Shirat HaChaim, Bellco and other investors, pursuant to which the company issued to the investors 951,774 shares of Series A preferred shares at $19.00 per share, of which 263,158, 184,211, 121,994, 56,954, 52,632 and 26,316 shares were issued to ProQuest, Arkin, Pontifax IL, Pontifax CM, Shirat HaChaim and Bellco, respectively.

Indemnification agreements

Our amended and restated articles of association permit us to exculpate, indemnify and insure each of our directors and office holders to the fullest extent permitted by the Israeli Companies Law. Immediately prior to the closing of this offering, we intend to enter into indemnification agreements with each of our directors and executive officers, undertaking to indemnify them to the fullest extent permitted by Israeli law, including with respect to liabilities resulting from a public offering of our shares, to the extent that these liabilities are not covered by insurance. We have also obtained Directors and Officers insurance for each of our executive officers and directors. For further information, see “Management—Exculpation, Insurance and Indemnification of Directors and Officers.”

Other Relationships

Family members of Chaim Hurvitz beneficially own more than 10% of Pontifax IL and Pontifax CM.

DESCRIPTION OF SHARE CAPITAL

The following descriptions of our share capital and provisions of our amended and restated articles of association which will be effective upon the closing of this offering are summaries and do not purport to be complete. A form of our amended and restated articles of incorporation will be filed with the SEC as an exhibit to our registration statement, of which this prospectus forms a part. The description of the ordinary shares reflects changes to our capital structure that will occur immediately prior to the closing of this offering.

General

Upon the closing of this offering, our authorized share capital will consist of ordinary shares, par value NIS 0.01 per share, of which shares will be issued and outstanding (assuming that the underwriters do not exercise their option to purchase additional ordinary shares).

All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

All ordinary shares will 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. Following the completion of this offering and the resulting registration of our shares for trading, our registration number will change to reflect our becoming a public company.

Conversion of Preferred Shares

Upon the closing of this offering, all of our preferred shares outstanding will automatically convert into ordinary shares, and will have no further preferences, privileges or priority rights of any kind.

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, subject to the special approval requirements for external directors described under “Management—Board Practices—External Directors.”

Under our amended and restated articles of association to be effective upon the closing of this offering, our board of directors must consist of at least and not more than directors, including at least two external directors required to be appointed under the Israeli Companies Law. Our board of directors will consist of directors upon the closing of this offering, including two new directors who are our nominees to serve as external directors and whose appointment will be effective upon the closing of this offering.

Pursuant to our amended and restated articles of association, each of our directors, other than the external directors, for whom special election requirements apply under the Israeli Companies Law, will be 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 will serve 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 voting power of our shareholders 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. External directors are elected for an initial term of three years, may be elected for additional terms of three years each under certain circumstances, and may be removed from office pursuant to the terms of the Israeli Companies Law. See “Management—Board Practices—External Directors.” 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 general meetings. Our board of directors may call extraordinary general 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 general 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;
- 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 general 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 and under our amended and restated articles of association, shareholders 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.

The Israeli Companies Law allows one or more of our shareholders holding at least 1% of the voting power of our company to request the inclusion of an additional agenda item for an upcoming shareholders meeting, assuming that it is appropriate for debate and action at a shareholders meeting. Under regulations promulgated under the Israeli Companies Law, such a shareholder request must be submitted within three or, for certain requested agenda items, seven days following our publication of notice of the meeting. If the requested agenda item includes the appointment of director(s), the requesting shareholder must comply with particular procedural and documentary requirements. If our board of directors determines that the requested agenda item is appropriate for consideration by our shareholders, we must publish an updated notice that includes such item within seven days following the deadline for submission of agenda items by our shareholders. The publication of the updated notice of the shareholders meeting does not impact the record date for the meeting. In lieu of this process, we may opt to provide pre-notice of our shareholders meeting at least 21 days prior to publishing official notice of the meeting. In that case, our 1% shareholders are given a 14 day period in which to submit proposed agenda items, after which we must publish notice of the meeting that includes any accepted shareholder proposals.

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. As a foreign private issuer, 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 25% 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. 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 described above under "Management—Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers—Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions." Additionally, (i) the approval and extension of a compensation policy and certain deviations therefrom require the approvals described above under "Management—Compensation Committee—Israeli

Companies Law Requirements," and (ii) the terms of employment or other engagement of the chief executive officer of the company require the approvals described above under "Management —Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions." Under our amended and restated articles of association, 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.

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 as part of the 2014 Share Purchase Agreement. Upon the closing of this offering, holders of a total of of our ordinary shares will have the right to require us to register these shares under the Securities Act under specified circumstances and will 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 after 180 days after the effective date of this registration statement, we receive a request from holders of at least 30% of the registrable securities then outstanding that we file a Form F-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 F-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 the 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 "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, our 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 F-3.

Form F-3 Registration Rights

If at any time when we are eligible to use a Form F-3 registration statement, we receive a request from holders of the registrable securities then outstanding that we file a Form F-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 F-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 F-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 F-3 demand registrations within the 12-month period immediately preceding the date of such request. A Form F-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 F-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) any bankruptcy or insolvency proceeding under any bankruptcy or insolvency or similar law, whether voluntary or involuntary, is properly commenced by or against us; and (iii) a receiver or liquidator has been appointed to all or substantially all of our assets, and (b) the fifth anniversary of the completion of this 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 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 (as described under "Management—Approval of Related Party Transactions under Israeli Law—Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions").

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 closing of this offering, 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 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 . Its address is and its telephone number is .

Listing

We intend to apply to have our ordinary shares listed on the NASDAQ Global Market under the symbol “URGN.”

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our ordinary shares. Sales of substantial amounts of our ordinary shares following this offering, or the perception that these sales could occur, could adversely affect prevailing market prices of our ordinary shares and could impair our future ability to obtain capital, especially through an offering of equity securities. Assuming that the underwriters do not exercise in full their option to purchase additional ordinary shares with respect to this offering and assuming no exercise of options outstanding following this offering, we will have an aggregate of ordinary shares outstanding upon the closing of this offering. Of these shares, the ordinary shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, unless purchased by "affiliates" (as that term is defined under Rule 144 of the Securities Act, or Rule 144), who may sell only the volume of shares described below and whose sales would be subject to additional restrictions described below.

The remaining ordinary shares will be held by our existing shareholders and will be deemed to be "restricted securities" under Rule 144. Subject to certain contractual restrictions, including the lock-up agreements described below, restricted securities may only be sold in the public market pursuant to an effective registration statement under the Securities Act or pursuant to an exemption from registration under Rule 144, Rule 701 or Rule 904 under the Securities Act. These rules are summarized below. Sales of these shares in the public market after the restrictions under the lock-up agreements lapse, or the perception that those sales may occur, could cause the prevailing market price of our ordinary shares to decrease or to be lower than it might be in the absence of those sales or perceptions.

Eligibility of Restricted Shares for Sale in the Public Market

The following indicates approximately when the ordinary shares that are not being sold in this offering, but which will be outstanding at the time at which this offering is complete, will be eligible for sale into the public market under the provisions of Rule 144 and Rule 701 (but subject to the further contractual restrictions arising under the lock-up agreements described below):

- upon the closing of this offering, ordinary shares held by non-affiliates of our company that have been held for at least one year will be available for resale under Rule 144(b)(1)(ii);
- beginning 90 days after the closing of this offering, up to approximately ordinary shares, constituting shares issuable upon exercise of outstanding options under our 2010 Israeli Share Option Plan that have vested as of, or within 60 days of , 2016, may be eligible for resale under Rule 701 and Rule 144, of which approximately are held by our affiliates and would therefore be subject to the volume, current public information, manner of sale and other limitations under Rule 144; and
- approximately ordinary shares will be eligible for resale pursuant to Rule 144 upon the expiration of various six month holding periods, so long as at least 90 days have elapsed after the closing of this offering, and subject to the current public information requirement under Rule 144 and, in the case of affiliates of our company, such eligibility will also be subject to the volume, manner of sale and other limitations under Rule 144.

Lock-Up Agreements

We, all of our directors and executive officers and holders of substantially all of our outstanding shares and our shares issuable upon the exercise of vested options have signed lock-up agreements. Pursuant to such lock-up agreements, such persons have agreed, subject to certain exceptions, not to sell or otherwise dispose of ordinary shares or any securities convertible into or exchangeable for ordinary shares for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Cowen and Company, LLC. Jefferies LLC and Cowen and Company, LLC may, in their sole discretion, at any time without prior notice, release all or any portion of the ordinary shares from the restrictions in any such agreement.

Rule 144

Shares Held for Six Months

In general, under Rule 144 as currently in effect, and subject to the terms of any lock-up agreement, commencing 90 days after the closing of this offering, a person (or persons whose shares are aggregated), including an affiliate, who has beneficially owned our ordinary shares for six months or more, including the holding period of any prior owner other than one of our affiliates (i.e., commencing when the shares were acquired from our company or from an affiliate of our company as restricted securities), is entitled to sell our shares, subject to the availability of current public information about us. In the case of an affiliate shareholder, the right to sell is also subject to the fulfillment of certain additional conditions, including manner of sale provisions and notice requirements, and to a volume limitation that limits the number of shares to be sold thereby, within any three-month period, to the greater of:

- 1% of the number of ordinary shares then outstanding; or
- the average weekly trading volume of our ordinary shares on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

The six month holding period of Rule 144 does not apply to sales of unrestricted securities. Accordingly, persons who hold unrestricted securities may sell them under the requirements of Rule 144 described above without regard to the six-month holding period, even if they were considered our affiliates at the time of the sale or at any time during the ninety days preceding such date.

Shares Held by Non-Affiliates for One Year

Under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who is not considered to have been one of our affiliates at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than one of our affiliates, is entitled to sell his, her or its shares under Rule 144 without complying with the provisions relating to the availability of current public information or with any other conditions under Rule 144. Therefore, unless subject to a lock-up agreement or otherwise restricted, such shares may be sold immediately upon the closing of this offering.

Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who received or purchased ordinary shares from us under our 2010 Israeli Share Option Plan or other written agreement before the closing of this offering is entitled to resell these shares.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of these options, including exercises after the closing of this offering. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described above (see “Lock-Up Agreements”), may be sold beginning 90 days after the closing of this offering in reliance on Rule 144 by:

- persons other than affiliates, without restriction; and
- affiliates, subject to the manner-of-sale, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

Options

As of December 31, 2015, options to purchase a total of 687,461 ordinary shares were issued and outstanding, whether under our 2010 Israeli Share Option Plan or otherwise. Such number excludes 9,000 ordinary shares issuable upon the vesting of restricted share units, the grant of which is contingent upon the closing of this offering and 3,000 ordinary shares, the grant of which is contingent upon the closing of this offering. Of the total number of issued and outstanding options, will be vested upon the closing of this offering. See “Management—2010 Israeli Share Option Plan.” All of our ordinary shares issuable under these options or restricted share units are subject to contractual lock-up agreements with us or the underwriters.

Form S-8 Registration Statement

Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register up to ordinary shares, in the aggregate, issued or reserved for issuance under the 2010 Israeli Share Option Plan. The registration statement on Form S-8 will become effective automatically upon filing.

Ordinary shares issued upon exercise of a share option and registered pursuant to the Form S-8 registration statement will, subject to vesting provisions and Rule 144 volume limitations applicable to our affiliates, be available for sale in the open market immediately unless they are subject to the 180 day lock-up period or, if subject to the lock-up, immediately after the 180 day lock-up period expires. See “Management—2010 Israeli Share Option Plan.”

Registration Rights

Following the closing of this offering, holders of a total of ordinary shares will have the right to require us to register these shares under the Securities Act under specified circumstances and will have incidental registration rights. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. For more information on these registration rights, see “Description of Share Capital—Registration Rights.”

TAXATION

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a brief summary of the material Israeli tax laws applicable to us. This section also contains a discussion of material Israeli tax consequences concerning the ownership and disposition of our ordinary shares purchased by investors in this offering. This summary does not discuss certain tax benefits, including under the Law for Encouragement of Capital Investments, 5719-1959, to which we may become eligible in the future if we establish a manufacturing facility for our products in Israel. This summary also does not discuss all the aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of such investors include residents of Israel or traders in securities who are subject to special tax regimes not covered in this discussion. Because parts of this discussion are based on new tax legislation that has not yet been subject to judicial or administrative interpretation, the appropriate tax authorities or the courts may not accept the views expressed in this discussion. The discussion below is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax, currently at the rate of 25% of a company's taxable income. In addition, capital gains realized by Israeli companies are subject to tax at the regular corporate tax rate.

Taxation of our Shareholders

Capital gains taxes applicable to non-Israeli resident shareholders. Capital gain is generally subject to tax at the corporate tax rate of 25% in 2016 and thereafter, if generated by a company, or at the rate of 25% if generated by an individual, or 30% in the case of sale of shares by a substantial shareholder at the time of sale or at any time during the preceding 12-month period. A person is considered to be a substantial shareholder if it holds, directly or indirectly, alone or together with another affiliated party, 10% or more of a company's means of control, which include, among other things, voting rights, the right to receive profits of the company, the right to receive proceeds upon liquidation and the right to appoint a director.

Notwithstanding the foregoing, a non-Israeli resident who derives capital gains from the sale of our shares that were purchased after the shares were listed for trading on the NASDAQ is exempt from Israeli tax on such capital gains so long as they were not attributable to a permanent establishment that the non-resident maintains in Israel. In the case of a shareholder that is a corporation, in order for it to qualify as a non-Israeli resident for these purposes, it must be incorporated in, as well as managed and controlled from, a jurisdiction other than the State of Israel, and persons who are Israeli residents may not either: (i) have a controlling interest (directly or indirectly, alone or together with another, or together with another Israeli resident) exceeding 25% in one or more of the means of control in such corporation or (ii) be the beneficiaries of, or entitled to, 25% or more of the revenues or profits of such corporation, whether directly or indirectly. Such exemption is not applicable to a person whose gains from selling or otherwise disposing of the shares are deemed to be business income.

Additionally, a sale of shares by a non-Israeli resident may be exempt from Israeli capital gains tax under the provisions of an applicable tax treaty.

Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at source at the time of sale. In transactions involving a sale of all of the shares of an Israeli resident company, such as a merger or other transaction, the Israel Tax Authority may, among other things, require from shareholders who are not liable for Israeli tax the execution of a declaration in the form specified by that authority or a specific exemption from the Israeli Tax Authority to confirm their status as non-Israeli residents may be required to be presented, and, in the absence of such declaration or exemption, may require the purchaser of the shares to withhold taxes.

In addition, with respect to mergers involving an exchange of shares, 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 in which the sellers receive shares in the acquiring entity that are publicly traded on a stock exchange, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of such shares has occurred.

Taxation of non-Israeli shareholders on receipt of dividends. Non-Israeli residents are generally subject to Israeli withholding tax on the receipt of dividends paid on our ordinary shares at the rate of 25%, unless relief is provided in a treaty between Israel and the shareholder's country of residence (subject to the receipt of a valid certificate from the Israel Tax Authority, allowing for such reduced withholding tax rate). With respect to a person who is considered a substantial shareholder at the time of receiving the dividend or at any time during the preceding 12 months, subject to the terms of an applicable tax treaty, the applicable withholding tax rate is 30%.

Under the Convention between the Government of the United States of America and the Government of the State of Israel with respect to Taxes on Income, or the U.S.-Israel Tax Treaty, the maximum rate of tax withheld at source in Israel on dividends paid to a holder of our ordinary shares who is a U.S. resident (for the purposes of the U.S.-Israel Tax Treaty) is 25%. However, with regard to dividends paid to a U.S. resident corporation which held 10% or more of our outstanding voting rights throughout the taxable year in which the dividend was distributed and which maintained its shareholdings at or above such threshold during the entire previous taxable year, the maximum rate of withholding tax is generally 12.5%, provided that no more than 25% of our gross income for such preceding year consists of certain types of dividends and interest.

U.S. residents who are subject to Israeli withholding tax on a dividend may be entitled to a credit or deduction for U.S. federal income tax purposes in the amount of the taxes withheld, subject to detailed limitations under U.S. laws applicable to foreign tax credits.

Excess Tax. Beginning on January 1, 2013, an additional tax liability at the rate of 2% was added to the applicable tax rate on the annual taxable income of the individuals (whether any such individual is an Israeli resident or non-Israeli resident) exceeding NIS 810,720 (in 2016) which amount is linked to the annual change in the Israeli consumer price index, including, but not limited to, dividends, interest and capital gain.

Material U.S. Federal Income Tax Consequences to U.S. Holders

The following discussion describes the material U.S. federal income tax consequences to U.S. Holders (as defined below) under present law of an investment in our ordinary shares. The effects of any applicable state or local laws, or other U.S. federal tax laws such as estate and gift tax laws are not discussed. This summary applies only to investors who hold the ordinary shares as capital assets (generally, property held for investment) and who have the U.S. dollar as their functional currency. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, U.S. Treasury regulations promulgated thereunder, judicial decisions, published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, and the U.S.-Israel Tax Treaty, all as in effect as of the date of this offering. All of the foregoing authorities are subject to change, which change could apply retroactively and could affect the tax consequences described below.

The following discussion does not address all U.S. federal income tax consequences relevant to a holder's particular circumstances or to holders subject to particular rules, including:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our ordinary shares as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment for U.S. federal income tax purposes;
- banks, insurance companies, and other financial institutions;
- real estate investment trusts or regulated investment companies;
- brokers, dealers or traders in securities, commodities or currencies;

- partnerships, S corporations, or other entities or arrangements treated as partnerships for U.S. federal income tax purposes;
- tax-exempt organizations or governmental organizations;
- persons who acquired our ordinary shares pursuant to the exercise of any employee share option or otherwise as compensation;
- persons that own or are deemed to own 10% or more of our voting stock;
- persons that hold their shares through a permanent establishment or fixed base outside the United States; and
- persons deemed to sell our ordinary shares under the constructive sale provisions of the Code.

U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL TAX RULES TO THEIR PARTICULAR CIRCUMSTANCES AS WELL AS THE U.S. STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF THE ORDINARY SHARES.

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:

- an individual who is a citizen or resident of the United States;
- 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;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- 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 you are a partner in a partnership (or other entity taxable as a partnership for U.S. federal income tax purposes) that holds our ordinary shares, your tax treatment generally will depend on your status and the activities of the partnership. Partnerships holding our ordinary shares and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences applicable to them.

As indicated below, this entire discussion is subject to the discussion of the U.S. federal income tax rules applicable to a "passive foreign investment company," or a PFIC.

Passive Foreign Investment Company Considerations

If we are classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation is classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of subsidiaries, either (i) at least 75% of its gross income is "passive income" or (ii) at least 50% of the average quarterly value of its total gross assets (which, assuming we are not a controlled foreign corporation for the year being tested, would be measured by fair market value of the assets, and for which purpose the total value of our assets may be determined in part by the market value of our ordinary shares, which is subject to change) is attributable to assets that produce "passive income" or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and generally includes amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S.

Holder owns our ordinary shares, regardless of whether we continue to meet the tests described above unless the holder makes a so-called "purging election" with respect to our ordinary shares. **U.S. Holders should consult with their tax advisors regarding the availability and consequences of any PFIC purging elections.**

We must determine our PFIC status annually based on tests which are factual in nature, and our status will depend on our income, assets and activities each year. In addition, our status as a PFIC may depend on how quickly we use the cash proceeds from this offering in our business. However, because we currently have no revenue-producing operations, we expect to be treated as a PFIC for our current taxable year. Unless and until we generate sufficient revenue from active licensing and other non-passive sources and otherwise satisfy the asset test above, we expect to be treated as a PFIC for future taxable years.

If we are a PFIC, and you are a U.S. Holder, then unless you make one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for our ordinary shares) and (b) any gain realized on the sale or other disposition of the ordinary shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. Holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "Taxation of Dividends and Other Distributions on our Ordinary Shares."

Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares. If a U.S. Holder makes the mark-to-market election, then in lieu of being subject to the tax and interest change rules disclosed above, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and our ordinary shares are "regularly traded" on a "qualified exchange." Our ordinary shares will be treated as "regularly traded" in any calendar year in which more than a *de minimis* quantity of the ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principle purposes the meeting of the trading requirement are disregarded). The NASDAQ Global Market is a qualified exchange for this purpose and, consequently, if the ordinary shares are regularly traded, the mark-to-market election will be available to a U.S. Holder.

We do not currently intend to provide the information necessary for U.S. Holders to make QEF elections. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs. A mark-to-market election cannot be made with respect to the stock of any of our subsidiaries.

Each U.S. Holder that is an investor of a PFIC is generally required to file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund)

containing such information as the U.S. Treasury Department may require. The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax. U.S. Holders should consult their tax advisors regarding whether we are a PFIC and the potential application of the PFIC rules.

Taxation of Dividends and Other Distributions on our Ordinary Shares

Subject to the discussion under "– Passive Foreign Investment Company Considerations," above, the gross amount of any distribution to you with respect to our ordinary shares will be included in your gross income as dividend income when actually or constructively received to the extent that the distribution is paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent the amount of the distribution exceeds our current and accumulated earnings and profits, it will be treated first as a return of your tax basis in our ordinary shares, and to the extent the amount of the distribution exceeds your tax basis, the excess will be taxed as capital gain. We do not intend to calculate our earnings and profits under U.S. federal income tax principles. Therefore, a U.S. Holder should expect that the entire amount of any distribution will generally be reported as dividend income. Any dividends will not be eligible for the dividends-received deduction allowed to corporations in respect of dividends received from other U.S. corporations.

If we are not a PFIC for a given year in which a dividend is paid and the taxable year preceding the dividend, non-corporate U.S. Holders may qualify for the preferential rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below). We believe that we qualify as a resident of Israel for purposes of, and are eligible for the benefits of, the U.S.-Israel Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-Israel Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion under "—Passive Foreign Investment Company Considerations" above, if the U.S.-Israel Tax Treaty is applicable, such dividends will generally be "qualified dividend income" in the hands of individual U.S. Holders, provided that certain conditions are met, including holding period and the absence of certain risk reduction transaction requirements are met. The dividends will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders. As discussed in "Taxation—Israeli Tax Considerations," payments of dividends by us may be subject to Israeli withholding tax. For U.S. federal income tax purposes, U.S. Holders will be treated as having received the amount of Israeli taxes withheld by us, and as then having paid over the withheld taxes to the Israeli taxing authorities. As a result of this rule, the amount of dividend income included in gross income for U.S. federal income tax purposes by a U.S. Holder with respect to a payment of dividends may be greater than the amount of cash actually received (or receivable) by the U.S. Holder from us with respect to the payment. Dividends will generally constitute foreign source income for foreign tax credit limitation purposes. Any tax withheld with respect to distributions on our ordinary shares at the rate applicable to a U.S. Holder may, subject to a number of complex limitations, be claimed as a foreign tax credit against such U.S. Holder's U.S. federal income tax liability or may be claimed as a deduction for U.S. federal income tax purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to our ordinary shares generally will constitute "passive category income" or "general category income." The rules with respect to the foreign tax credit are complex and involve the application of rules that depend upon a U.S. Holder's particular circumstances. You are urged to consult your tax advisor regarding the availability of the foreign tax credit under your particular circumstances.

Taxation of Disposition of the Ordinary Shares

Subject to the discussion above under "– Passive Foreign Investment Company Considerations," you will recognize gain or loss on any sale, exchange or other taxable disposition of an ordinary share equal to the difference between the amount realized on the disposition of the ordinary share and your adjusted tax basis in the ordinary share. The tax basis in an ordinary share generally will be the cost of such ordinary share. Any such gain or loss will be capital gain or loss, and will be long-term capital gain or loss if you have held the ordinary share for more than one year at the time of sale, exchange or other taxable disposition. Otherwise, such gain or loss will be short-term capital gain or loss. Long-term capital gains recognized by certain non-corporate U.S. Holders, including individuals, generally will be taxable at a reduced rate. The deductibility of capital losses is subject to limitations. Any such gain or loss you recognize generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

Additional Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ordinary shares. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in our ordinary shares.

Certain Reporting Requirements With Respect to Payments of Offer Price

U.S. Holders paying more than $100,000 for our shares will generally be required to file IRS Form 926 reporting such payment for our ordinary shares to us. Substantial penalties may be imposed upon a U.S. Holder that fails to comply. Each U.S. Holder should consult its own tax advisor as to the possible obligation to file IRS Form 926.

Information Reporting and Backup Withholding

U.S. backup withholding tax and information reporting requirements may apply to certain payments to certain holders of our ordinary shares. Information reporting will generally apply to payments of dividends on, and to proceeds from the sale or redemption of, our ordinary shares made within the United States, or by a U.S. payer or U.S. middleman, to a holder of our shares, other than an exempt recipient (including a payee that is not a U.S. person that provides an appropriate certification and certain other persons). Certain U.S. Holders are exempt from backup withholding, including corporations and certain tax-exempt organizations. A U.S. Holder will be subject to backup withholding if such holder is not otherwise exempt and such holder:

- fails to furnish the holder's taxpayer identification number, which for an individual is ordinarily his or her social security number;
- furnishes an incorrect taxpayer identification number;
- is notified by the IRS that the holder previously failed to properly report payments of interest or dividends; or
- fails to certify under penalties of perjury that the holder has furnished a correct taxpayer identification number and that the IRS has not notified the holder that the holder is subject to backup withholding.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against the U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS. U.S. Holders should consult their tax advisors regarding their qualification for an exemption from backup withholding and the procedures for obtaining such an exemption.

Additional Reporting Requirements

Certain U.S. Holders who are individuals (and under proposed regulations, certain entities) are required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. Holders should consult their tax advisors regarding the possible implications of these tax return disclosure obligations.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2016, Jefferies LLC, 520 Madison Avenue, New York, New York 10022, and Cowen and Company, LLC, 599 Lexington Avenue, 27th Floor, New York, New York 10022, are serving as the representatives of the underwriters named below and the joint book-running managers for this offering. Pursuant to such agreement, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of ordinary shares shown opposite its name below:

Underwriter	NUMBER OF ORDINARY SHARES
Jefferies LLC	
Cowen and Company, LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the ordinary shares if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the ordinary shares as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the ordinary shares, that you will be able to sell any of the ordinary shares held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the ordinary shares subject to their acceptance of the ordinary shares from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Commission and Expenses

The underwriters have advised us that they propose to offer the ordinary shares to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per ordinary share. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per ordinary share to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ordinary shares.

	PER ORDINARY SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL ORDINARY SHARES	WITH OPTION TO PURCHASE ADDITIONAL ORDINARY SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL ORDINARY SHARES	WITH OPTION TO PURCHASE ADDITIONAL ORDINARY SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We also have agreed to reimburse the underwriters for up to $ for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

Determination of Offering Price

Prior to this offering, there has not been a public market for our ordinary shares. Consequently, the initial public offering price for our ordinary shares will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the ordinary shares will trade in the public market subsequent to the offering or that an active trading market for the ordinary shares will develop and continue after the offering.

Listing

We intend to apply to have our ordinary shares listed on the NASDAQ Global Market under the symbol "URGN."

Stamp Taxes

If you purchase ordinary shares offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus. However, no stamp taxes will be payable to the State of Israel in connection with the sale of shares offered hereby.

Option to Purchase Additional Ordinary Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of ordinary shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional ordinary shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more ordinary shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of substantially all of our outstanding share capital have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open “put equivalent position” within the meaning of Rule 16a-l(h) under the Exchange Act, or
- otherwise dispose of any share capital, options or warrants to acquire shares, or securities exchangeable or exercisable for or convertible into shares currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Cowen and Company, LLC.

This restriction terminates after the close of trading of the ordinary shares on and including the 180th day after the date of this prospectus.

Jefferies LLC and Cowen and Company, LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the ordinary shares at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional ordinary shares in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional ordinary shares or purchasing our ordinary shares in the open market. In determining the source of ordinary shares to close out the covered short position, the underwriters will consider, among other things, the price of ordinary shares available for purchase in the open market as compared to the price at which they may purchase ordinary shares through the option to purchase additional ordinary shares.

“Naked” short sales are sales in excess of the option to purchase additional ordinary shares. The underwriters must close out any naked short position by purchasing ordinary shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our ordinary shares in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of ordinary shares on behalf of the underwriters for the purpose of fixing or maintaining the price of the ordinary shares. A syndicate covering transaction is the bid for or the purchase of ordinary shares on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our ordinary shares or preventing or retarding a decline in the market price of our ordinary shares. As a result, the price of our ordinary shares may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the ordinary shares originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our ordinary shares. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our ordinary shares on the NASDAQ Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of our ordinary shares in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of ordinary shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the ordinary shares offered hereby. Any such short positions could adversely affect future trading prices of the ordinary shares offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Investors

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive, each referred to herein as a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, referred to herein as the Relevant Implementation Date, no offer of any securities which are the subject of the offering contemplated by this prospectus has been or will be made to the public in that Relevant Member State other than any offer where a prospectus has been or will be published in relation to such securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the relevant competent authority in that Relevant Member State in accordance with the Prospectus Directive, except that with effect from and including the Relevant Implementation Date, an offer of such securities may be made to the public in that Relevant Member State:

- to any legal entity which is a “qualified investor” as defined in the Prospectus Directive;
- to fewer than 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of securities shall require the company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including Directive 2010/73/EU, the “2010 PD Amending Directive”)), and includes any relevant implementing measure in the Relevant Member State.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

- to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;
- where no consideration is given for the transfer; or
- where the transfer is by operation of law.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated. Each such person is referred to herein as a Relevant Person.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the ordinary shares is directed only at, (i) a limited number of persons in accordance with section 15A of the Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals”, each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Canada

(A) Resale Restrictions

The distribution of ordinary shares in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the ordinary shares in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

(B) Representations of Canadian Purchasers

By purchasing ordinary shares in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the ordinary shares without the benefit of a prospectus qualified under those securities laws as it is an “accredited investor” as defined under National Instrument 45-106—*Prospectus Exemptions*,
- the purchaser is a “permitted client” as defined in National Instrument 31-103—*Registration Requirements, Exemptions and Ongoing Registrant Obligations*,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

(C) Conflicts of Interest

Canadian purchasers are hereby notified that the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105—*Underwriting Conflicts* from having to provide certain conflict of interest disclosure in this document.

(D) Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

(E) Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

(F) Taxation and Eligibility for Investment

Canadian purchasers of ordinary shares should consult their own legal and tax advisors with respect to the tax consequences of an investment in the ordinary shares in their particular circumstances and about the eligibility of the ordinary shares for investment by the purchaser under relevant Canadian legislation.

EXPENSES OF THIS OFFERING

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by us in connection with the sale of our ordinary shares being registered. All amounts are estimates except for the SEC registration fee, the FINRA filing fee and the NASDAQ Global Market listing fee.

ITEM	AMOUNT TO BE PAID
SEC registration fee	*
FINRA filing fee	*
The NASDAQ Global Market listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment.

LEGAL MATTERS

The validity of the issuance of our ordinary shares offered in this prospectus and certain other matters of Israeli law will be passed upon for us by Hamburger Evron & Co., Tel Aviv, Israel. As of the date of this prospectus, Hamburger Evron & Co. beneficially owns an aggregate of 26,228 of our ordinary shares. Certain matters of U.S. law will be passed upon for us by Cooley LLP, New York, New York. Legal counsel to the underwriters are Gornitzky & Co., Tel Aviv, Israel, with respect to Israeli law, and Covington & Burling LLP, New York, New York, with respect to U.S. law.

EXPERTS

The financial statements as of December 31, 2015 and 2014 and for each of the two years in the period ended December 31, 2015 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the company's ability to continue as a going concern as described in Note 1 to the financial statements) of Kesselman & Kesselman, Certified Public Accountants (Israel), an independent registered public accounting firm and a member firm of PricewaterhouseCoopers International Limited, given on the authority of said firm as experts in auditing and accounting.

ENFORCEMENT OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this registration statement, most of whom reside outside of the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and officers are located outside of the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

We have been informed by our legal counsel in Israel, Hamburger Evron & Co., that it may be difficult 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 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 proved as a fact which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

We have irrevocably appointed Urogen Pharma, Inc. as our agent to receive service of process in any action against us in any U.S. federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering. Subject to specified time limitations and legal procedures, Israeli courts may enforce a U.S. judgment in a civil matter which, subject to certain exceptions, is non-appealable, including a judgment based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that among other things:

- the judgment was obtained after due process before a court of competent jurisdiction, according to the laws of the state in which the judgment was given and the rules of private international law currently prevailing in Israel;
- the prevailing law of the foreign state in which the judgment was rendered allows for the enforcement of judgments of Israeli courts;
- adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard and to present his or her evidence;
- the judgment is not contrary to public policy of Israel, and the enforcement of the civil liabilities set forth in the judgment is not likely to impair the security or sovereignty of Israel;
- the judgment was not obtained by fraud and do not conflict with any other valid judgments in the same matter between the same parties;
- an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court; and
- the judgment is enforceable according to the laws of Israel and according to the law of the foreign state in which the relief was granted.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act relating to this offering of our ordinary shares. This prospectus does not contain all of the information contained in the registration statement. The rules and regulations of the SEC allow us to omit certain information from this prospectus that is included in the registration statement. Statements made in this prospectus concerning the contents of any contract, agreement or other document are summaries of all material information about the documents summarized, but are not complete descriptions of all terms of these documents. If we filed any of these documents as an exhibit to the registration statement, you may read the document itself for a complete description of its terms.

You may read and copy the registration statement, including the related exhibits and schedules, and any document we file with the SEC without charge at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains a website that contains reports and other information regarding issuers that file electronically with the SEC. Our filings with the SEC are also available to the public through the SEC's website at *http://www.sec.gov*.

Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act that are applicable to foreign private issuers, and under those requirements will file reports with the SEC. These other reports or other information may be inspected without charge at the locations described above. As a foreign private issuer, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We maintain a corporate website at *http://www.urogen.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus.

INDEX TO FINANCIAL STATEMENTS

	PAGE
Audited Financial Statements:	
Report of Independent Registered Public Accounting Firm	F-2
Balance Sheets as of December 31, 2015 and 2014	F-3
Statements of Operations for the years ended December 31, 2015 and 2014	F-4
Statements of Changes in Shareholders' Equity for the years ended December 31, 2015 and 2014	F-5
Statements of Cash Flows for the years ended December 31, 2015 and 2014	F-6
Notes to the Financial Statements	F-7

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

UROGEN PHARMA LTD.

In our opinion, the accompanying balance sheets and the related statements of operations, changes in shareholders' equity and cash flows present fairly, in all material respects, the financial position of Urogen Pharma Ltd. (the Company) at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in United States of America. These financial statements are the responsibility of the Company's management and Board of Directors. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management and Board of Directors, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 1 to the financial statements, the Company is in the research and development stage and has not yet generated revenue from its operations. During its years of operation, the Company has incurred cumulative losses and negative cash flows from operating activities. As of December 31, 2015 the accumulated deficit was $25,273 thousand. Subsequent to December 31, 2015 the Company incurred additional significant losses and expects to continue to incur negative cash flows from operations. As a result, there are substantial doubts about the Company's ability to continue as a going concern. These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Tel-Aviv, Israel
April 20, 2016

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

UROGEN PHARMA LTD.

BALANCE SHEETS

(U.S. dollars in thousands, except share and per share data)

	DECEMBER 31,	
	2015	2014
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,975	$ 3,870
Restricted deposit	21	20
Prepaid expenses and other current assets	1,135	398
TOTAL CURRENT ASSETS	19,131	4,288
NON-CURRENT ASSETS		
Property and equipment, net	259	71
TOTAL ASSETS	$ 19,390	$ 4,359
Liabilities and Shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable, accrued expenses and advances	$ 1,728	$ 573
Employee related accrued expenses	509	318
TOTAL CURRENT LIABILITIES	2,237	891
NON-CURRENT LIABILITIES		
Warrants for preferred shares	872	305
COMMITMENTS AND CONTINGENCIES (Note 5)		
TOTAL LIABILITIES	3,109	1,196
SHAREHOLDERS' EQUITY:		
Ordinary shares, NIS 0.01 par value: 5,500,000 and 8,000,000 shares authorized at December 31, 2015 and 2014, respectively; 719,060 issued and outstanding as of December 31, 2015 and 2014	2	2
Series A and A-1 preferred shares, NIS 0.01 par value: 4,500,000 and 2,000,000 shares authorized at December 31, 2015 and 2014, respectively; 1,622,957 and 270,973 shares issued and outstanding at December 31, 2015 and 2014, respectively	4	1
Additional paid-in capital	41,548	15,744
Accumulated deficit	(25,273)	(12,584)
TOTAL SHAREHOLDERS' EQUITY	16,281	3,163
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 19,390	$ 4,359

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

UROGEN PHARMA LTD.

STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share and per share data)

	YEAR ENDED DECEMBER 31,	
	2015	2014
RESEARCH AND DEVELOPMENT EXPENSES, NET	$ 10,515	$ 3,479
GENERAL AND ADMINISTRATIVE EXPENSES	1,895	890
OPERATING LOSS	12,410	4,369
FINANCE EXPENSES, NET	279	107
NET LOSS	$ 12,689	$ 4,476
LOSS PER ORDINARY SHARE BASIC AND DILUTED	$ 18.83	$ 6.34
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER ORDINARY SHARE	719,060	719,060

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

UROGEN PHARMA LTD.

STATEMENTS OF CHANGES IN SHAREHOLDERS EQUITY

(U.S. dollars in thousands, except share data)

	ORDINARY SHARES		PREFERRED SHARES		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL
	NUMBER OF SHARES	AMOUNT	NUMBER OF SHARES	AMOUNT	AMOUNTS		
BALANCE AS OF JANUARY 1, 2014	719,060	$ 2			$ 10,847	$ (8,108)	$ 2,741
CHANGES DURING 2014:							
Issuance of share capital, net of issuance costs			236,912	1	4,025		4,026
Issuance of preferred shares in respect of conversion of convertible notes			34,061	(*)	579		579
Share-based compensation					293		293
Net loss						(4,476)	(4,476)
BALANCE AS OF DECEMBER 31, 2014	719,060	$ 2	270,973	$ 1	$ 15,744	$ (12,584)	$ 3,163
CHANGES DURING 2015:							
Issuance of preferred shares, net of issuance costs			1,135,984	2	21,253		21,255
Purchase of IP R&D in consideration of Preferred A Shares			216,000	1	4,102		4,103
Share-based compensation					449		449
Net loss						(12,689)	(12,689)
BALANCE AS OF DECEMBER 31, 2015	719,060	$ 2	1,622,957	$ 4	$ 41,548	$ (25,273)	$ 16,281

The accompanying notes are an integral part of these financial statements.
(*) Represents amount less than one thousand

UROGEN PHARMA LTD.

STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	YEAR ENDED DECEMBER 31,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,689)	$ (4,476)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	113	30
In process R&D	4,103	—
Share based compensation	449	293
Exchange rates differences	(1)	—
Fair value adjustment of convertible notes	—	(28)
Fair value adjustment of warrants for preferred shares	241	(13)
Changes in operating asset and liabilities:		
Increase in prepaid expenses and other current assets	(737)	(330)
Increase in accounts payable, accrued expenses and advances	1,155	239
Increase in employee related accrued expenses	191	168
Net cash used in operating activities	(7,175)	(4,117)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Change in restricted deposit	—	23
Purchase of property and equipment	(301)	(24)
Net cash used in investing activities	(301)	(1)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of preferred shares and warrants, net of issuance costs	21,581	4,304
Proceeds from issuance of convertible notes, net of issuance costs	—	647
Net cash provided by financing activities	21,581	4,951
INCREASE IN CASH AND CASH EQUIVALENTS	14,105	833
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF THE YEAR	3,870	3,037
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF THE YEAR	$ 17,975	$ 3,870
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING ACTIVITIES:		
Purchase of IP R&D in consideration of Preferred A Shares	$ 4,103	—
Conversion of convertible notes into preferred A shares	$ —	$ 579
Conversion of convertible notes into warrants for preferred shares	$ —	$ 40

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

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 1-NATURE OF OPERATIONS

UroGen Pharma Ltd. (formerly TheraCoat Ltd., the "Company") is an Israeli company incorporated in April 2004.

The Company is a clinical stage biopharmaceutical company focused on developing novel therapies designed to change the standard of care for urological pathologies.

The Company is in the research and development stage and has not yet generated revenue from its operations. During its years of operation, the Company has incurred cumulative losses and negative cash flows from operating activities. As of December 31, 2015 the accumulated deficit was $25,273. Subsequent to December 31, 2015 the Company incurred additional significant losses and expects to continue to incur negative cash flows from operations. As a result, there are substantial doubts about the Company's ability to continue as a going concern.

Management plans include raising capital from existing and external investors and applying for research and development grants. There are no assurances, however, that the Company will be successful in obtaining sufficient financing needed for its operations. If the Company is unsuccessful in raising capital, it may need to reduce or curtail activities or cease operations.

These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 2-SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

b. Use of estimates in the preparation of financial statements

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 financial statements, the most significant estimates and assumptions relate to the fair value of share-based compensation and the fair value of the warrants for preferred shares.

c. Functional currency

The U.S. dollar ("dollar") is the currency of the primary economic environment in which the operations of the Company are conducted. Therefore, the functional currency of the Company is the dollar.

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items in the statements of operations, the following exchange rates are used: (i) for transactions exchange rates at transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization, etc.) -historical exchange rates. Currency transaction gains and losses are presented in financial expense (income).

d. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

e. Property and equipment

1) Property and equipment are stated at cost, net of accumulated depreciation.
2) The Company's property and equipment are depreciated using the straight-line method on the basis of their estimated useful lives.

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 2-SIGNIFICANT ACCOUNTING POLICIES (continued)

e. Property and equipment (continued)

Annual rates of depreciation are as follows:

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

Leasehold improvements are amortized using the straight-line method over the shorter of the expected lease term and the estimated useful life of the improvements.

f. Impairment of long-lived assets

The Company tests long-lived assets, comprised solely of property and equipment, for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future undiscounted cash flows of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would be written down to their estimated fair values, calculated based on the present value of expected future discounted cash flows or some other fair value measure.

As of December 31, 2015 and 2014, the Company did not recognize an impairment loss for its long-lived assets.

g. Contingencies

Certain conditions may exist as of the date of the financial statements, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company's management assesses such contingent liabilities and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or unasserted claims that may result in such proceedings, the Company's management evaluates the perceived merits of any legal proceedings or unasserted claims as well as the perceived merits of the amount of relief sought or expected to be sought.

Management applies the guidance in ASC 450-20-25 when assessing losses resulting from contingencies. If the assessment of a contingency indicates that it is probable that a loss has been incurred and the amount of the liability can be estimated, then the estimated liability is recorded as accrued expenses in the Company's financial statements. If the assessment indicates that a potential loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of possible loss if determinable are disclosed.

In accruing a provision for loss, the Company recognizes an accrual for the amount within a range of loss that represents the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company accrues for the minimum amount within the range.

h. Financial instruments

When the Company issues preferred shares, it considers the provisions of ASC 480 in order to determine whether the preferred share should be classified as a liability. If the instrument is not within the scope of ASC 480, the Company further analyses the instrument's characteristics in order to determine whether it should be classified within temporary equity (mezzanine) or within permanent equity in accordance with the provisions of ASC 480-10-S99.

When the Company issues other freestanding instruments, the Company first analyses the provisions of ASC 480 in order to determine whether the instrument should be classified as a liability, with subsequent changes in fair value recognized in earnings in each period.

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 2-SIGNIFICANT ACCOUNTING POLICIES (continued)

h. Financial instruments (continued)

If the instrument is not within the scope of ASC 480, the Company further analyses the provisions of ASC 815-40 in order to determine whether the instrument should be classified within equity or rather classified as an asset or liability, with subsequent changes in fair value recognized in earnings in each period. See also note 6 and note 7.

i. Share-based compensation

The Company accounts 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, net of estimated forfeitures. The Company estimates forfeitures based on historical experience and anticipated future conditions.

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

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

j. Research and development costs

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 and professional services. Grants received from the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor (the "OCS") are recognized when the grant becomes receivable, provided there is reasonable assurance that the Company will comply with the conditions attached to the grant and there is reasonable assurance the grant will be received. The grant is deducted from the research and development expenses as the applicable costs are incurred. In December 2015 and 2014, the Company deducted from research and development expenses an amount of $537 and $529, respectively. 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 in 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 research and development costs at the time the costs are incurred.

The intellectual property costs totaling $4,103, as described in note 7a(5), were expensed as incurred to research and development costs in accordance with ASC 730, as the intellectual property was purchased from others for a particular research and development project and has no alternative future use and therefore no separate economic value.

k. Income taxes:

1) Deferred taxes
   Income 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.
2) Uncertain income tax positions
   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 based on technical merits. If this threshold is met, the second

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 2-SIGNIFICANT ACCOUNTING POLICIES (continued)

k. Income taxes (continued):

step is to measure the tax benefit as the largest amount that is more likely than not of being realized upon ultimate settlement.

l. Loss per share

Basic loss per share ("LPS") is computed by dividing net loss for the year, after reducing cumulative dividends on preferred shares by the weighted average number of ordinary shares of the Company outstanding for each period.

The calculation of diluted net loss per share excludes potential share issuances of ordinary shares upon the exercise of share options, warrants for preferred shares, convertible note and convertible preferred share as each of their effect is anti-dilutive.

m. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

As of December 31, 2015 and 2014 the fair value of the financial assets and liabilities, approximate their carrying amounts.

n. Concentration of credit risks

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

o. Comprehensive loss

The Company has no other comprehensive loss components other than net loss.

p. Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments. The Company operates in one operating segment.

q. Newly issued and recently adopted accounting pronouncements

1) In February, 2016, the FASB issued a new ASU which revise lease accounting guidance. Under the new guidance, lessees will be required to recognize a right-of-use asset and a lease liability for all leases, other than

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 2-SIGNIFICANT ACCOUNTING POLICIES (continued)

q. Newly issued and recently adopted accounting pronouncements (continued)

leases that meet the definition of a short-term lease. The liability and the right-of-use asset arising from the lease will be measured as the present value of the lease payments. The new standard is effective for fiscal year beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The new standard must be adopted using a modified retrospective transition approach. The Company is currently evaluating the impact of the adoption of the new lease accounting guidance on its consolidated financial statements.

2) In August 2014, FASB issued ASU 2014-15—Presentation of Financial Statements—Going Concern (ASC Subtopic 205-40): "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern". The update requires management to assess a company's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. All entities are required to apply the new requirements in annual periods ending after December 15, 2016, and interim periods thereafter. Early application is permitted. The Company is required to adopt these provisions for the annual period ending December 31, 2016.

NOTE 3-PROPERTY AND EQUIPMENT

	DECEMBER 31,	
	2015	2014
Cost:		
Leasehold improvements	$ 66	$ 19
Computers and software	59	38
Laboratory equipment	105	44
Manufacturing equipment	125	—
Furniture	61	30
	416	131
Less- Accumulated depreciation	(157)	(60)
Property and equipment, net	$ 259	$ 71

Depreciation expense was $113 and $30 for the years ended December 31, 2015 and 2014, respectively.

NOTE 4-EMPLOYEE RIGHTS UPON RETIREMENT

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

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

The Company operates pension and severance compensation plans subject to Section 14 of the Israeli Severance Pay Law. 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.

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 5-COMMITMENT AND CONTINGENCIES

a. Lease agreement

In April 2016, the Company signed an addendum to November 2014 lease agreement in order to increase the office space rented and to extend the rent period. The Company has a lease agreement effect until 2019.
The rent expenses for the years ending December 31, 2015 and 2014 are approximately $121 and $74, respectively.

The future minimum lease payments required in each of the next seven years under the lease agreements are $184 in 2016, $211 per year for the years 2017 and 2018, and $158 in 2019.

b. Grants from the Office of the Chief Scientist of the State of Israel (the – "OCS")

The Company has received grants from the OCS for research and development funding. Up until 2007, the OCS 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 OCS 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 OCS, royalties of 3%-4.5% 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, 2015, the maximum royalty amount payable by the Company under these funding arrangements is $1,886 (excluding interest).

c. Financing success fees

The Company entered into agreements with third parties and shareholders in connection with fundraising efforts. In consideration of the services rendered, the Company undertook to pay those third parties and shareholders certain success fees from funds actually received by the Company and/or options to purchase equity of the Company, at a rate agreed between the parties.

Total success fees to third parties for the year ended December 31, 2015 were $108 and were payable in cash. For the year ended December 31, 2014, total success fees to third parties were $52, which consisted of cash and 859 options to third parties to purchase ordinary shares with a fair value of $2.

d. International pharmaceutical company ("Pharma Co.")

In August 2015 the Company entered into an agreement with a large international pharmaceutical company ("Pharma Co.") pursuant to which the Company undertook to supply its gel product and supporting services to the Pharma Co. for consideration of $750, to allow Pharma Co. to conduct certain scientific investigations aimed at testing utility of the Company's gel product for the delivery of a certain proprietary product of Pharma Co. Further, the Company granted Pharma Co. a time limited option to negotiate an exclusive, worldwide right to research, develop, make and have made, use, sell, offer to sell and import the Company's product in combination with Pharma Co.'s product.

The amount received from Pharma Co. is deducted from research and development expenses in the statements of operations as the applicable costs are incurred. As of December 31, 2015 an amount of $624 was deducted from research and development expenses. Also, the Company has an advanced grant from Pharma Co. in the amount of $126. The advanced grant is recorded in "Accounts payable, accrued expenses and advances".

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 6-FINANCIAL INSTRUMENTS AT FAIR VALUE THROUGH PROFIT OR LOSS

a. Convertible Notes

1) During 2014, the Company issued a series of convertible notes (the "convertible notes") in the aggregate amount of approximately $647. The convertible notes are to be automatically converted into ordinary shares at a conversion price of $16.00 at December 2017, or to the most senior preferred shares or ordinary shares upon occurrence of certain events (each a "Qualifying Event"), such as an IPO, M&A or a financing round in an amount of at least $5 million in a single transaction or a series of related transactions. Conversion of the convertible notes upon a Qualifying Event is to a variable number of shares, at a conversion price that generally reflects a fixed discount on the price per share reflected in these events.

   In July 2014, the Company offered the convertible noteholders an option to convert the note according the terms of the next financial round in lieu of the conversion for discount. In October 2014, at the initial closing of the Share Purchase Agreement (the – "SPA") (see note 7) the Company issued 34,061 shares of Series A preferred shares and granted warrants to purchase additional 17,031 shares of Series A-1 preferred shares upon conversion of the convertible notes.

2) Accounting treatment of the convertible notes

   Under ASC 480, a financial instrument that embodies a conditional obligation, that the issuer may settle by issuing a variable number of its equity shares shall be classified as a liability if, at inception, the monetary value of the obligation is based solely or predominantly on a fixed monetary amount known at inception.

   At inception the Company concluded and determined that the convertible notes should be classified as a liability under the provision of ASC 480.

   The convertible notes are accounted for at fair value at each reporting period with changes in fair value recorded in the statement of operations within financial income (expense).

   As of October 20, 2014, the fair value of the convertible notes was measured in accordance with an option pricing method ("OPM"). The fair value was determined mainly based on the SPA price per share of $19.00 of Series A preferred shares and assumptions related to achieving the required milestone for additional investment that was determined in the SPA and expected volatility at a rate of 68.9%. The change in fair value until conversion was $28.

b. Warrants for preferred shares

1) As part of the SPA, the Company issued warrants (the "A-1 warrants") for preferred shares, see note 7a2.

2) The A1 Warrants are exercisable into preferred A-1 shares of the Company, nominal value NIS 0.01 per share, for an exercise price of $25.00 per share commencing on the date of the issuance and until the earlier of an IPO, M&A events or four years.

   The warrants are exercisable for preferred A-1 shares, in consideration of cash representing the exercise price. In the event that the warrant is exercised in connection with an IPO or M&A events, the holder may elect to convert the warrant on a net share basis.

   The A1 warrants are classified as liabilities in accordance with ASC 480, as they are freestanding instruments, exercisable into preferred A-1 shares, which are redeemable upon certain events that represent "Deemed Liquidation" events (see also Note 7c3). Accordingly, the A1 Warrants are measured at fair value in every reporting period, and changes in their fair value are recognized in earnings within financial income (expense).

   As of December 31 2014, the fair value of the warrants of preferred shares was measured using an option pricing method ("OPM"). The fair value was determined mainly based on the SPA price per share of $19.00 of Series A preferred shares and assumptions related to achieving the required milestone for additional investment that was determined in the SPA, and, expected volatility at a rate of 68.3%.

   As of December 31 2015, the fair value of the warrants for preferred shares was measured in accordance with the Hybrid Method. The Hybrid Method combines the probabilities of an IPO scenario which was estimated at

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 6-FINANCIAL INSTRUMENTS AT FAIR VALUE THROUGH PROFIT OR LOSS (continued)

b. Warrants for preferred shares (continued)

15% and a liquidation event scenario which was estimated at 85%. The valuation methodology was changed in 2015 to the Hybrid Method due to management assessment of the probability of an IPO. The fair value was determined mainly based on the SPA price per share of $19.00 of Series A preferred shares and assumptions related to achieving the required milestone for additional investment that was determined in the SPA, and, expected volatility at a rate of 75.4%.

c. *The Company financial instruments measured in fair value and classified as Level 3.*

The table below sets forth a summary of the changes in the fair value of the financial instruments liabilities classified as Level 3 for the year ended December 31 ,2015:

	WARRANTS
Balance at beginning of year	$ 305
Issuance of warrants for preferred shares	326
Changes in fair value of warrants for preferred shares	241
Balance at end of year	$ 872

The table below sets forth a summary of the changes in the fair value of the financial instruments liabilities classified as Level 3 for the year ended December 31, 2014:

	CONVERTIBLE NOTES	WARRANTS
Balance at beginning of year	$ —	$ —
Issuance of convertible notes	647	—
Changes in fair value of convertible notes	(28)	—
Conversion of convertible notes	(619)	—
Issuance of warrants for preferred shares	—	318
Changes in fair value of warrants for preferred shares	—	(13)
Balance at end of year	$ —	$ 305

NOTE 7-SHARE CAPITAL

a. Share capital

1) As of December 31, 2015 and 2014 the share capital of the Company was as follows:

	NUMBER OF SHARES			
	AUTHORIZED DECEMBER 31		ISSUED AND OUTSTANDING DECEMBER 31	
	2015	2014	2015	2014
Ordinary shares of NIS 0.01 par value	5,500,000	8,000,000	719,060	719,060
Series A and A-1 preferred shares of NIS 0.01 par value	4,500,000	2,000,000	1,622,957	270,973

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 7-SHARE CAPITAL (continued)

a. Share capital (continued)

2) In September 2014 (closing in October 2014), the Company signed a SPA with shareholders and new investors for an aggregate amount of up to $8,000 in exchange of Series A preferred Shares at a price per share of $19.00 and warrants to purchase Series A-1 preferred Shares at a per share exercise price of $25.00. According to the SPA, each investor that invests more than $500 shall transfer 50% of its investment at the initial closing in October 2014 (the "Initial Closing") and additional 50% once the Company meets certain milestones the ("Milestone Closing") or upon an investors' waiver of attainment of the milestone. As part of the SPA, in October 2014 the convertible notes were converted (see note 6).

   Following the Initial Closing the Company approved the reclassification of ordinary shares from the authorized share capital of the Company, into 1,000,000 preferred A share, par value NIS 0.01 each and 1,000,000 preferred A-1 Share par value NIS 0.01 each.

   During 2014, the Company received $4,304 and additional amount of $130 in January 2015, net of issuance costs of $67, in exchange for 236,912 shares of Series A preferred shares and 118,465 A-1 warrants.

   In July 2015, at the Milestone Closing the Company issued for total consideration of $3,500, 184,210 shares of Series A preferred shares and 92,106 A-1 warrants at $25.00 price per Series A preferred share.

3) In October 2015, the Company reclassified 2,500,000 Ordinary Shares from the authorized but unissued share capital of the Company, into 2,500,000 preferred A Shares NIS 0.01 each, so that the authorized share capital of the Company, after giving effect to the additional preferred A shares, shall be follows:

CLASS OF SHARES	NUMBER OF SHARES	PAR VALUE
Ordinary shares NIS 0.01	5,500,000	55,000
preferred A shares NIS 0.01	3,500,000	35,000
preferred A-1 shares NIS 0.01	1,000,000	10,000

4) In October 2015 (closing in November 2015), the Company signed a share purchase agreement (the "2015 SPA") with shareholders and new investors for an aggregate amount of up to $18,084 in exchange of 951,774 shares of Series A preferred shares of the Company at a price per share of $19.00.

5) 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 of the aggregate amount of 216,000 shares of Series A preferred shares of the Company at a price per share of $19.00 (this includes 54,000 Series A preferred shares, which are being held in escrow and will be automatically released to TMX on the earlier of (i) 12 months from the date of initial closing, as set forth in the asset purchase agreement, and (ii) consummation of this offering). The Company will issue an additional 29,000 Series A preferred shares of the Company upon occurrence of each of three milestones for a maximum potential of 87,000 Series A preferred shares of the Company in aggregate. The intellectual property costs totaling $4,103 were expensed as incurred to research and development costs as there is no alternative future use and therefore no separate economic value.

b. Terms of the Company's ordinary shares

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.

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 7-SHARE CAPITAL (continued)

c. Terms of the Company's convertible preferred shares:

Preferred shares of the Company include A and A-1 preferred shares. The exercise price of preferred A share is $19.00 and the exercise price of preferred A-1 share is $25.00.

1) The holder of each preferred share shall: (i) be entitled to the number of votes which is equal to the number of ordinary shares into which such preferred share is then convertible (ii) have voting rights and powers equal to the voting rights and powers of any holder of ordinary shares and shall vote as a single class with the holders of ordinary shares; and (iii) be entitled to notice of any meeting of the shareholders.

2) From and after the date of the issuance of any preferred shares, dividends at the rate per annum of 8% of the Original Purchase Price (as defined) per share shall accrue on such preferred shares (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the preferred shares).

3) In the event of: (i) any dissolution or liquidation of the Company; (ii) any bankruptcy or insolvency proceeding under any bankruptcy or insolvency or similar law, whether voluntary or involuntary, is properly commenced by or against the Company; (iii) a receiver or liquidator has been appointed to all or substantially all of the Company's assets, (iv) a Deemed Liquidation (as defined below) event (each of the foregoing, a "Liquidation Event"), or (v) distribution of Dividends, then any Dividends, assets or proceeds of the Company available for distribution to the shareholders ("Distributable Proceeds"), shall be distributed among the shareholders pursuant to the following order of preference:

   a) First, the holders of the preferred shares shall be entitled to receive out of the Distributable Proceeds, prior to and in preference to any distribution to any of the holders of the ordinary shares an amount per preferred share equal to the higher of: (i) the Original Purchase Price plus any Accruing Dividends (as defined), accrued but unpaid thereon, whether or not declared, together with any other dividends declared but unpaid thereon less any amount of Distributable Proceeds previously paid with regard to such shares (collectively, the "Preferential A Amount") and (ii) such amount per share as would have been payable had all preferred shares been converted into ordinary shares immediately prior to such Liquidation Event.

   b) If the assets (or securities) available for distribution shall be insufficient to permit the payment to holders of the preferred shares of the full Preferential A Amount, then the entire assets (or securities) available for distribution shall be distributed pro-rata among the holders of the preferred shares in proportion to the Preferential A Amount each such holder is otherwise entitled to receive.

   c) Second, after payment in full of the Series A Liquidation Amount, the remaining assets of the Company available for distribution to the Company's shareholders shall be distributed among the holders of ordinary shares, pro rata based on the number of shares held by each such holder.

   d) Any of the following events shall be deemed a Liquidation Event (each a "Deemed Liquidation"): a transaction or a series of related transactions which entails (i) any sale of all, or substantially all, of the Company's assets or technology, including by way of granting an exclusive license that is equivalent to the sale of all, or substantially all of the Company's intellectual property; (ii) the consolidation, merger, or reorganization of the Company into any other entity, in which the Company is not the surviving entity; except, in each case, any transaction in which the shareholders of the Company prior to the transaction hold more than fifty percent (50%) of the outstanding share capital of the Company or the surviving company, as applicable, immediately following such transaction; provided, however, that shares of the surviving entity held by shareholders of the Company acquired by means other than the exchange or conversion of the shares of this Company shall not be used in determining if the shareholders of the Company own more than fifty percent (50%) of the outstanding share capital of the surviving entity (or its parent), but shall be used for determining the total outstanding share capital of the surviving entity); and (iii) any sale of all, or substantially all, of the Company's issued and outstanding share capital.

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 7-SHARE CAPITAL (continued)

c. Terms of the Company's convertible preferred shares (continued):

4) The holders of preferred shares shall have the following conversion rights:
   a) Optional conversion- each preferred share shall be convertible, at the option of the holder thereof, at any time after the date of issuance of such share into such number of fully paid shares of ordinary shares as is determined by dividing the Original Purchase Price by the conversion price applicable to such share, in effect on the date that the certificate is surrendered for conversion. The initial conversion price of the preferred shares shall be the Original Purchase Price; and provided, however, that the conversion price for the preferred shares shall be subject to certain adjustments.
   b) Automatic conversion- Each preferred share shall automatically be converted into ordinary shares at the Conversion Price at the time in effect for such preferred share, on the consummation of any one of the following events:
      i) Upon the closing of an IPO, where the Company's pre-money valuation is $75,000 or more with net proceeds to the Company of $25,000 or more (a "Qualified Public Offering"); or
      ii) In the event that holders of a majority of sixty percent (60%) of the then outstanding preferred shares, voting as a single class, consent to such.
5) The preferred shares also confer on their holders certain anti-dilution rights that adjust the conversion ratio in the event that the Company issues new shares at the price lower than the price original issue to the respective preferred shareholders.
   The preferred A shares are classified within permanent equity as they are not subject to liability classification under the scope of ASC 480, and meet all the requirements of equity classification under ASC 480-10-S99.

d. 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 share option plan is subject to Section 3(i) of the Israeli Income Tax Ordinance.

The expected volatility is based on the historical volatility of comparable companies. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted in dollar terms. The expected term is the length of time until the expected dates of exercising the options, and is estimated for employees (except senior management) using the simplified method due to insufficient specific historical information of employees' exercise behavior, and for non-employees, directors and senior management using the contractual term.

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 7-SHARE CAPITAL (continued)

d. Share-based compensation (continued)

For the years ended December 31, 2015 and 2014, the Company granted options to certain employees and non-employees as follows:

1) Options granted to employees and directors:

Set forth below are grants made by the Company to employees as of December 31, 2015. The majority of the options vests over a period of four years and expire on the seventh anniversary of the date of grant.

a) During 2014, the Company granted 50,873 options to employees and directors with an exercise price of $16 per share.

b) In October 2014, the Company modified the terms of the options granted during 2010-2013 to certain retired directors in, by extending the life of the options until the earlier of: (i) 24 months from the retirement date, and (ii) an initial public offering or an M&A event. At the date of modification, all of the options were fully vested. At the date of the modification, the Company recorded an expense of $15.9 based on the incremental increase in the value of the awards.

c) During 2015, the Company granted 343,371 options to employees and directors with an exercise prices ranging from $0 to $19 per share.

The fair value of options granted to employees and directors during 2015 and 2014 was $2,334 and $128, respectively.

The total unrecognized compensation cost of employee options at December 31, 2015 is $2,198, which is expected to be recognized over a weighted average period of 2 years.

2) Options granted to consultants and other service providers:

During 2015 and 2014, the Company granted 63,694 and 9,859 options, respectively, to consultants and service providers with an exercise price of $16.00 per share.

The fair value of options granted to consultants and other service providers during 2015 and 2014 was $57 and $12, respectively.

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

	2015	2014
Value of ordinary shares	$ 9.54-9.64	$ 5.06
Dividend yield	0%	0%
Expected volatility	69.78-76.68%	68.45-74.78%
Risk-free interest rate	0.38%–2.08%	1.38%–2.27%
Expected term	1-7 years	3.9-7.3 years

The fair value of the ordinary shares for 2015 and 2014 was measured in accordance with an option pricing model (see note 7a2).

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 7-SHARE CAPITAL (continued)

d. Share-based compensation (continued)

3) The following table summarizes the number of options outstanding under the Plan for the years ended December 31, 2015 and 2014, and related information:

	EMPLOYEES AND DIRECTORS		CONSULTANTS AND SERVICE PROVIDERS	
	NUMBER OF OPTIONS	WEIGHTED AVERAGE PRICE PER SHARE	NUMBER OF OPTIONS	WEIGHTED AVERAGE PRICE PER SHARE
Outstanding at January 1, 2014	148,827	$ 13.77	94,052	$ 12.60
Granted	50,873	$ 5.06	9,859	$ 5.06
Canceled/Forfeited	(13,500)	$ 7.90	—	—
Outstanding at December 31, 2014	186,200	$ 11.82	103,911	$ 11.88
Granted	343,371	$ 9.56	63,694	$ 9.54
Canceled/Forfeited	(2,500)	$ 16.00	(7,215)	$ 7.47
Outstanding at December 31, 2015	527,071	$ 10.33	160,390	$ 11.15

4) The following tables summarizes the outstanding and exercisable options as of December 31, 2015:

	DECEMBER 31, 2015			
	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	86,000	6.6	—	—
$ 0.01	15,825	2.8	15,825	2.8
$ 5.70	17,000	6.8	—	—
$ 7.84	56,297	1.7	56,297	1.7
$12.85	60,687	3.3	60,687	3.3
$16.00	363,445	6.0	103,586	4.4
$19.00	75,000	7.0	—	—
$21.53	13,207	1.7	13,207	1.7
	687,461		249,602	

For the years ended December 31, 2015 and 2014, no options were exercised.
The aggregate intrinsic value of the total vested and exercisable options as of December 31, 2015 is $2,274.

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 7-SHARE CAPITAL (continued)

d. Share-based compensation (continued)

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

	YEAR ENDED DECEMBER 31,	
	2015	2014
Research and development expenses	$ 170	$ 108
General and administrative expenses	279	185
	$ 449	$ 293

NOTE 8-TAXES ON INCOME

The Company is taxed under Israeli tax laws:

a. Tax rates

The income of the Company is taxed at the regular rate. The corporate tax rate for 2015 and 2014 was 26.5%.

On January 4, 2016, amendment No. 216 to the Israeli Tax Ordinance was published, which reduced the corporate tax rate from 26.5% to 25% commencing on January 1, 2016.

b. Tax assessments

All the tax assessments filed by 2012 are considered final.

c. Losses for tax purposes carried forward to future years

As of December 31, 2015, the Company had approximately $13,928 of net carry forward tax losses available to reduce future taxable income without limitation of use.

d. Deferred income taxes:

	DECEMBER 31,	
	2015	2014
In respect of:		
Net operating loss carry forward	$ 3,691	$ 2,067
Research and Development expenses	742	444
Other	66	40
Less—valuation allowance	(4,499)	(2,551)
Net deferred tax assets	$ —	$ —

The change in valuation allowance for the years ended December 31, 2015 and 2014 were as follows:

	2015	2014
Balance at the beginning of the year	$(2,551)	$(1,830)
Changes during the year	(1,948)	(721)
Balance at the end of the year	$(4,499)	$(2,551)

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 8-TAXES ON INCOME (continued)

d. Deferred income taxes (continued):

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

e. ***As of December 31, 2015 and 2014, the Company had not accrued a provision for uncertain tax positions.***

NOTE 9-LOSS PER ORDINARY SHARE:

The following table sets forth the calculation of basic and diluted loss per share for the periods indicated:

	YEAR ENDED DECEMBER 31,	
	2015	2014
Basic and diluted:		
Loss attributable to equity holders of the Company	$ 12,689	$ 4,476
Dividend accumulated for preferred shares during the period	$ 852	$ 81
Loss attributable to equity holders of the Company, after deducting dividend accumulated for preferred shares	$ 13,541	$ 4,557
Weighted average number of ordinary shares	719,060	719,060
Loss per ordinary share (LPS)	$ 18.83	$ 6.34

For the years ended December 31, 2015 and 2014, all ordinary shares underlying outstanding options, A-1 warrants, convertible notes and convertible preferred shares have been excluded from the calculation of the diluted loss per share since their effect was anti-dilutive. Diluted LPS does not include 687,461 and 290,111 ordinary shares underlying outstanding options for the years ended December 31, 2015 and 2014, respectively, 227,602 and 135,496 shares issuable upon exercise of the A-1 warrants for preferred A-1 shares for the years ended December 31, 2015 and 2014, respectively, 1,622,957 and 270,973 shares issuable upon conversion of preferred shares for the years ended December 31, 2015 and 2014, respectively and 34,061 shares issuable upon conversion of the convertible notes for the year ended December 31, 2014.

NOTE 10-RELATED PARTIES-TRANSACTIONS AND BALANCES:

Related parties include the Chairman of the Board of Directors, the board members and the Chief Executive Officer of the Company.

a. Transactions with related parties

	YEAR ENDED DECEMBER 31,	
	2015	2014
Expenses:		
Payroll and related expenses	$ 440	$ 324
Management fees	139	132
	$ 579	$ 456

UROGEN PHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share and per share data)

NOTE 10-RELATED PARTIES-TRANSACTIONS AND BALANCES (continued):

b. Balances with related parties:

	DECEMBER 31,	
	2015	2014
Accounts payable and accrued expenses	$ 12	$ 60

c. In October 2015 the Company entered into an asset purchase agreement with TMX. A beneficial owner of the Company is also a beneficial owner of TMX. See also note 7a5.

NOTE 11-SUBSEQUENT EVENTS:

The Company has evaluated subsequent events through April 20, 2016:

In February, March and April 2016, the Company increased the number of ordinary shares reserved for issuance under the Company's share option/incentive plans and arrangements by 100,000, 65,000 and 43,000 ordinary shares, respectively, to a total amount of 775,665 ordinary shares.

Table of Contents

Ordinary Shares

UroGen Pharma Ltd.

PRELIMINARY PROSPECTUS

Jefferies

Cowen and Company

, 2016

Through and including , 2016 (25 days after the date of this prospectus), all dealers that buy, sell or trade our ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. Indemnification of Directors, Officers and Employees.

Under the Israeli Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care, but only if a provision authorizing such exculpation is included in its articles of association. Our amended and restated articles of association to be effective upon the closing of this offering include such a provision. A company may not exculpate in advance a director from liability arising out of a breach of the duty of care with respect to a distribution.

Under the Israeli Companies Law, a company may indemnify an office holder with respect to the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Israeli Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder, if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of the duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- a financial liability imposed on the office holder in favor of a third party.

Under the Israeli Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of the duty of care committed intentionally or recklessly, excluding a breach arising out of the negligent conduct of the office holder;

- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, civil fine, monetary sanction or forfeit levied against the office holder.

Under the Israeli Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders. See “Management—Approval of Related Party Transactions under Israeli Law—Fiduciary Duties of Directors and Executive Officers.”

Our amended and restated articles of association to be effective upon the closing of this offering will permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Israeli Companies Law.

We have obtained directors and officers liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Israeli Companies Law. In addition, prior to the closing of this offering, we intend to enter into agreements with each of our directors and executive officers exculpating them from liability to us for damages caused to us as a result of a breach of duty of care and undertaking to indemnify them, in each case, to the fullest extent permitted by our amended and restated articles of association to be effective upon the closing of this offering and Israeli law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance.

Insofar as the indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or persons controlling the registrant, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 7. Recent Sales of Unregistered Securities.

The following list sets forth information as to all securities we have sold since January 1, 2013, which were not registered under the Securities Act.

- Between January 1, 2013 and December 31, 2013, we issued shares to certain new investors and existing shareholders totaling 220,502 ordinary shares for total consideration of $3.5 million.
- In February 2014, we issued a series of unsecured subordinated convertible promissory notes to new investors and several of our existing shareholders These notes were amended in July 2014 and are referred to as the 2014 notes, as amended. Pursuant to the 2014 notes, we initially received an aggregate principal amount of $647,112, bearing interest at 6% per annum. The principal and all accrued interest on the 2014 notes was to be, on the consummation of the investment of a specified amount, automatically converted into either: (i) Series A preferred shares at a five percent (5%) discount on the price per share; or (ii) into ordinary shares at a fifteen percent (15%) discount on the price per share, on the date of conversion, as determined by our board of directors, all at the election of the 2014 note holders. On October 20, 2014, in lieu of such automatic conversion, we offered the holders of the 2014 notes the right to convert the 2014 notes into Series A preferred shares at a price per share of $19.00 and to receive warrants for no additional consideration, all as if they were subscribing to purchase securities pursuant to the 2014 Share Purchase Agreement. All of the 2014 note holders elected to convert the principal amounts of their notes on these terms immediately prior to the initial closing of the 2014 Share Purchase Agreement and waived their right to interest due or payable on the principal amount. All 2014 notes were cancelled.
- On October 20, 2014, June 28, 2015 and July 7 and 28, 2015, (i) we issued to certain investors and existing shareholders, 421,122 preferred shares for approximately $8.0 million, which will be converted into ordinary shares prior to this offering. We further granted such investors and existing shareholders 210,571 warrants to purchase preferred shares (to be converted into warrants to purchase ordinary shares prior to this offering) at an exercise price of $25.00 per share; and (ii) we issued to the 2014 notes holders 34,061 preferred shares and 17,031 warrants to purchase preferred shares (to be converted into ordinary shares and warrants prior to this offering) at an exercise price of $25.00 in exchange for their conversion of all principal and accrued interest due on the notes in an aggregate amount of $647,112.

- On November 12, 2015, we issued to Telormedix SA, or TMX, 216,000 preferred shares in consideration of any and all owned knowledge or data of TMX, whether registered or unregistered, including, but not limited to, intellectual property, goodwill, clinical studies, and licenses. These shares will be converted into ordinary shares prior to this offering. We also undertook to issue to TMX 87,000 additional preferred shares upon the achievement of certain milestones, which may be met in the future.
- On December 10, 2015, we issued to certain investors and existing shareholders 951,774 preferred shares, which will be converted into ordinary shares prior to this offering for $18.1 million.

The sales of the above securities were deemed to be exempt from registration under the Securities Act because they were made outside of the U.S. to certain non-U.S. individuals or entities pursuant to Regulation S or, in reliance upon the exemption from registration provided under Section 4(a)(2) of the Securities Act and the regulations promulgated thereunder.

Additionally, we granted share options to employees, directors, consultants and service providers under our 2010 Israeli Share Option Plan covering an aggregate of 773,859 ordinary shares, with exercise prices ranging from $0.01 to $21.53 per share. Such number excludes 9,000 restricted share units and 3,000 options, the grant of which is contingent upon the closing of this offering.

We claimed exemption from registration under the Securities Act for these option grants described above under Section 4(a)(2), Regulation S, or under Rule 701 of the Securities Act as transactions pursuant to written compensatory plans or pursuant to a written contract relating to compensation.

No underwriters were employed in connection with the securities issuances set forth in this Item.

Item 8. Exhibits and Financial Statement Schedules.

(a) Exhibits. See the Exhibit Index attached to this registration statement, which is incorporated by reference herein.

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 9. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer, or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(1) for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective; and

(2) for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Ra'anana, Israel on this day of , 2016.

UROGEN PHARMA LTD.

By: _____
Ron Bentsur
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Ron Bentsur and Gary Titus, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Registration Statement, including post-effective amendments or any abbreviated registration statement and any amendments thereto filed pursuant to Rule 462(b) increasing the number of securities for which registration is sought, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, 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 for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
Ron Bentsur	Chief Executive Officer *(Principal Executive Officer)*	,2016
Gary Titus	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	,2016
Arie Belldegrun, M.D.	Chairman	,2016
Stuart Holden, M.D.	Director	,2016
Chaim Hurvitz	Director	,2016
Ran Nussbaum	Director	,2016
Pini Orbach, Ph.D.	Director	,2016

Urogen Pharma, Inc.

By: _____
Name: Ron Bentsur
Title: President and CEO

Authorized U.S. Representative , 2016

Table of Contents

EXHIBIT INDEX

EXHIBIT NUMBER	EXHIBIT DESCRIPTION
1.1*	Form of Underwriting Agreement
3.1	Amended and Restated Articles of Association of the Registrant, adopted October 28, 2015
3.2*	Form of Amended and Restated Articles of Association of the Registrant, to be effective upon closing of this offering
4.1*	Specimen Share Certificate
5.1*	Opinion of Hamburger Evron & Co., Israeli counsel to the Registrant, as to the validity of the ordinary shares
10.1*	Form of director and officer indemnification agreement by and between the Registrant and each of its directors and executive officers, to be effective upon closing of this offering
10.2	2010 Israeli Share Option Plan
10.3	Investors' Rights Agreement, dated September 18, 2014, as amended on October 1, 2015 and April 12, 2016, among the Registrant and certain of the Registrant's shareholders
10.4	Asset Purchase Agreement, dated October 1, 2015, between the Registrant and Telormedix, SA
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
23.2*	Consent of Hamburger Evron & Co. (included in Exhibit 5.1)
24.1*	Power of Attorney (included in signature pages of Registration Statement)
99.1	Consent of Dr. J. Gregory Wirth

* To be provided by amendment.

Exhibit 3.1

THE COMPANIES LAW, 5759-1999
A PRIVATE COMPANY LIMITED BY SHARES

AMENDED AND RESTATED
ARTICLES OF ASSOCIATION
OF
UroGen Pharma Ltd.
P.C. 51-353762-1
(the "**Company**")

(Adopted on 28th day of October, 2015)

PRELIMINARY

1. **THE COMPANY'S NAME**

The Company's English name is **UroGen Pharma Ltd.** and in Hebrew: בע"מ יורוג'ן פארמה ..

2. **INTERPRETATION**

2.1. Unless the subject or the context otherwise requires: words and expressions defined in the Companies Law (as defined below) in force on the date when these Articles (as defined below) first became effective shall have the same meanings herein; words and expressions importing the singular shall include the plural and vice versa; words and expressions importing the masculine gender shall include the feminine gender; and words and expressions importing persons shall include bodies corporate.

2.2. The captions in these Articles are for convenience only and shall not be deemed a part hereof or affect the construction of any provision hereof.

2.3. The terms below shall have the meanings defined next to each term:

2.3.1. "**Affiliate**" of an entity shall mean a person or entity that controls or is controlled by or is under common control with the respective entity; the term "control" means the possession, directly or indirectly, of more than fifty percent (50%) of the voting power or the right to appoint more than fifty percent (50%) of the members of the Board of Directors or the right to receive more than fifty percent (50%) of the distributed profits;

2.3.2. "**Arkin**" shall mean Arkin Communications Ltd. and any Permitted Transferee thereof;

2.3.3. "**Articles**" shall mean these Articles of Association of the Company, as they may be amended or replaced from time to time;

2.3.4. "**as converted basis**" shall mean assuming the theoretical conversion of all outstanding Preferred Shares into Ordinary Shares, at the then applicable conversion ratio in accordance with the provisions of these Articles;

2.3.5. The "**Board**" or the "**Board of Directors**" shall mean the Board of Directors of the Company;

2.3.6. "**Bonus Shares**" shall mean shares issued by the Company for no consideration to Shareholders entitled to receive them on a pro rata basis;

2.3.7. The "**Companies Law**" shall mean the Companies Law, 5759-1999, and the regulations promulgated thereunder, or any law, which may replace or amend it, as shall be in force from time to time;

2.3.8. "**Chairman**" shall mean the chairman of the Board of Directors;

2.3.9. "**Dividend**" shall mean any asset transferred by the Company to a Shareholder in respect of such Shareholder's shares, whether in cash or in any other way, including a transfer without valuable consideration, but excluding Bonus Shares;

2.3.10. An "**Eligible Holder(s)**" shall mean any holder of the Company's shares whose shares constitute at least five percent (5%) of the Company's issued and outstanding share capital, on an as converted basis;

2.3.11. The "**Investors**" shall mean Arkin, Pontifax and all other holders of the Preferred Shares;

2.3.12. The "**IPO**" shall mean the consummation of the initial underwritten public offering of the Company's securities pursuant to an effective registration statement under the United States Securities Act of 1933, as amended, or any equivalent law of another jurisdiction;

2.3.13. "**Ordinary Majority**" shall mean a majority of the voting power attending and voting, in person or by proxy, at any General Meeting or class meeting, provided that the votes of shareholders abstaining at such meetings shall not be counted for the purpose of such majority;

2.3.14. "**Ordinary Resolution**" shall mean a resolution adopted at any General Meeting or class meeting by holders of an Ordinary Majority;

2.3.15. "**Ordinary Shares**" shall mean the Ordinary Shares of the Company, each of nominal value NIS 0.01;

2.3.16. The "**Original Issue Date**" shall mean as defined in Article 6.4.4;

2.3.17. The "**Original Purchase Price**" per share of Preferred A Shares shall mean US$ 19.00, and per share of Preferred A-1 Shares shall mean US$ 25.00, all subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Shares;

2.3.18. A "**Permitted Transferee**" of a Shareholder shall mean any of the following: (i) a Shareholder may transfer any of its shares to a transferee by operation of law; (ii) a corporate Shareholder may transfer any of its shares to any successor of such Shareholder by amalgamation, merger, or consolidation, or to any person, firm or corporation to which at the same time, substantially all the business and assets of such Shareholder are being sold, or to an Affiliate of such Shareholder; (iii) a Shareholder which is a limited or general partnership may transfer any of its shares to its partners and to affiliated partnerships managed by the same management company or managing (general) partner or by an entity that is Affiliated with such management company or managing (general) partner, (iv) an individual Shareholder may transfer his shares to a company in which such Shareholder

owns, directly or indirectly, more than ninety percent (90%) of the equity and voting capital, or to any Relative; (v) a Shareholder may transfer any of its shares to an acquirer that acquires in one transaction the entire outstanding share capital of the Company from the Shareholders, whether pursuant to Article 21 herein or Section 341 of the Companies Law or otherwise, including by way of a merger; and (vi) and any Shareholder may transfer shares to a trust which does not permit any of the settled property or the income therefrom to be applied otherwise than for the benefit of such Shareholder and/or its Permitted Transferees and no power or control over the voting powers conferred by any shares are subject to the consent of any person other than the trustees of such Shareholder and/or its Permitted Transferees, and a trust may transfer the shares held in trust back to the Shareholder beneficiary, or to any Permitted Transferee of the beneficiary, *provided however*, that in any of the foregoing events, the Permitted Transferee shall have first assumed in writing, a copy of which was delivered to the Company, all the transferring shareholder's obligations and undertakings to the Company and to any other shareholders (which relate to the Company). All shares held (beneficially or of record), at the time of applicable calculation, by Shareholders who are Permitted Transferees of each other, shall be aggregated together for the purpose of determining the availability to such holders of any rights under these Articles, and such rights - to the extent they are determined to be available at such time - may be exercised (up to the maximum extent so determined to be available in the aggregate to all such Shareholders) by any, some or all of such Shareholders who are Permitted Transferees of each other who may apportion such rights as among themselves in any manner they deem appropriate;

2.3.19. "**Pontifax**" shall mean Pontifax (Cayman) III L.P. and Pontifax (Israel) III L.P. (collectively referred to as "**Pontifax**") and Permitted Transferees thereof, provided however that any right of Pontifax designated in these Articles may be exercised by the Pontifax entity, or entities, that hold a majority in interest of the Company securities held by all of the Pontifax entities;

2.3.20. "**Preferred A Shares**" shall mean the Series A Preferred Shares of the Company, nominal value NIS 0.01 each, having the rights and obligations set forth in these Articles

2.3.21. "**Preferred A-1 Shares**" shall mean the Series A-1 Preferred Shares of the Company, nominal value NIS 0.01 each, having the rights and obligations set forth in these Articles.;

2.3.22. "**Preferred Shares**" shall mean the Preferred A Shares and the Preferred A-1 Shares;

2.3.23. A "**Qualified Public Offering**" shall mean as defined in Article 6.4.2 below;

2.3.24. A "**Qualified Transaction**" shall mean either of (i) an IPO; or (ii) any consolidation, merger or reorganization of the Company with, or into, another corporation or entity, in which the shareholders of the Company immediately prior to the transaction hold less than fifty percent (50%) or more of the outstanding shares of the surviving entity due to their holdings in the Company;

2.3.25. "**Register of Members**" shall mean the register of shareholders that must be maintained pursuant to Sections 127 and 130 of the Companies Law;

2.3.26. A "**Relative**" shall mean any lineal ascendant or descendant of an individual Shareholder, including without limitation any descendant of the Shareholder recognized by law as his descendant, his spouse, any ascendant or descendant of said Shareholder's spouse, or the spouse of any of said Shareholder's ascendants or descendants;

2.3.27. "**Repurchase**" shall mean the acquiring or the financing of the acquiring, directly or indirectly, by the Company or by a subsidiary of the Company or other corporate entity under the Company's control, of shares of the Company or securities convertible into or exercisable for shares of the Company, or the redemption of redeemable securities that are part of the Company's share capital pursuant to Section 312(d) of the Companies Law, including an obligation to do any of the same, and all provided that the seller is not the Company itself or another corporate entity fully owned by the Company;

2.3.28. A "**Shareholder**" shall mean any person registered in the Register of Shareholders of the Company as the owner of shares of the Company, at any given time;

2.3.29. "**Special Resolution**" shall mean any resolution of the General Meeting which is not an Ordinary Resolution adopted at any General Meeting or class meeting by holders of the Ordinary Majority;

2.3.30. The "**Transfer**" of shares shall mean any one of the following: direct or indirect, sale, assignment, transfer, pledge, hypothecation, grant of any security interest, mortgage or disposition of, by gift or otherwise, of all or any of the securities of the Company, or in any way the encumbrance of all or any of the shares of the Company, or attempted disposal of all or any portion of a security, or any interest or rights in a security. "**Transferred**" means the accomplishment of a Transfer, and "**Transferee**" means the recipient of a Transfer;

2.3.31. "**written**" or "**in writing**" shall include print, lithography, and any other legible form of writing or impression of letters, digits or other symbols in a visible or visually decipherable form, including material transmitted by letter, telex, or cable, or by facsimile or by electronic mail or by any other means of electronic communication producing a legible copy of the transmitted material.

3. PRINCIPAL OBJECTIVES, PURPOSE LIMITED LIABILITY AND RESTRICTIONS

3.1. Principal Objective. The principal objectives for which the Company is founded are:

3.1.1. To develop and commercialize medical know-how and products in the field of a novel drug delivery systems; and

3.1.2. In general: to engage in any business, commercial or other activity of any kind and to have the legal capacity for any right or obligation and for the execution of any legal act.

3.2. Donations. The Company may, from time to time, make charitable donations to worthy causes, as the Board may determine in its discretion, even if such donations are not made within the framework of the Company's business considerations.

3.3. Limitation of Liability. The liability of the members is limited to the unpaid portion of the nominal value of each share to which they may from time to time subscribe.

3.4. Restrictions. The Company is a private company and accordingly the following restrictions shall apply:

3.4.1. any invitation to the public to subscribe for any shares or debentures or debenture stock of the Company is hereby prohibited; and

3.4.2. the right to transfer shares in the Company shall be restricted as hereinafter provided.

SHARE CAPITAL

4. **INITIAL SHARE CAPITAL**

The registered share capital of the Company is One Hundred Thousand New Israeli Shekels (NIS 100,000) divided into: (i) Five Million Five Hundred Thousand (5,500,000) Ordinary Shares each of a nominal value of One Agorah (NIS 0.01); (ii) Three Million Five Hundred Thousand (3,500,000) Preferred A Shares each of a nominal value of One Agorah (NIS 0.01); and (ii) One Million (1,000,000) Preferred A-1 Shares each of a nominal value of One Agorah (NIS 0.01).

The powers, preferences, rights, restrictions, and other matters relating to the Ordinary Shares and the Preferred Shares are as set forth in the following Articles.

5. **ORDINARY SHARES**

5.1. The Ordinary Shares shall rank pari passu between them.

5.2. The holders of Ordinary Shares are entitled: (i) to receive notices of, and to attend, all General Meetings of the Shareholders; (ii) to one vote for each share held at all Shareholders' meetings for all purposes; and (iii) subject to the rights and privileges of the Preferred Shares, to share equally, on a per pro-rata share basis, in such share Dividends, Bonus Shares, profits or distributions as may be declared by the Board out of funds legally available therefor, and upon liquidation or dissolution - in the assets of the Company legally available for distribution to shareholders after payment of all debts and other liabilities of the Company (in each case, proportionally to the number of Ordinary Shares outstanding).

6. **PREFERRED SHARES**

6.1. Voting Rights. Except as otherwise provided in Article 34 hereof, and except as otherwise required by law, with respect to all matters submitted to a vote of holders of Ordinary Shares generally, the holder of each Preferred Share shall: (i) be entitled to the number of votes which is equal to the number of Ordinary Shares into which such Preferred Share is then convertible pursuant to Article 6.4 hereof, (ii) have voting rights and powers equal to the voting rights and powers of any holder of Ordinary Shares and shall vote as a single class with the holders of Ordinary Shares; and (iii) be entitled to notice of any meeting of the Shareholders. Fractional votes shall not, however, be permitted and any fractional voting rights resulting from the above formula (after aggregating all shares into which Preferred Shares held by each holder could then be converted) shall be rounded to the nearest whole number (with one-half being rounded upward).

6.2. Series A Accruing Dividends. From and after the date of the issuance of any Preferred Shares, dividends at the rate per annum of eight percent (8%) of the Original Purchase Price per share shall accrue on such Preferred Shares (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar

recapitalization with respect to the Preferred Shares) (the "**Accruing Dividends**"). Accruing Dividends shall accrue from day to day, whether or not declared, and shall be cumulative; provided however, that except as set forth in the following sentence of this Sub-article 6.2 such Accruing Dividends shall be payable only when, as, and if declared by the Board of Directors and the Company shall be under no obligation to pay such Accruing Dividends.

6.3. Liquidation and Dividend Preference. Subject to the applicable law, in the event of: (i) any dissolution or liquidation of the Company; (ii) any bankruptcy or insolvency proceeding under any bankruptcy or insolvency or similar law, whether voluntary or involuntary, is properly commenced by or against the Company; (iii) a receiver or liquidator has been appointed to all or substantially all of the Company's assets, (iv) a Deemed Liquidation (as defined below) event (each of the foregoing, a "**Liquidation Event**"), or (v) distribution of Dividends, then any Dividends, assets or proceeds of the Company available for distribution to the Shareholders ("**Distributable Proceeds**"), shall be distributed among the Shareholders pursuant to the following order of preference:

6.3.1. First, the holders of the Preferred Shares shall be entitled to receive out of the Distributable Proceeds, prior to and in preference to any distribution to any of the holders of the Ordinary Shares an amount per Preferred Share equal to the higher of: (i) the Original Purchase Price plus any Accruing Dividends, accrued but unpaid thereon, whether or not declared, together with any other dividends declared but unpaid thereon less any amount of Distributable Proceeds previously paid with regard to such shares (collectively, the "**Preferential A Amount**") and (ii) such amount per share as would have been payable had all Preferred Shares been converted into Ordinary Shares pursuant to Article 6.4 immediately prior to such Liquidation Event (the amount payable pursuant to this sentence, the "**Series A Liquidation Amount**").

6.3.2. If the assets (or securities) available for distribution shall be insufficient to permit the payment to holders of the Preferred Shares of the full Preferential A Amount, then the entire assets (or securities) available for distribution shall be distributed pro-rata among the holders of the Preferred Shares in proportion to the Preferential A Amount each such holder is otherwise entitled to receive.

6.3.3. Second, after payment in full of the Series A Liquidation Amount, the remaining assets of the Company available for distribution to the Company's shareholders shall be distributed among the holders of Ordinary Shares, pro rata based on the number of shares held by each such holder.

6.3.4. Any of the following events shall be deemed a Liquidation Event for the purposes of Article 6.2 (each a "**Deemed Liquidation**"): a transaction or a series of related transactions which entails (i) any sale of all, or substantially all, of the Company's assets or technology, including by way of granting an exclusive license that is equivalent to the sale of all, or substantially all of the Company's intellectual property; (ii) the consolidation, merger, or reorganization of the Company into any other entity, in which the Company is not the surviving entity; except, in each case, any transaction in which the shareholders of the Company prior to the transaction hold more than fifty percent (50%) of the outstanding share capital of the Company or the surviving company, as applicable, immediately following such transaction; provided, however, that shares of the surviving entity held by shareholders of the Company acquired by means other than the exchange or conversion of the shares of this Company shall not be used in determining if the shareholders of the Company own more than fifty percent (50%) of the outstanding share capital of the

surviving entity (or its parent), but shall be used for determining the total outstanding share capital of the surviving entity); and (iii) any sale of all, or substantially all, of the Company's issued and outstanding share capital.

6.4. Conversion

The holders of Preferred Shares shall have the following conversion rights (the "**Conversion Rights**"):

6.4.1. **Optional Conversion**. Each Preferred Share shall be convertible, at the option of the holder thereof, at any time after the date of issuance of such share into such number of fully paid shares of Ordinary Shares as is determined by dividing the Original Purchase Price by the conversion price applicable to such share, determined as hereinafter provided (the "**Conversion Price**"), in effect on the date that the certificate is surrendered for conversion. The initial Conversion Price of the Preferred Shares shall be the Original Purchase Price; and *provided*, *however*, that the Conversion Price for the Preferred Shares shall be subject to adjustment as set forth in this Article 6.4.

6.4.2. **Automatic Conversion**. Each Preferred Share shall automatically be converted into Ordinary Shares at the Conversion Price at the time in effect for such Preferred Share, on the consummation of any one of the following events:

i. upon the closing of an IPO, where the Company's pre-money valuation is US$ 75,000,000 or more with net proceeds to the Company of US$ 25,000,000 or more (a **"Qualified Public Offering"**);

ii. in the event that holders of a majority of sixty percent (60%) of the then outstanding Preferred Shares, voting as a single class, consent to such conversion;

6.4.3. **Mechanism of Conversion**. Before any holder of Preferred Shares shall be entitled to convert the same into Ordinary Shares, the holder shall surrender the certificate or certificates therefore, duly-endorsed, at the office of the Company or of any transfer agent for the Preferred Shares, and shall give notice to the Company at its principal corporate office of the election to convert the same and shall state therein the name or names in which the certificate or certificates for the Ordinary Shares are to be issued. Upon conversion of only a portion of the number of shares covered by a certificate representing Preferred Shares surrendered for conversion, the Company shall issue and deliver, at the expense of the Company, a new certificate covering the number of Preferred Shares representing the unconverted portion of the certificate so surrendered. The Company shall, as soon as practicable thereafter, issue and deliver at such office to such holder of Preferred Shares, or to the nominee or nominees of such holder, a certificate or certificates for the number of Ordinary Shares to which such holder shall be entitled as aforesaid and a cash amount in respect of any fractional interest in a share of Ordinary Shares as provided in Article 6.4.4 below. Such conversion shall be deemed to have been made immediately prior to the close of business on the date of such surrender of the Preferred Shares to be converted, and the person or persons entitled to receive the Ordinary Shares issuable upon such conversion shall be treated for all purposes as the record holder or holders of such Ordinary Shares as of such date. If the conversion is in connection with an underwritten offering of securities pursuant to an IPO, the conversion may, at the option of any holder tendering Preferred Shares for conversion, be conditioned upon the closing with the underwriters of the sale of securities pursuant to such offering, in which event the person(s) entitled to receive the Ordinary Shares upon such conversion of the Preferred Shares shall not be deemed to have converted such Preferred Shares until immediately prior to the closing of such sale of securities.

6.4.4. **Conversion Price Adjustments of Preferred Shares for Certain Dilutive Issuances**.

The conversion price of the Preferred Shares shall be subject to adjustment from time to time as follows:

i. After the date upon which any Preferred Shares were first issued (the **"Original Issue Date"**) and until IPO, if the Company shall issue any Additional Shares (as defined below) without consideration or for consideration per share less than the applicable Conversion Price for the Preferred Shares in effect immediately prior to the issuance of such Additional Shares (a "**Dilutive Issuance**"), then the applicable Conversion Price of the Preferred Shares in effect immediately prior to each such issuance shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following broad-based weighted average formula:

$$CP_2 = CP_1 * [(A + B) \div (A + C)]$$

For purposes of the foregoing formula, the following definitions shall apply:

CP2 shall mean the applicable conversion price in effect immediately after such issue of Additional Shares;

CP1 shall mean the applicable conversion price in effect immediately prior to such issue of Additional Shares;

"**A**" shall mean the number of Ordinary Shares outstanding immediately prior to such issue of Additional Shares on an issued but as converted basis, treating for this purpose as outstanding all Ordinary Shares issuable upon conversion of all issued Preferred Shares.

"**B**" shall mean the number of Ordinary Shares that would have been issued if such Additional Shares had been issued at a price per share equal to CP1 (determined by dividing the aggregate consideration received by the Company in respect of such issue by CP1).

"**C**" shall mean the number of such Ordinary Shares issued (or deemed issued on the conversion of such Additional Shares into Ordinary Shares) in such transaction.

ii. In the case of the issuance of Additional Shares for cash, the consideration shall be deemed to be the amount of cash paid therefor. The consideration for any Additional Shares shall be taken into account at the U.S. Dollar equivalent thereof, on the day such Additional Shares are issued, or deemed to be issued.

iii. In the case of the deemed issuance (as defined in Article 6.4.4vii below) of Additional Shares, the consideration for the Additional Shares shall be deemed to be the aggregate consideration received by the Company on the issuance of the securities themselves, taken together with any additional consideration (if any) to be paid to the Company on the exercise or conversion of the securities.

iv. In the case of the issuance of the Additional Shares for consideration in whole or in part other than cash, the consideration other than cash shall be deemed to be the fair value thereof as determined by the Board of Directors in good-faith.

v. In the case of the issuance of options to purchase or rights to subscribe for Ordinary Shares, or securities by their terms convertible into or exchangeable for Ordinary Shares or options to purchase or rights to subscribe for such convertible or exchangeable securities, the aggregate maximum number of Ordinary Shares deliverable upon exercise (assuming the satisfaction of any conditions to exerciseability, including without limitation, the passage of time, but without taking into account potential anti-dilution adjustments) of such options to purchase or rights to subscribe for Ordinary Shares, or upon the exchange or conversion of such security, shall be deemed to have been issued at the time of the issuance of such options, rights or securities, at a consideration equal to the consideration (determined in the manner provided in Sub-article 6.4.4i - 6.4.4iii, received by the Company upon the issuance of such options, rights or securities plus any additional consideration payable to the Company pursuant to the term of such options, rights or securities (without taking into account potential anti-dilution adjustments) for the Ordinary Shares covered thereby; *provided*, *however*, that if any options as to which an adjustment to the Conversion Price has been made pursuant to this Sub-Article 6.4.4 expire without having been exercised, then the Conversion Price shall be readjusted as if such options had not been issued (without any effect, *however*, on adjustments to the Conversion Price as a result of other events described in this Article).

vi. "**Additional Shares**" shall mean any Ordinary Shares issued, or deemed issued (as defined below) by the Company, which are issued after the Original Issue Date, other than Excluded Securities (as defined Article 12.2 below).

vii. For the purposes of the above, a "**deemed issuance**" shall mean the issuance of options or warrants to purchase or rights to subscribe to any Additional Shares, or securities by their terms convertible of exchangeable for Additional Shares, or options to purchase or rights to subscribe to such convertible or exchangeable securities, which may be exercised of converted into Additional Shares.

6.4.5. In the event the Company should at any time, or from time to time after the Original Issue Date, fix a record date for effecting a split or subdivision of the outstanding shares of Ordinary Shares or the determination of holders of Ordinary Shares entitled to receive a dividend or other distribution payable in additional shares of Ordinary Shares or other securities or rights convertible into, or entitling the holder thereof to receive, directly or indirectly, additional shares of Ordinary Shares (hereinafter referred to as "**Ordinary Shares Equivalents**") without payment of any consideration by such holder for the additional shares of Ordinary Shares or the Ordinary Shares Equivalents (including the additional shares of Ordinary Shares issuable upon conversion or exercise thereof), then, as of such record date (or the date of such dividend distribution, split or subdivision if no record date is fixed), the conversion price of the Preferred Shares shall be appropriately decreased so that the number of shares of Ordinary Shares issuable on conversion of the Preferred Shares shall be adjusted in proportion to such increase of the aggregate of shares of Ordinary Shares outstanding and those issuable with respect to such Ordinary Shares Equivalents with the number of shares issuable with respect to Ordinary Shares Equivalents determined from time to time in the manner provided for deemed issuances in Article 6.4.4v.

6.4.6. If the number of shares of Ordinary Shares outstanding at any time after the Original Issue Date is decreased by a combination or reverse Shares-split of the outstanding shares of Ordinary Shares, then, following the record date of such combination,

the conversion price of the Preferred Shares shall be appropriately increased so that the number of shares of Ordinary Shares issuable on conversion of each share of such Preferred Shares shall be decreased in proportion to such decrease in outstanding shares.

6.4.7. **Other Distributions**. In the event the Company shall declare a distribution payable in securities of other persons, evidences of indebtedness issued by the Company or other persons, assets (excluding cash dividends), options, or rights not referred to in Article 6.4 then, in each such case for the purpose of this Article 6.4.7 the holders of the Preferred Shares shall be entitled to a proportionate share of any such distribution as though they were the holders of the number of shares of Ordinary Shares into which their Preferred Shares are convertible as of the record date fixed for the determination of the holders of Ordinary Shares entitled to receive such distribution.

6.4.8. **Recapitalizations**. If at any time, or from time to time, there shall be a recapitalization of the Ordinary Shares, provision shall be made so that the holders of the Preferred Shares shall thereafter be entitled to receive upon conversion of the Preferred Shares the number of shares or other securities or property of the Company or otherwise to which a holder of Ordinary Shares deliverable upon conversion would have been entitled on such recapitalization. In the event of any capital reorganization of the Company, any reclassification of the Shares of the Company (other than a change in par value or from par value to no par value or from no par value to par value or as a result of a Shares dividend or subdivision, split-up or combination of shares), or any consolidation or merger of the Company (other than a consolidation or merger in which the Company is the continuing corporation and which does not result in any change in the Ordinary Shares or in which the holders of fifty percent (50%) of the voting securities of the Company immediately prior to the transaction continue, by virtue of their holdings of securities of the Company, to hold such securities after the transaction), each Preferred Share shall, after such reorganization, reclassification, consolidation, or merger, be convertible into the kind and number of shares or other securities or property of the Company, or of the corporation resulting from such consolidation or surviving such merger, to which the holder of the number of shares of Ordinary Shares deliverable (immediately prior to the time of such reorganization, reclassification, consolidation, or merger) upon conversion of such Preferred Shares would have been entitled upon such reorganization, reclassification, consolidation, or merger. In any such case, appropriate adjustment shall be made in the application of the provisions of this Article 6.4 with respect to the rights of the holders of the Preferred Shares after any such reorganization, reclassification, consolidation, merger, or recapitalization to the end that the provisions of this Article 6.4 (including adjustment of the conversion price then in effect and the number of shares purchasable upon conversion of the Preferred Shares) shall be applicable after that event as nearly equivalent as may be practicable.

6.4.9. **No Fractional Shares and Certificate as to Adjustments**.

No fractional shares shall be issued upon conversion of any share or shares of the Preferred Shares, and the number of Ordinary Shares to be issued shall be rounded down to the nearest whole share. Whether or not fractional shares are issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Shares the holder is at the time converting into Ordinary Shares and the number of shares of Ordinary Shares issuable upon such aggregate conversion.

6.4.10. Upon the occurrence of each adjustment or readjustment of the Conversion Price of Preferred Shares pursuant to this Article 6.4, the Company, at its

expense, shall promptly compute such adjustment or readjustment in accordance with the terms hereof and prepare and furnish to each holder of Preferred Shares a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based. The Company shall, upon the written request at any time of any holder of Preferred Shares, furnish or cause to be furnished to such holder a like certificate setting forth:

i. such adjustment and readjustment;

ii. the conversion price for the Preferred Shares at the time in effect;

iii. the number of shares of Ordinary Shares; and

iv. the amount, if any, of other property which at the time would be received upon the conversion of the applicable Preferred Shares.

6.4.11. **Record Date**. In the event of any taking by the Company of a record of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any dividend (other than a cash dividend) or other distribution, any right to subscribe for, purchase or otherwise acquire any shares of Shares of any class or any other securities or property, or to receive any other right, the Company shall give to each holder of Preferred Shares, at least ten (10) days prior to the date specified therein, a notice specifying the date on which any such record is to be taken for the purpose of such dividend, distribution, or right, and the amount and character of such dividend, distribution, or right.

6.4.12. **Reservation of Shares Issuable Upon Conversion**. The Company shall at all times reserve and keep available out of its authorized but unissued shares of Ordinary Shares, solely for the purpose of effecting the conversion of the Preferred Shares, such number of its shares of Ordinary Shares as shall, from time to time, be sufficient to effect the conversion of all outstanding Preferred Shares. If at any time the number of authorized but unissued shares of Ordinary Shares shall not be sufficient to effect the conversion of all then-outstanding Preferred Shares, in addition to such other remedies as shall be available under applicable law to the holder of the Preferred Shares, the Company will take such corporate action as may, in the opinion of its counsel, be necessary to increase its authorized but unissued shares of Ordinary Shares to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in commercially reasonable efforts to obtain the requisite Shareholders approval of any necessary amendment to the Articles.

6.4.13. **Notices**. Any notice required by the provisions of this Article 6.4 to be given to the holder Preferred Shares shall be deemed given in accordance with Article 72.

6.5. Termination of Rights. All rights incident to a Preferred Share will terminate automatically upon the conversion of such share(s) into Ordinary Shares.

7. INCREASE OF SHARE CAPITAL

7.1. Subject to Article 54, the Company may, from time to time, adopt a resolution by Ordinary Majority, whether or not all the shares then authorized have been issued, and whether or not all the shares theretofore issued have been called up for payment, increase its share capital by the creation of new shares. Any such increase shall be of such amount and shall be divided into shares of such nominal amounts, and such shares shall confer such rights and preferences, and shall be subject to such restrictions, as such resolution shall provide.

7.2. Except to the extent otherwise provided in such resolution, such new shares shall be subject to all the provisions applicable to the shares of the original capital of the same class and par value.

8. **SPECIAL RIGHTS; MODIFICATION OF RIGHTS**

8.1. Special Rights. Subject to Article 54, the Company may, from time to time, adopt a resolution by Ordinary Majority, to provide for shares with such preferred or deferred rights or rights of redemption or other special rights and/or such restrictions, whether in regard to dividends, voting, repayment of share capital or otherwise, as may be stipulated in such resolution.

8.2. Modification of Rights.

8.2.1. If at any time the share capital is divided into different classes of shares, the rights attached to any class, unless otherwise provided by the Articles, may be modified or abrogated by the Company, by a majority of the holders of the issued shares of such class passed at a separate General Meeting of the holders of the shares of such class.

8.2.2. Unless otherwise provided by the Articles, the enlargement of an existing class of shares, or the issuance of additional shares thereof, shall not be deemed, for purposes of this Article, to modify or abrogate the rights attached to the previously issued shares of such class or of any other class.

9. **CONSOLIDATION, SUBDIVISION, CANCELLATION AND REDUCTION OF SHARE CAPITAL AND PURCHASE OF SHARES**

9.1. The Company may, from time to time, by Ordinary Resolution (*subject, however*, to the provisions of Articles 8 and 54 hereof and to applicable law):

9.1.1. consolidate and divide all or any of its issued or unissued share capital into shares of larger nominal value than its existing shares;

9.1.2. subdivide its shares (issued or unissued) or any of them, into shares of smaller nominal value than is fixed by the Articles, and the resolution whereby any share is subdivided may determine that, as among the holders of the shares resulting from such subdivision, one or more of the shares may, as compared with the others, have any such preferred or deferred rights or rights of redemption or other special rights, or be subject to any such restrictions, as the Company has power to attach to unissued or new shares;

9.1.3. cancel any shares which, at the date of the adoption of such Ordinary Resolution, have not been taken or agreed to be taken by any person, and diminish the amount of its share capital by the amount of the shares so canceled;

9.1.4. reduce its share capital in any manner, and with and subject to any incident authorized, and consent required, by Section 287 of the Companies Law;

9.1.5. increase its share capital, regardless of whether or not all of its shares have been issued, or whether the shares issued have been paid in full, by the creation of new shares, divided into shares in such par value, and with such preferred or deferred or other special rights (subject always to the provisions of the Articles), and subject to any conditions and restrictions with respect to Dividends, return of capital, voting or otherwise, as shall be directed by the resolution;

9.1.6. convert part of its issued and paid-up shares into deferred shares; or

9.1.7. cancel any securities that are repurchased by the Company, in accordance with Section 308 of the Companies Law.

Subject to any provision to the contrary in the resolution authorizing the increase in share capital pursuant to the Articles, the new share capital shall be deemed to be part of the original share capital of the Company and shall be subject to the same provisions with reference to payment of calls, liens, title, forfeiture, transfer and otherwise as apply to the original share capital.

9.2. With respect to any consolidation of issued shares into shares of larger nominal value, and with respect to any other action which may result in fractional shares, the Board of Directors may settle any difficulty which may arise with regard thereto, as it deems fit, including, inter alia, resort to one or more of the following actions:

9.2.1. determine, as to the holder of shares so consolidated, which issued shares shall be consolidated into each share of larger nominal value;

9.2.2. allot, in contemplation of or subsequent to such consolidation or other action, such shares or fractional shares sufficient to preclude or remove fractional share holdings;

9.2.3. redeem, in the case of redeemable preference shares, and subject to applicable law, such shares or fractional shares sufficient to preclude or remove fractional share holdings;

9.2.4. cause the transfer of fractional shares by certain shareholders of the Company to other shareholders thereof so as to most expediently preclude or remove any fractional shareholdings, and cause the transferees to pay the transferors the fair value of fractional shares so transferred, and the Board of Directors is hereby authorized to act as agent for the transferors and transferees with power of substitution for purposes of implementing the provisions of this sub-Article 9.2.4.

9.3. Subject to the provisions of the Companies Law, the Company may from time to time, purchase its own shares or other securities.

SHARES

10. **ISSUANCE OF SHARE CERTIFICATES; REPLACEMENT OF LOST CERTIFICATES**

10.1. Share certificates shall be issued under the seal or the stamp of the Company and shall bear the signatures of two (2) Directors (or if there be only one (1) Director, the signature of such Director), or of any other person or persons authorized thereto by the Board of Directors.

10.2. Each member shall be entitled to one (1) numbered certificate for all the shares of any class registered in his name, and if the Board of Directors so approves, to several certificates, each for one or more of such shares.

10.3. A share certificate registered in the names of two (2) or more persons shall be delivered to the person first named in the Registrar of Members in respect of such co-ownership.

10.4. If a share certificate is defaced, lost or destroyed, it may be replaced, upon payment of such fee, and upon the furnishing of such evidence of ownership and such indemnity, as the Board of Directors may think fit.

11. **REGISTERED HOLDER**

Except as otherwise provided in the Articles, the Company shall be entitled to treat the registered holder of any shares as the absolute owner thereof, and, accordingly, shall not, except as ordered by a court of competent jurisdiction, or as required by statute, be bound to recognize any equitable or other claim to, or interest in such share on the part of any other person.

12. **ALLOTMENT OF SHARES; PRE-EMPTIVE RIGHTS**

12.1. Allotment of Shares

12.1.1. Subject to the provisions of Article 3.4 the authorized but unissued shares of the Company shall be under the control of the Board of Directors, who shall have the power to offer, allot shares, or otherwise dispose of them to such persons or entities, on such terms and conditions (including inter alia terms relating to calls as set forth in Article 14.6 hereof) as the Company by resolution of the Board determines, and either at par or at a premium, or, subject to the provisions of the Companies Law, at a discount, and at such times, as the Board of Directors may think fit, and the power to give to any person the option to acquire from the Company any shares, either at par or at a premium, or, subject as aforesaid, at a discount, during such time and for such consideration as the Board of Directors may think fit.

12.1.2. The Board may issue shares having the same rights as the existing shares, or having preferred or deferred rights or restricted rights, or any other special right in respect of dividend distributions, voting, appointment or dismissal of directors, return of share capital, distribution of Company's property, or otherwise, all as determined by the Board from time to time, subject to the provisions of the Articles, including Article 54 below.

12.2. Pre-emptive Rights

12.2.1. Until the consummation of the Company's IPO, should the Company, at any time or from time to time propose to issue and sell New Securities (as defined hereinafter), such New Securities (the "**Offered New Securities**"), shall first be offered (as hereinafter provided), on a pro-rata basis (on an as converted basis), to all the Eligible Holders. An Eligible Holder's "Pro Rata Share" shall be the ratio of the number of Ordinary Shares of the Company then held by such Eligible Holder as of the date of the Rights Notice, as defined herein, to the sum of the total number of Ordinary Shares of the Company held by all of the Eligible Holders as of such date (all on an as converted basis). In the event that any Eligible Shareholder that has preemptive rights does not exercise this right, the exercising Eligible Shareholders will have an over-allotment right. These preemptive rights shall be subject to the following provisions:

i. If the Company proposes to issue New Securities, it shall give each Eligible Holder written notice (the "**Rights Notice**") of its intention, describing the New Securities, the price (including the minimum consideration for such New Securities, if any), the general terms and conditions upon which the Company proposes to issue them and the Pro Rata Share of the Eligible Holder. Each Eligible Holder shall have ten (10) business days from delivery of the Rights Notice to agree to purchase all or any part of such offered New Securities in each case for the price and upon the general terms specified in the Rights

Notice, by giving written notice to the Company setting forth the quantity of New Securities to be purchased by the Eligible Holder (each, an "**Acceptance Notice**"); to remove any doubt it is clarified that failure by a Eligible Holder to respond within said ten (10) business day period shall constitute rejection of the Rights Notice and a waiver of the preemptive rights in full in connection with the offered New Securities

ii. The Company shall allot the Offered New Securities to the accepting Eligible Holders in accordance with the terms of the Rights Notice and their respective Acceptance Notices. If the Eligible Holders who elect to participate in the offer elect to purchase in the aggregate more than one hundred percent (100%) of the New Securities, such New Securities shall be allocated as follows: (i) First: each Eligible Holder shall be issued its Pro Rata Portion of the New Securities, but no more than the number of New Securities accepted by the Eligible Holder; and (ii) Second: the remaining New Securities unallocated in accordance with (i) above, shall be allocated among the Eligible Holders in accordance with their respective Pro-Rata Portions, but each Eligible Holder shall be allocated a maximum of the total number of New Securities accepted by each such Eligible Holder; and (iii) Third, any remaining unallocated New Securities shall be allocated in accordance with the mechanism detailed in (ii) above, in the same manner, until all the New Securities have been allocated.

iii. If the Eligible Holders fail to exercise in full their preemptive rights within the period specified in Sub-Article i, the Company shall have one hundred and twenty (120) days after the date of the Rights Notice to sell the unsold New Securities at a price and upon general terms no more favorable to the purchasers thereof than specified in the Rights Notice. If the Company has not sold the New Securities within said one hundred and twenty (120) day period the Company shall not thereafter issue or sell any New Securities without first offering such securities to the Eligible Holders in the manner provided above unless waived in writing.

12.2.2. By way of written notice to the Company, an Eligible Holder is entitled to assign the rights to purchase New Securities as detailed above to one or more Permitted Transferees of such Eligible Holder who may then respond to the Rights Notice as if the Rights Notice was addressed to such assignee(s) with regard to the assigned rights.

12.2.3. "**New Securities**" means any share capital of the Company, whether or not now authorized, and rights, options or warrants to purchase share capital, and securities of any type whatsoever that are, or may become, convertible into or exercisable for share capital, other than the Excluded Securities. For the purpose of these Articles, "**Excluded Securities**" shall mean any and all: (i) issuances of options, shares or other securities to employees, officers, directors, consultants, contractors or advisors of the Company under employee equity based plans approved by the Board; (ii) issuances upon stock splits, stock dividend, bonus shares, reclassification and similar recapitalization events; (iii) securities issued upon an IPO; (iv) securities issued by the Company pursuant to the acquisition whether by merger or purchase of all or, substantially all, of the assets or securities of another corporation; (v) securities issued to lending institutions or financing institutions in connection with financing arrangements or otherwise securities issued in connection with any credit line or other similar financing in an amount not exceeding five percent (5%) of the Company's issued and outstanding share capital on an as converted basis; (vi) securities issued in an issuance with respect to which Eligible Shareholders holding in the aggregate at least eighty

percent (80%) of the aggregate shares held by all such Eligible Shareholders shall have waived in writing their pre-emptive rights; (vii) securities issued as consideration in connection with the acquisition of another company, business entity or line of business of another business entity by the Company by merger, consolidation, purchase of all or substantially all of the assets and/or shares, or other reorganization but which does not constitute a Deemed Liquidation Event;(viii) securities issued as a dividend or distribution to all shareholders of the Company; and (ix) securities issued upon the exercise of any warrant or granted option or due to conversion of convertible securities if said warrants, options or convertible securities were issued as New Securities.

12.2.4. If the offer to Eligible Holders under this Article 12.2 may, in the opinion of the Company's counsel, constitute an offer to the public under applicable laws which is subject to prospectus requirements then such offer shall be limited to (i) Eligible Holders to whom the Company may offer such securities in reliance on an exemption from such prospectus requirement due to a category exemption other than the limited number of total offerees, and (ii) to such limited number of Eligible Holders which are the largest shareholders of the Company at the date of such offer to whom the offer may be made in reliance on an exemption from such prospectus requirement due to the limited number of total offerees.

13. **PAYMENT IN INSTALLMENTS**

If by the terms of allotment of any share, the whole or any part of the price thereof shall be payable in installments, every such installment shall, when due, be paid to the Company by the then registered holder(s) of the share or the person(s) entitled thereto.

14. **CALLS ON SHARES**

14.1. The Board of Directors may, from time to time, make such calls as it may think fit upon members in respect of any sum unpaid in respect of shares held by such members which is not, by the terms of allotment thereof or otherwise, payable at a fixed time, and each member shall pay the amount of every call so made upon him (and of each installment thereof if the same is payable in installments), to the person(s) and at the time(s) and place(s) designated by the Board of Directors, as any such time(s) may be thereafter extended and/or such person(s) or place(s) changed. Unless otherwise stipulated in the resolution of the Board of Directors (and in the notice hereafter referred to), each payment in response to a call shall be deemed to constitute a pro-rata payment on account of all the shares in respect of which such call was made.

14.2. Notice of any call shall be given in writing to the member(s) in question not less than fourteen (14) days prior to the time of payment, specifying the time and place of payment, and designating the person to whom such payment shall be made, *provided*, *however*, that before the time for any such payment, the Board of Directors may, by notice in writing to such member(s), revoke such call in whole or in part, extend such time, or alter such person and/or place. In the case of a call payable in installments, only one notice thereof need be given.

14.3. If, by the terms of allotment of any share or otherwise, any amount is made payable at any fixed time, every such amount shall be payable as if it were a call duly made by the Board of Directors and of which due notice had been given, and all the provisions herein contained with respect to such calls shall apply to each such amount.

14.4. The joint holders of a share shall be jointly and severally liable to pay all calls in respect thereof and all interest payable thereon.

14.5. Any amount unpaid in respect of a call shall bear such index linkage differentials and interest from the date on which it is payable until actual payment thereof, at such rate (not exceeding the then prevailing debitory rate charged by leading commercial banks in Israel), and at such time(s) as the Board of Directors may prescribe.

14.6. Upon the allotment of shares, the Board of Directors may provide for differences among the allottees of such shares as to the amount of calls and/or the times of payment thereof.

15. **PREPAYMENT**

With the approval of the Board of Directors, any member may pay to the Company any amount not yet payable in respect of his shares, and the Board of Directors may approve the payment of interest on any such amount until the same would be payable if it had not been paid in advance, at such rate and time(s) as may be approved by the Board of Directors. The Board of Directors may at any time cause the Company to repay all or any part of the money so advanced, without premium or penalty. Nothing in this Article 15 shall derogate from the right of the Board of Directors to make any call before or after receipt by the Company of any such advance.

16. **FORFEITURE AND SURRENDER**

16.1. If any member fails to pay any amount payable in respect of a call, or interest thereon as provided for herein, on or before the day fixed for payment of the same, the Company, by resolution of the Board of Directors, may at any time thereafter, so long as the said amount or interest remains unpaid, demand the forfeiture of all or any of the shares in respect of which said call had been made. Any expense incurred by the Company in attempting to collect any such amount or interest, including, inter alia, attorneys' fees and litigation costs, shall be added to, and shall, for all purposes (including the accrual of interest thereon), constitute a part of, the amount payable to the Company in respect of such call.

16.2. Upon the adoption of a resolution of forfeiture, the Board of Directors shall cause notice thereof to be given to such member, which notice shall state that, in the event of the failure to pay the entire amount so payable within a period stipulated in the notice (which period shall be not less than seven (7) days and which may be extended by the Board of Directors), such shares shall be ipso facto forfeited, *provided*, *however*, that, prior to the expiration of such period, the Board of Directors may nullify such resolution of forfeiture, but no such nullification shall estop the Board of Directors from adopting a further resolution of forfeiture in respect of the non-payment of the same amount.

16.3. Whenever shares are forfeited as herein provided, all dividends theretofore declared in respect thereof and not actually paid shall be deemed to have been forfeited at the same time.

16.4. The Company, by resolution of the Board of Directors, may accept the voluntary surrender of any share.

16.5. Any share forfeited or surrendered as provided herein shall become the property of the Company, and the same, subject to provisions of these Articles, may be sold, re-allotted or otherwise disposed of as the Board of Directors thinks fit.

16.6. Any member whose shares have been forfeited or surrendered shall cease to be a member in respect of the forfeited or surrendered shares, but shall, notwithstanding, be liable to pay, and shall forthwith pay, to the Company, all calls, interest and expenses owing upon or in respect of such shares at the time of forfeiture or surrender, together with interest thereon from the time of forfeiture or surrender until actual payment, at the rate prescribed in Article 14.5 above, and the Board of Directors, in its discretion, may enforce the payment of such moneys, or any part thereof, but shall not be under any obligation to do so. In the event of such forfeiture or surrender, the Company, by resolution of the Board of Directors, may accelerate the date(s) of payment of any or all amounts then owing by the member in question (but not yet due) in respect of all shares owned by such member, solely or jointly with another, and in respect of any other matter or transaction whatsoever.

16.7. The Board of Directors may at any time, before any share so forfeited or surrendered shall have been sold, re-allotted or otherwise disposed of, nullify the forfeiture or surrender on such conditions as it thinks fit, but no such nullification shall estop the Board of Directors from re-exercising its powers of forfeiture pursuant to this Article 16.

17. LIEN

17.1. Except to the extent the same may be waived or subordinated in writing, the Company shall have a first and paramount lien upon all the shares registered in the name of each member (without regard to any equitable or other claim of interest in such shares on the part of any other person), and upon the proceeds of the sale thereof, for his debts, liabilities and engagements to the Company arising from any amount payable by such member in respect of any unpaid or partly paid share, whether or not such debt, liability or engagement has matured. Such lien shall extend to all dividends from time to time declared or paid in respect of such share. Unless otherwise provided, the registration by the Company of a transfer of shares shall be deemed to be a waiver on the part of the Company of the lien (if any) existing on such shares immediately prior to such transfer.

17.2. The Board of Directors may cause the Company to sell a share subject to such a lien when the debt, liability or engagement giving rise to such lien has matured, in such manner as the Board of Directors deems fit, but no such sale shall be made unless such debt, liability or engagement has not been satisfied within fourteen (14) days after written notice of the intention to sell shall have been served on such member, his executors, administrators or assigns.

17.3. The net proceeds of any such sale, after payment of the costs thereof, shall be applied in or toward satisfaction of the debts, liabilities or engagements of such member in respect of such share (whether or not the same have matured), and the remainder (if any) shall be paid to the member, his executors, administrators or assigns.

18. SALE AFTER FORFEITURE OR SURRENDER OR IN ENFORCEMENT OF LIEN

Upon any sale of a share after forfeiture or surrender or for the enforcement of a lien, the Board of Directors may appoint any person to execute an instrument of transfer of the share so sold and cause the purchaser’s name to be entered in the Register of Members in respect of such share. The purchaser shall be registered as the shareholder and shall not be bound to see to the regularity of the sale proceedings, or to the application of the proceeds of such sale, and after his name has been entered in the Register of Members in respect of such share, the validity of the sale shall not be impeached by any person, and the remedy of any person aggrieved by the sale shall be in damages only and against the Company exclusively.

19. **REDEEMABLE SHARES**

The Company may, subject to applicable law, issue redeemable shares and redeem the same.

TRANSFER OF SHARES

20. **RESTRICTIONS OF TRANSFER; BOARD APPROVAL; RIGHT OF FIRST REFUSAL; AND, REGISTRATION**

20.1. No Transfer of shares in the Company, and no assignment of an option to acquire such shares from the Company, shall be effective unless the Transfer or assignment has been approved by the Board of Directors, and the Board of Directors may, in its reasonable discretion, either approve or refuse to approve any such Transfer or assignment.

20.2. No Transfer of shares shall be registered unless a proper instrument of transfer (in form and substance satisfactory to the Board of Directors, or as detailed below) has been submitted to the Company, together with the share certificate(s) and such other evidence of title as the Board of Directors may reasonably require. Until the transferee has been registered in the Register of Members in respect of the shares so transferred, the Company may continue to regard the transferor as the owner thereof. The Board of Directors, may, from time to time, prescribe a fee for the registration of a transfer.

"Share Transfer Deed

I, [*specify name of transferor*], of [*specify address of transferor*] ("**Transferor**") do hereby transfer to [*specify name of transferee*] of [*specify address of transferee*] ("**Transferee**") [*specify number and class*] share(s), par value NIS 0.01 each, of TheraCoat Ltd. to hold unto the Transferee, Transferee's executors, administrators and assigns, subject to the same terms and conditions on which I held the same at the time of the execution hereof; and I, the Transferee, do hereby agree to take the said share(s) subject to the aforesaid terms and conditions.

In witness whereof we have hereunto set our hands this day of .

Transferee	Transferor
Name:	Name:
Title:	Title:"

20.3. **Right of First Refusal**. Without derogating from the provisions of Article 20.1 or 20.2, the following provisions shall govern Transfers of shares in the Company:

20.3.1. Any Shareholder proposing to Transfer all, or any, of such Shareholder's shares (the "**Offeror**") shall first offer in writing such shares (the "**Offered Shares**"), on the terms of the proposed Transfer, to all the Eligible Holders (the "**Offerees**") and shall also provide the Company with such written notice. The Offeror shall send the Company and the Offerees a written notice dated with the date that the offer is sent (the "**Offer**"), stating therein the identity of the Offeror and the proposed transferee(s), the consideration for the Offered Shares and the proposed material terms of sale of the Offered

Shares. At the written request of the Offeror, the Company shall use commercially reasonable efforts to assist such Offeror with the delivery of the Offer by providing the Offeror with the names and address of the Offerees that are available to the Company. Any Offeree may accept such offer in respect of all, or any, of the Offered Shares by giving the Offeror notice to that effect within fourteen (14) business days after the date of the Offer; to remove any doubt it is hereby clarified that failure to accept the Offer within said fourteen (14) day period shall constitute rejection of the Offer and waiver of the right of first refusal.

20.3.2. If the acceptances, in the aggregate, are in respect of more than the number of Offered Shares, then the accepting Offerees shall acquire the Offered Shares, on the terms aforementioned, in proportion to their respective holdings of the issued and outstanding share capital of the Company on an as converted to Ordinary Shares basis, *provided* that no Offerees shall be entitled to acquire under the provisions of this Article 20.3.2 more than the number of Offered Shares initially accepted by such Offeree, and upon the allocation to an Offeree of the full number of shares so accepted, the Offeree shall be disregarded in any subsequent computations and allocations hereunder. Any shares remaining after the computation of such respective entitlements shall be re-allocated among the accepting Offerees (other than those to be disregarded as aforesaid), in the same manner, until one hundred percent (100%) of the Offered Shares have been allocated as aforesaid.

20.3.3. If the acceptances, in the aggregate, are in respect of less than the number of Offered Shares, the Offeror, at the expiration of the aforementioned fourteen (14) day period, shall be entitled, at the Offerror's option to transfer to the accepting Offerees (but not to less than all of them) the numbers of shares as to which they respectively accepted the Offer (or such lesser numbers as they may then respectively agree to accept), and to transfer all or any part of the balance of the Offered Shares to the proposed transferee(s) identified in the Offer, or, in such event, the Offeror may, at the Offerror's sole discretion, regard the Offer as entirely rejected, and thereupon transfer all (but not less than all) of the Offered Shares to such proposed transferee(s), *provided, however*, that in no event shall the Offeror transfer any of the Offered Shares to any transferee other than such accepting Offerees or such proposed transferee(s) specifically stated in the Offer, and *provided, further* that any of the Offered Shares not transferred within ninety (90) days after the expiration of said fourteen (14) day period shall again be subject to the provisions of this Article 20.3.

20.3.4. If the acceptances, in the aggregate, are in respect of all Offered Shares, the Offeror, at the expiration of the aforementioned fourteen (14) day period, shall be bound, upon actual receipt of the payment of the offer price, to transfer to the accepting Offerees (but not to less than all of them) the numbers of shares as to which they respectively are entitled. If, after becoming so bound, the Offeror defaults in transferring the Offered Shares, the Company may receive the purchase price therefor and the Offeror shall be deemed to have appointed any member of the Board as his agent to execute a transfer of the Offered Shares to the accepting Offerees, and, upon execution of such Transfer, the Company shall hold the purchase price therefor in trust for the Offeror.

20.3.5. For the purposes of any Offer under this Article 20.3 the respective holdings of any number of accepting Offerees shall mean their respective proportions of the aggregate issued and outstanding share capital determined as of the date of the Offer on an as converted basis.

20.3.6. If the offer to Eligible Holders under this Article 20.3 may, in the opinion of the Company's counsel, constitute an offer to the public under applicable laws

which is subject to prospectus requirements then such offer shall be limited to (i) Eligible Holders to whom the Offeror may offer such securities in reliance on an exemption from such prospectus requirement due to a category exemption other than the limited number of total offerees, and (ii) to such limited number of Eligible Holders which are the largest shareholders of the Company at the date of such offer to whom the offer may be made in reliance on an exemption from such prospectus requirement due to the limited number of total offerees.

20.3.7. A Shareholder may Transfer shares to a Permitted Transferee without such Transfer being subject to the above rights of first refusal, *provided, however*, that no such Transfer shall be made to any transferee, unless such transferee agrees in writing to be bound by all shareholder or Company agreements binding upon the transferring shareholder, immediately prior to the transfer to the Permitted Transferee.

All transfers made in accordance with this Article 20.3.7 are exempt from any first refusal right detailed in Article 20.3.

21. **BRING-ALONG RIGHTS**

21.1. If, at any time prior to an IPO, the holders of at least seventy five percent (75%) of the Company's voting power (collectively the "**Accepting Shareholders**"), accept a bona fide offer from a potential buyer (the "**Buyer**") to purchase all of the Company's securities (the "**Purchase Offer**"), and such offer is conditional by the Buyer upon the sale of all of shares of the Company, all shareholders shall be required to participate in such sale on the same terms and conditions.

21.2. For the purposes of determining the acceptance of the Purchase Offer in accordance with Section 21.1 above, shares held by or the consent of any shareholder who is a "related party" (as such term is defined in Section 1 of the Securities Law) to the party making such Purchase Offer, shall not be taken into account or required.

21.3. The proceeds of such sale shall be distributed among the Company's shareholders in accordance with the Liquidation Event distribution preferences applicable in accordance with these Articles. The majority set forth in Article 21.1 for the Accepting Shareholders shall be deemed the majority required under Section 341 of the Companies Law

21.4. Such decision shall be binding upon the Company and all of the Shareholders and the Shareholders will not object to, and to the extent applicable shall vote in favor of (including in all class votes), shall execute the relevant documents in connection with, and shall otherwise take all corporate and other actions necessary and reasonable to effect, such Purchase Offer on the same terms and conditions for all Shareholders. All Shareholders shall be deemed to have given an irrevocable proxy to such person as shall be designated by the Accepting Shareholders to vote for, and sign all documents in connection with, the acceptance of such Purchase Offer and at the closing of such Purchase Offer all of the Shareholders will transfer all their securities to such person or entity at the same price and terms as the Purchase Offer. In the event that a Shareholder fails to surrender its share certificate, or any other instrument evidencing its securities in connection with the consummation of the Purchase Offer, such certificate or instrument shall be deemed cancelled, the Company shall be authorized to issue a new certificate or instrument in the name of the person making the Purchase Offer, the Board of Directors shall be authorized to establish an escrow account into which the consideration for such cancelled securities shall be deposited and a trust to administer such account.

21.5. The Company shall not issue any securities, or any other right to subscribe for, or convert to, securities (including options or shares issued or granted under option or share incentive plans approved by the Board), or effect any transfer of securities by any shareholder until it has satisfactory evidence that such subscriber or transferee (to the extent not a Shareholder prior to the issuance or transfer) shall be bound by, and be subject to, the provisions of this Article 21.5.

22. **SUSPENSION OF REGISTRATION**

The Board of Directors may suspend the registration of transfers during the twenty-one (21) days immediately preceding the Annual General Meetings.

TRANSMISSION OF SHARES

23. **DECEDENTS' SHARES**

23.1. In case of a share registered in the names of two (2) or more holders, the Company may recognize the survivor(s) as the sole owner(s) thereof unless and until the provisions of Article 23.2 have been effectively invoked.

23.2. Any person becoming entitled to a share in consequence of the death of any person, upon producing evidence of the grant of probate or letters of administration or declaration of succession (or such other evidence as the Board of Directors may reasonably deem sufficient that he sustains the character in respect of which he proposes to act under this Article or of his title), shall be registered as a member in respect of such share, or may, subject to the regulations as to transfer herein contained, transfer such share.

24. **RECEIVERS AND LIQUIDATORS**

24.1. The Company may recognize the receiver or liquidator of any corporate member in winding-up or dissolution, or the receiver or trustee in bankruptcy of any member, as being entitled to the shares registered in the name of such member.

24.2. The receiver or liquidator of a corporate member in winding-up or dissolution, or the receiver or trustee in bankruptcy of any member, upon producing such evidence as the Board of Directors may deem sufficient that he sustains the character in respect of which he proposes to act under this Article or of his title, shall with the consent of the Board of Directors (which the Board of Directors may grant or refuse in its absolute discretion), be registered as a member in respect of such shares, or may, subject to the regulations as to transfer herein contained, transfer such shares.

GENERAL MEETINGS

25. **ANNUAL GENERAL MEETING**

An Annual General Meeting may be held once in every calendar year at such time (within a period of not more than fifteen (15) months after the last preceding Annual General Meeting) and at such place either in or outside of the State of Israel as may be determined by the Board of Directors.

26. **SPECIAL GENERAL MEETINGS**

All General Meetings other than Annual General Meetings shall be called "Special General Meetings". The Board of Directors may, whenever it thinks fit, convene a Special General Meeting at such time and place, in or outside of the State of Israel, as may be determined by the Board of Directors, and shall be obliged to do so upon a requisition in writing in accordance with Section 63 of the Companies Law.

27. **NOTICE OF GENERAL MEETINGS; OMISSION TO GIVE NOTICE**

27.1. Not less than seven (7) days and not more than forty five (45) days prior notice shall be given of every General Meeting. Each such notice shall specify the place and day and hour of the meeting and the general nature of each item to be acted upon thereat. Notice shall be given to all members who would be entitled to attend and vote at such meeting, if it were held on the date when such notice is issued. In the event that the items to be acted upon at the meeting include any resolution which is defined hereunder as a Special Resolution, the prior notice to the shareholders shall specify such Special Resolution and shall further specify the majority of votes that is required for its adoption. Anything herein to the contrary notwithstanding, with the consent of all members entitled to vote thereon, a resolution may be proposed and passed at such meeting although a lesser notice than hereinabove prescribed has been given.

27.2. The accidental omission to give notice of a meeting to any member, or the non-receipt of notice sent to such member, shall not invalidate the proceedings at such meeting.

PROCEEDINGS AT GENERAL MEETINGS

28. **QUORUM**

28.1. Three (3) or more members (not in default in payment of any sum referred to in Article 34 hereof), present in person including by way of a telephone conference call, or by proxy, *provided* at least one (1) of them is a holder of Ordinary Shares and at least two (2) of them are holders of Preferred Shares (provided that the two (2) present Preferred Shareholders are not Affiliates of one another), and holding shares conferring in the aggregate a majority of the voting power of the Company, shall constitute a quorum at General Meetings. No business shall be transacted at a General Meeting, or at any adjournment thereof, unless the requisite quorum is present when the meeting proceeds to business.

28.2. If within half (½) an hour from the time appointed for the meeting a quorum is not present, the meeting, shall stand adjourned to the same day in the next week, at the same time and place, or to such day and at such time and place as the chairman of the meeting may determine with the consent of the holders of a majority of the voting power represented at the meeting in person or by proxy and voting on the questions of adjournment. No business shall be transacted at any adjourned meeting except business which might lawfully have been transacted at the meeting as originally called. At such adjourned meeting, any two (2) members (not in default as aforesaid) present in person or by proxy, shall constitute a quorum, except that if convened upon requisition under Sections 63 or 64 of the Companies Law, a quorum shall consist of one (1), or more, shareholders, holding at least ten percent (10%) of the issued equity and at least one percent (1%) of the Company's voting power.

29. **CHAIRMAN**

The Chairman, if any, shall preside as chairman at every General Meeting of the Company. If there is no such Chairman, or if at any meeting he is not present within fifteen (15) minutes after the time fixed for holding the meeting or is unwilling to act as chairman of the General Meeting, the members present shall choose someone of their number to be chairman. The office of chairman shall not, by itself, entitle the holder thereof to vote at any General Meeting nor shall it entitle such holder to a second or casting vote (without derogating, *however*, from the rights of such chairman to vote as a shareholder or proxy of a shareholder if, in fact, he is also a shareholder or such proxy).

30. **ADOPTION OF RESOLUTIONS AT SHAREHOLDERS MEETINGS**

30.1. An Ordinary Resolution and a Special Resolution shall be deemed adopted if approved by an Ordinary Majority.

30.2. Every question submitted to a General Meeting shall be decided by a show of hands, but if a written ballot is demanded by any member present in person or by proxy and entitled to vote at the meeting, the same shall be decided by such ballot. A written ballot may be demanded before the proposed resolution is voted upon. The demand for a written ballot may be withdrawn at any time before the same is conducted, in which event another member may then demand such written ballot. The demand for a written ballot shall not prevent the continuance of the meeting for the transaction of business other than the question on which the written ballot has been demanded.

30.3. A declaration by the Chairman of the meeting that a resolution has been carried unanimously, or carried by a particular majority, or lost, and an entry to that effect in the minute book of the Company, shall be conclusive evidence of the fact without proof of the number or proportion of the votes recorded in favor of or against such resolution.

31. **RESOLUTIONS IN WRITING**

A resolution in writing signed by all members of the Company then entitled to attend and vote at General Meetings or to which all such members have given their written consent (by letter, telegram, telex, facsimile, electronic mail or otherwise), shall be deemed to have been unanimously adopted by a General Meeting duly convened and held.

32. **POWER TO ADJOURN**

32.1. The chairman of a General Meeting at which a quorum is present may, with the consent of the holders of a majority of the voting power represented in person or by proxy and voting on the question of adjournment (and shall if so directed by the meeting), adjourn the meeting from time to time and from place to place, but no business shall be transacted at any adjourned meeting except business which might lawfully have been transacted at the meeting as originally called.

32.2. It shall not be necessary to give any notice of an adjournment, whether pursuant to Article 28.2 or Article 32.1, unless the meeting is adjourned for more than twenty-one (21) days in which event notice thereof shall be given in the manner required for the meeting as originally called.

33. **VOTING POWER**

Subject to the provisions of Article 34 and subject to any provision hereof conferring special rights as to voting, or restricting the right to vote, every member shall have one (1) vote for each share held by him of record, on every resolution, without regard to whether the vote thereon is conducted by a show of hands, by written ballot or by any other means.

34. **VOTING RIGHTS**

34.1. No member shall be entitled to vote at any General Meeting (or be counted as a part of the quorum thereat), unless all calls and other sums then payable by him in respect of his shares in the Company have been paid.

34.2. A company or other corporate body being a member of the Company may, by resolution of its directors or any other managing body thereof, authorize any person to be its representative at any meeting of the Company. Any person so authorized shall be entitled to exercise on behalf of such member all the power which the latter could have exercised if it were an individual shareholder. Upon the request of the chairman of the meeting, written evidence of such authorization (in form acceptable to the chairman) shall be delivered to him.

34.3. Any member entitled to vote may vote personally or by proxy (who need not be a member of the Company), or, if the member is a company or other corporate body, by a representative authorized pursuant to Article 35.

34.4. If two (2) or more persons are registered as joint holders of any share, the vote of the senior who tenders a vote, in person or by proxy, shall be accepted to the exclusion of the vote(s) of the other joint holder(s); and for this purpose seniority shall be determined by the order in which the names stand in the Register of Members.

PROXIES

35. **INSTRUMENT OF APPOINTMENT**

35.1. The instrument appointing a proxy shall be in writing and shall be substantially in the following form:

"I of

(*Name of Shareholder*) (*Address of Shareholder*)

being a member of TheraCoat Ltd. hereby appoint

of

(*Name of Proxy*) (*Address of Proxy*)

as my proxy to vote for me and on my behalf at the General Meeting of the Company to be held on the day of 20 and at any adjournment(s) thereof.

Signed this day of 20 .

_____

(*Signature of Appointer*)

or in any usual or common form or in such other form as may be approved by the Board of Directors. It shall be duly signed by the appointer or his duly authorized attorney or, if such appointer is a company or other corporate body, under its common seal or stamp or the hand of its duly authorized agent(s) or attorney(s).

35.2. The instrument appointing a proxy (and the power of attorney or other authority, if any, under which such instrument has been signed) shall either be delivered to the Company (at its Registered Office or at its principal place of business or at such place as the Board of Directors may specify) not less than twelve (12) hours before the time fixed for the meeting at which the person named in the instrument proposes to vote, or presented to the Chairman at such meeting.

36. **EFFECT OF DEATH OF APPOINTOR OR REVOCATION OF APPOINTMENT**

A vote cast pursuant to an instrument appointing a proxy shall be valid notwithstanding the previous death of the appointing member (or of his attorney-in-fact, if any, who signed such instrument), or the revocation of the appointment or the transfer of the share in respect of which the vote is cast, *provided* no written notice of such death, revocation or transfer shall have been received by the Company or by the Chairman of the meeting before such vote is cast and *provided, further*, that the appointing member, if present in person at said meeting, may revoke the appointment by means of a written or oral notification to the chairman.

BOARD OF DIRECTORS

37. **POWERS OF BOARD OF DIRECTORS**

37.1. In General.

The management of the business of the Company shall be vested in the Board of Directors, which may exercise all such powers and do all such acts and things as the Company is authorized to exercise and do, and are not hereby, or by law required to be, exercised or done by the Company in General Meeting or by the General Manager. The authority conferred on the Board of Directors by this Article 37 shall be subject to the provisions of the Companies Law, of the Articles and any regulation or resolution consistent with these Articles adopted from time to time by the Company in General Meeting, *provided, however*, that no such regulation or resolution shall invalidate any prior act done by or pursuant to a decision of the Board of Directors which would have been valid if such regulation or resolution had not been adopted.

37.2. Borrowing Power.

The Board of Directors may from time to time, in its discretion, cause the Company to borrow or secure the payment of any sum or sums of money for the purposes of the Company, and may secure or provide for the repayment of such sum or sums in such manner, at such times and upon such terms and conditions in all respects as it thinks fit, and, in particular, by the issuance of bonds, perpetual or redeemable debentures, debenture stock, or any mortgages, charges, or other securities on the undertaking or the whole or any part of the property of the Company, both present and future, including its uncalled or called but unpaid capital for the time being.

37.3. Reserves. The Board of Directors may, from time to time, set aside any amount(s) out of the profits of the Company as a reserve or reserves for any purpose(s) which the Board of Directors, in its absolute discretion, shall think fit, and may invest any sum so set aside in any manner and from time to time deal with and vary such investments, and dispose of all or any part thereof, and employ any such reserve or any part thereof in the business of the Company without being bound to keep the same separate from other assets of the Company, and may subdivide or re-designate any reserve or cancel the same or apply the funds therein for another purpose, all as the Board of Directors may from time to time think fit.

38. EXERCISE OF POWERS OF BOARD OF DIRECTORS

38.1. A meeting of the Board of Directors at which a quorum is present, including by way of a telephone conference call, shall be competent to exercise all the authorities, powers and discretion vested in or exercisable by the Board of Directors.

38.2. A resolution proposed at any meeting of the Board of Directors shall be deemed adopted if approved by a majority of the Directors present, including by way of a telephone conference call, when such resolution is put to a vote and voting thereon.

38.3. A resolution in writing signed by all Directors then in office or to which all such Directors have given their written consent (by letter, telegram, telex, facsimile or otherwise) shall be deemed to have been unanimously adopted by a meeting of the Board of Directors duly convened and held.

38.4. Without derogating from any statutory duties of the Board of Directors, the matters set forth in Sub-Articles 54.5, 54.7, 54.12, 54.13, 54.14, 54.16 and 54.20 shall require the approval of the Board of Directors.

39. DELEGATION OF POWERS

39.1. The Board of Directors may delegate any or all of its powers to committees, each consisting of two (2) or more persons (who need not be Directors), and it may from time to time revoke such delegation or alter the composition of any such committee. Any Committee so formed (in these Articles referred to as a "**Committee of the Board of Directors**"), shall, in the exercise of the powers so delegated, conform to any regulations imposed on it by the Board of Directors. The meetings and proceedings of any such Committee of the Board of Directors shall, *mutatis mutandis*, be governed by the provisions herein contained for regulating the meetings of the Board of Directors, so far as not superseded by any regulations adopted by the Board of Directors under this Article 39. Unless otherwise expressly provided by the Board of Directors in delegating powers to a Committee of the Board of Directors, such Committee of the Board of Directors shall not be empowered to further delegate such powers.

39.2. The Board of Directors may from time to time appoint a Secretary to the Company, as well as officers, agents, employees and independent contractors, as the Board of Directors may think fit, and may terminate the service of any such person. The Board of Directors may determine the powers and duties, as well as the salaries and emoluments, of all such persons, and may require security in such cases and in such amounts as it thinks fit.

39.3. The Board of Directors may from time to time, by power of attorney or otherwise, appoint any person, company, firm or body of persons to be the attorney or attorneys of the Company at law or in fact for such purpose(s) and with such powers, authorities

and discretion, and for such period and subject to such conditions, as it thinks fit, and any such power of attorney or other appointment may contain such provisions for the protection and convenience of persons dealing with any such attorney as the Board of Directors may think fit, and may also authorize any such attorney to delegate all or any of the powers, authorities and discretion vested in him.

40. **NUMBER OF DIRECTORS**

Subject to Article 54 below and until otherwise determined by Ordinary Resolution of the Company, the Board of Directors of the Company shall consist of up to nine (9) Directors.

41. **APPOINTMENT AND REMOVAL OF DIRECTORS**

The Board shall be comprised of up to nine (9) directors to be appointed as follows:

41.1. The holders of a majority in interest of the Ordinary Shares of the Company, excluding Pontifax, by written notice to the Company, shall be entitled to appoint one (1) director to the Board;

41.2. Arkin by written notice to the Company, shall be entitled to appoint one (1) director to the Board (the "**Arkin Director**"). and, as long as Arkin holds, in the aggregate, at least ten (10%) of the issued and outstanding share capital of the Company (on an as-converted basis), Arkin shall have the right to appoint one (1) representative to attend all meetings of the Board of Directors in a nonvoting observer capacity;

41.3. Pontifax by written notice to the Company, shall be entitled to appoint one (1) director to the Board (the "**Pontifax Director**");

41.4. The holders of a majority in interest of the Preferred Shares, excluding Arkin and Pontifax, shall be entitled, by written notice to the Company, to appoint one (1) director to the Board; and

41.5. One (1) director shall be an industry expert appointed unanimously by all the other directors. The initial industry expert shall be Mr. Arie Belldegrun who shall also serve as the initial Chairman. Dismissal of such industry expert director may be carried out by the majority of the directors and appointment of a new industry expert director may be carried by the unanimous resolution of the directors.

41.6. The incumbent directors appointed pursuant to Articles 41.1-41.5 above, by a majority vote, may, subject to Article 40 above, appoint additional directors who will serve until the next annual general meeting.

41.7. The Arkin Director and the Pontifax Director have the right to be appointed as a member of any of the Committees of the Board of Directors, at their sole and several discretion.

41.8. Each director shall have one (1) vote at any meeting of the Board, provided that a holder or group of holders, entitled to appoint more than one (1) director by virtue of their shareholdings, may elect to appoint fewer than the maximum number of directors than they are entitled to appoint and may in this event notify the Company in the letter of appointment that a certain director is to have one (1) additional vote on the Board, provided that no one Director can have more than two (2) votes at the Board of Directors.

41.9. Holder(s) entitled to appoint a director, or to empower a director with more than one vote, may remove from the Board any director so appointed, or alter the number of votes to which such director is entitled and may fill any vacancy in the Board of the Directors due to the termination of the term of office of any Director appointed by the said holder(s), however such vacancy was created. Any such act shall become effective on the date fixed in such notice, or upon the delivery thereof to the Company, whichever is later.

42. **QUALIFICATION OF DIRECTORS**

No person shall be disqualified to serve as a Director by reason of his not holding shares in the Company or by reason of his having served as a Director in the past.

43. **CONTINUING DIRECTORS IN THE EVENT OF VACANCIES**

In the event of one or more vacancies in the Board of Directors, the continuing Directors may continue to act in every matter.

44. **VACATION OF OFFICE AND REDUCTION IN NUMBER OF VOTES**

44.1. The office of a Director shall be vacated, ipso facto, upon his death, or if he be found lunatic or become of unsound mind, or if he becomes bankrupt, or, if the Director is a company, upon its winding-up.

44.2. The office of a Director shall be vacated by his written resignation. Such resignation shall become effective on the date fixed therein, or upon the delivery thereof to the Company, whichever is later

44.3. The office of a Director shall be vacated on written notice to the Company, by the Shareholder, or group of Shareholders, who appointed such Director, or if the Shareholder, or group of Shareholders, who appointed such Director, do not maintain sufficient voting power to appoint the Director.

44.4. If the Shareholder(s) who appointed a director entitled to more than one (1) vote at the Board meetings do not maintain sufficient voting power to grant a director the number of votes specified in their letter of appointment, then the number of votes to which the director is entitled shall automatically be reduced in accordance with their actual voting power, from time to time.

45. **REMUNERATION OF DIRECTORS**

No Director shall be paid any remuneration by the Company for his services as Director except as may be provided by the Board of Directors, with such additional approval as required in accordance with the Companies Law and the Articles.

46. **CONFLICT OF INTERESTS; APPROVAL OF RELATED PARTY TRANSACTIONS**

46.1. No Director shall be disqualified by virtue of his office as Director from holding any office (other than that of Auditor) or place of profit under the Company or under any company in which the Company shall be a shareholder or otherwise interested.

46.2. A Director shall not be disqualified from contracting with the Company as vendor, purchaser or otherwise, nor shall any such contract, or any contract or arrangement entered into by or on behalf of the Company in which any Director shall be in any way interested, be avoided, nor shall any Director be liable to account to the Company for any profit arising from any such office or place of profit or realized by any such contract or arrangement by reason only of such Director’s holding in the Company or of the fiduciary relations thereby established, *provided* that the nature of his interest, including all significant

facts and documents, be disclosed by him at the meeting of the Board of Directors at which the contract or arrangement is first considered, if his interest then exists, or, in any other case, within a reasonable period of time after the acquisition of his interest and in advance of contracting with the Company. Should the Director acquire a personal (direct or indirect) interest in a company or firm with which the Company has business dealings, he shall give notice of such to the Board of Directors at the earliest possible opportunity. A general notice that a Director is a member of any firm or company and is to be regarded as interested in all transactions with that firm or company shall be a sufficient disclosure under this Article 46, and after such general notice it shall not be necessary to give any special notice relating to any particular transactions with such firm or company.

46.3. Any transactions in which a Director has a personal interest, as illustrated in sub-articles 46.2 above, shall be subject to the approval of the Board of Directors and any other procedures, if any, mandated by the Companies Law.

46.4. Subject to Section 278 of the Companies Law and any other provisions mandated by the Companies Law, a Director or other Office Holder (as that term is defined in Section 1 of the Companies Law), shall not participate in deliberations concerning, nor vote upon a resolution of the Board of Directors approving, a transaction with the Company in which he has a personal interest.

47. **ALTERNATE DIRECTORS**

47.1. A Director may, by written notice to the Company, appoint an alternate for himself (in these Articles referred to as **"Alternate Director"**), remove such Alternate Director and appoint another Alternate Director in place of any Alternate Director appointed by him whose office has been vacated for any reason whatsoever. Unless the appointing Director, by the instrument appointing an Alternate Director or by written notice to the Company, limits such appointment to a specified period of time or restricts it to a specified meeting or action of the Board of Directors, or otherwise restricts its scope, the appointment shall be for an indefinite period, and for all purposes.

47.2. Any notice given to the Company pursuant to Article 47.1 shall become effective on the date fixed therein, or upon the delivery thereof to the Company, whichever is later.

47.3. An Alternate Director shall have all the rights and obligations of the Director who appointed him, *provided*, *however*, that he may not in turn appoint an alternate for himself (unless the instrument appointing him otherwise expressly provides), and *provided further* that an Alternate Director shall have no standing at any meeting of the Board of Directors or any committee thereof while the Director who appointed him is present.

47.4. Any natural person may act as an Alternate Director. An Alternative Director shall have the same number of votes as the Director that appoints him, unless a lower number is stipulated in the letter of appointment.

47.5. An Alternate Director shall alone be responsible for his own acts and defaults, and he shall not be deemed the agent of the Director(s) who appointed him.

47.6. The office of an Alternate Director shall be vacated under the circumstances, mutatis mutandis, set forth in Article 44, and such office shall ipso facto be vacated if the Director who appointed such Alternate Director ceases to be a Director.

PROCEEDINGS OF THE BOARD OF DIRECTORS

48. **MEETINGS**

48.1. The Board of Directors may meet and adjourn its meetings and otherwise regulate such meetings and proceedings as the Directors think fit.

48.2. Any Director may at any time, and the Secretary, upon the request of such Director, shall, convene a meeting of the Board of Directors, but not less than three (3) days' notice shall be given of any meeting so convened.

49. **QUORUM**

Directors who hold a majority of the voting power of all of the Directors then in office shall constitute a quorum at meetings of the Board of Directors. No business shall be transacted at a meeting of the Board of Directors unless the requisite quorum is present, including by way of a telephone conference call, when the meeting proceeds to business.

50. **CHAIRMAN OF THE BOARD OF DIRECTORS**

The Board of Directors may from time to time elect one of its members to be the Chairman, remove such Chairman from office and appoint another in its place. The initial Chairman shall be Mr. Arie Belldegrun. The Chairman shall not have a casting vote in the event that an equal number of votes are cast for and against a resolution. The Chairman shall preside at every meeting of the Board of Directors, but if there is no such Chairman, or if at any meeting he is not present within fifteen (15) minutes of the time fixed for the meeting, or if he is unwilling to take the chair, the Directors present shall choose one of their number to be the chairman of such meeting.

51. **VALIDITY OF ACTS DESPITE DEFECTS**

Subject to the provisions of the Companies Law, all acts done *bona fide* at any meeting of the Board of Directors, or of a Committee of the Board of Directors, or by any person(s) acting as Director(s), shall, notwithstanding that it may afterwards be discovered that there was some defect in the appointment of the participants in such meetings or any of them or any person(s) acting as aforesaid, or that they or any of them were disqualified, be as valid as if there were no such defect or disqualification.

CHIEF EXECUTIVE OFFICER

52. **CHIEF EXECUTIVE OFFICER**

The Board of Directors may from time to time appoint one or more persons, whether or not Directors, as Chief Executive Officer of the Company and may confer upon such person(s), and from time to time modify or revoke, such title(s) (including General Manager, Managing Director, Director General or any similar or dissimilar title) and such duties and authorities of the Board of Directors as the Board of Directors may deem fit, subject to such limitations and restrictions as the Board of Directors may from time to time prescribe. Such appointment(s) may be either for a fixed term or without any limitation of time, and the Board of Directors may from time to time (subject to the provisions of any contract between any such person and the Company) fix his or their salaries and emoluments, remove or dismiss him or them from office and appoint another or others in his or their place or places.

MINUTES

53. **MINUTES**

53.1. Minutes of each General Meeting and of each meeting of the Board of Directors shall be recorded and duly entered in books provided for that purpose. Such minutes shall, in all events, set forth the names of the persons present at the meeting and all resolutions adopted thereat.

53.2. Any minutes as aforesaid, if purporting to be signed by the chairman of the meeting or by the chairman of the next succeeding meeting, shall constitute prima facie evidence of the matters recorded therein.

SPECIAL VOTING RIGHTS AND MAJOR DECISIONS

54. Until the earlier of (i) IPO or (ii) such date on which the holders of Preferred Shares no longer hold more than ten percent (10%) of the issued and outstanding share capital of the Company on a fully diluted basis, any action or resolution of the Board or the General Meeting, as the case may be (and any subsidiary thereof), on any of the following matters shall require the affirmative consent of Arkin and of Pontifax:

54.1. any amendment or change of the rights, preferences, privileges or powers of, or the restrictions provided for the benefit of the Preferred Shares;

54.2. any amendment of the Company's Articles of Association;

54.3. any resolution that creates or issues any class or series of shares or other securities of the Company or which results in the repurchase of any shares or other securities by the Company;

54.4. any acquisition of another company or business entity;

54.5. any Qualified Transaction;

54.6. the sale, lease, exclusive license or other disposition of a material asset or the sale of all or substantially all of the Company's or a subsidiary's assets;

54.7. the liquidation or dissolution of the Company or a subsidiary or the execution by the Company of any arrangements under the provision of Article 350 of the Companies Law, or the approval of any transaction that constitutes a Deemed Liquidation event;

54.8. the declaration or payment of a dividend or other distribution of cash, securities or other assets of the Company;

54.9. any change in the rights of the shareholders to appoint members of the Board of Directors;

54.10. any transactions between the Company and any interested party (including without limitation any transaction with an officer, Director or Shareholder of the Company);

54.11. results in a material change in the business or strategic direction of the Company;

54.12. approval of any material changes to the Work Plan;

54.13. approval of the Company's annual budget and any material changes thereto, including;

54.14. creation of a pledge or granting of security interest in a material asset or in all or substantially all assets of the Company or a subsidiary (other than for the benefit of the State of Israel);

54.15. any capital expenditure or commitment in excess of fifty thousand US Dollars (US$50,000) which is not included in the annual budget;

54.16. effects any transaction out of the ordinary course of business, including without limitation, any licensing, sale, or transfer of intellectual property;

54.17. involves the appointment, removal, or modification of the terms of any existing employment or engagement contract of any of the Company's executive management;

54.18. results in the adoption of or amendment to any employee stock option plan or other similar incentive arrangement, including the increase of the amount of shares reserved for allocation thereunder;

54.19. creation of any Committee of the Board of Directors;

54.20. the release of the Company's independent auditors and appointment of new auditors or any change in the accounting principles adopted; and

54.21. the grant of registration rights to any person or entity other than the holders of Preferred Shares that are superior, or equal to those rights granted to the holders of Preferred Shares.

55. The protective provisions pursuant to Sub-Articles 54.2-54.7, 54.9-54.11 and 54.13-54.19 shall expire on the consummation of a Qualified Transaction that is not an IPO.

DIVIDENDS

56. **DECLARATION OF DIVIDENDS**

Subject to Article 54 above and the provisions of Sections 301 through 311 (inclusive) of the Companies Law, the Company, at a General Meeting and upon recommendation of the Board of Directors, may from time to time declare, and cause the Company to pay, such interim, or final, dividend as may appear to the Board of Directors to be justified by the profits of the Company. The Board of Directors shall determine the time for payment of such dividends, both interim and final, and the record date for determining the shareholders entitled thereto.

57. **FUNDS AVAILABLE FOR PAYMENT OF DIVIDENDS**

No dividend shall be paid otherwise than out of the profits of the Company. The term "profits" shall be interpreted in accordance with the definition contained in Section 302 of the Companies Law.

58. **AMOUNT PAYABLE BY WAY OF DIVIDENDS**

Subject to Article 6.3 as to dividends, any dividend paid by the Company shall be allocated among the members entitled thereto in proportion to the nominal value of their respective holdings of the shares in respect of which such dividend is being paid without taking into account the premium paid up for the shares, all on an as converted basis.

59. **INTEREST**

No dividend shall carry interest as against the Company.

60. **PAYMENT IN SPECIE**

Upon the decision of the Board of Directors, a dividend may be paid, wholly or partly, by the distribution of specific assets of the Company or by distribution of paid up shares, debentures or debenture stock of the Company or of any other companies, or in any one or more of such ways.

61. **CAPITALIZATION OF PROFITS - RESERVE FUND**

Upon the resolution of the Board of Directors, the Company:

61.1. may cause any moneys, investments, or other assets forming part of the undivided profits of the Company, standing to the credit of a reserve fund, or to the credit of a reserve fund for the redemption of capital, or in the hands of the Company and available for dividends, or representing premiums received on the issuance of shares and standing to the credit of the share premium account, to be capitalized and distributed among such of the shareholders as would be entitled to receive the same if distributed by way of dividend and in the same proportion, on the footing that they become entitled thereto as capital, or may cause any part of such capitalized fund to be applied on behalf of such shareholders in paying up in full, either at par or at such premium as the resolution may provide, any unissued shares or debentures or debenture stock of the Company which shall be distributed accordingly, in payment, in full or in part, of the uncalled liability on any issued shares or debentures or debenture stock; and

61.2. may cause such distribution or payment to be accepted by such shareholders in full satisfaction of their interest in the said capitalized sum.

62. **IMPLEMENTATION OF POWERS UNDER ARTICLES 60 AND 61**

For the purpose of giving full effect to any resolution under Articles 60 or 61, and without derogating from the provisions of Article 8.2 hereof, the Board of Directors may settle any difficulty which may arise in regard to the distribution as it thinks expedient, and, in particular, may issue fractional certificates, and may fix the value for distribution of any specific assets, and may determine that cash payments shall be made to any members on the basis of the value so fixed, or that fractions of less value than the nominal value of one share may be disregarded in order to adjust the rights of all parties, and may vest any such cash, shares, debentures, debenture stock or specific assets in trustees upon such trusts for the persons entitled to the dividend or capitalized fund as may seem expedient to the Board of Directors. Where necessary, a proper contract shall be filed in accordance with Section 291 of the Companies Law, and the Board of Directors may appoint any person to sign such contract on behalf of the persons entitled to the dividend or capitalized fund.

63. **DEDUCTIONS FROM DIVIDENDS**

The Board of Directors may deduct from any dividend or other moneys payable to any member in respect of a share any and all sums of money then payable by him to the Company on account of calls or otherwise in respect of shares of the Company and/or on account of any other matter or transaction whatsoever.

64. **RETENTION OF DIVIDENDS**

64.1. The Board of Directors may retain any dividend or other moneys payable or property distributable in respect of a share on which the Company has a lien, and may apply the same in or toward satisfaction of the debts, liabilities, or engagements in respect of which the lien exists.

64.2. The Board of Directors may retain any dividend or other moneys payable or property distributable in respect of a share in respect of which any person is, under Articles 23 or 24, entitled to become a member, or which any person is, under said Articles, entitled to transfer, until such person shall become a member in respect of such share or shall transfer the same.

65. **UNCLAIMED DIVIDENDS**

All unclaimed dividends or other moneys payable in respect of a share may be invested or otherwise made use of by the Board of Directors for the benefit of the Company until claimed. The payment by the Directors of any unclaimed dividend or such other moneys into a separate account shall not constitute the Company a trustee in respect thereof, and any dividend unclaimed after a period of seven (7) years from the date of declaration of such dividend, and any such other moneys unclaimed after a like period from the date the same were payable, shall be forfeited and shall revert to the Company, *provided, however*, that the Board of Directors may, at its discretion, cause the Company to pay any such dividend or such other moneys, or any part thereof, to a person who would have been entitled thereto had the same not reverted to the Company.

66. **MECHANICS OF PAYMENT**

Any dividend or other moneys payable in cash in respect of a share may be paid by check or warrant sent through the post to, or left at, the registered address of the person entitled thereto or by transfer to a bank account specified by such person (or, if two or more persons are registered as joint holders of such share or are entitled jointly thereto in consequence of the death or bankruptcy of the holder or otherwise, to any one (1) of such persons or to his bank account), or to such person and at such address as the person entitled thereto may by writing direct. Every such check or warrant shall be made payable to the order of the person to whom it is sent, or to such person as the person entitled thereto as aforesaid may direct, and payment of the check or warrant by the banker upon whom it is drawn shall be a good discharge to the Company. Every such check or warrant shall be sent at the risk of the person entitled to the money represented thereby.

67. **RECEIPT FROM A JOINT HOLDER**

If two (2) or more persons are registered as joint holders of any share, or are entitled jointly thereto in consequence of the death or bankruptcy of the holder or otherwise, any one (1) of them may give effectual receipts for any dividend or other moneys payable or property distributable in respect of such share.

ACCOUNTS

68. **BOOKS OF ACCOUNT**

The Company will operate accurate books of account to be kept in accordance with the provisions of the Companies Law and of any other applicable law. Such books of account shall be kept at the Registered Office of the Company, or at such other place or places as the Board of Directors may think fit, and they shall always be open to inspection by all Directors. No member, not being a Director, shall have any right to inspect any account or book or other similar document of the Company, except as conferred by law or authorized by the Board of Directors or by Ordinary Resolution of the Company.

69. **AUDIT**

At least once in every fiscal year the accounts of the Company shall be audited and the correctness of the profit and loss account and balance sheet certified by one or more duly qualified auditors.

70. **AUDITORS**

The appointment, authorities, rights and duties of the auditor(s) of the Company, shall be regulated by applicable law, *provided*, *however*, that in exercising its authority to fix the remuneration of the auditor(s), the members in General Meeting may, by Ordinary Resolution, act (and in the absence of any action in connection therewith shall be deemed to have so acted), to authorize the Board of Directors to fix such remuneration subject to such criteria or standards, if any, as may be provided in such Ordinary Resolution, and if no such criteria or standards are so provided, such remuneration shall be fixed in an amount commensurate with the volume and nature of the services rendered by such auditor(s).

RIGHTS OF SIGNATURE, STAMP AND SEAL

71. **RIGHTS OF SIGNATURE, STAMP AND SEAL**

71.1. Subject to the provision of the Articles, the Board of Directors shall be entitled to authorize any person or persons (who need not be Directors) to act and sign on behalf of the Company, and the acts and signature of such person(s) on behalf of the Company shall bind the Company insofar as such person(s) acted and signed within the scope of his or their authority.

71.2. The printed, stamped or typed name of the Company by any means next to the signatures of the authorized signatories of the Company, as aforesaid, shall bind the Company.

NOTICES

72. **NOTICES**

72.1. Any written notice or other document may be served by the Company upon any member either personally or by sending it by prepaid registered mail (airmail if sent to a place outside Israel) addressed to such member at his address as described in the Register of Members or such other address as he may have provided the Company in writing. Any written notice or other document may be served by any member upon the Company by tendering the same in person to the Secretary or the General Manager of the Company at the

principal office of the Company or by sending it by prepaid registered mail (airmail if posted outside Israel) to the Company at its Registered Address. Any such notice or other document shall be deemed to have been served two (2) business days after it has been posted (seven (7) business days if sent by airmail), or when actually received by the addressee if sooner than two (2) or seven (7) days, as the case may be, after it has been posted, or when actually tendered in person, to such member (or to the Secretary or the General Manager), *provided*, *however*, that notice may be sent by cablegram, telex, facsimile, e-mail or other electronic means and such notice shall be deemed to have been given on the first business day following dispatch with confirmation of delivery. If a notice is, in fact, received by the addressee, it shall be deemed to have been duly served, when received, notwithstanding that it was defectively addressed or failed, in some other respect, to comply with the provisions of this Article.

72.2. All notices to be given to the members shall, with respect to any share to which persons are jointly entitled, be given to whichever of such persons is named first in the Register of Members, and any notice so given shall be sufficient notice to the holders of such share.

72.3. Any member whose address is not described in the Register of Members, and who shall not have designated in writing an address for the receipt of notices, shall not be entitled to receive any notice from the Company.

INSURANCE AND INDEMNITY

73. **EXEMPTION**

Subject to the provisions of the Companies Law, including the receipt of all approvals as required therein or under any applicable law, the Company may resolve to exempt in advance an Office Holder to the fullest extent permitted by Companies Law, from all or part of such Office Holder's responsibility or liability for damages caused to the Company due to any breach of such Office Holder's duty of care towards the Company.

74. **EXEMPTION FROM DUTY OF CARE**

Subject to the provisions of the Companies Law including the receipt of all approvals as required therein or under any applicable law, the Board of Directors may resolve in advance to exempt an Office Holder from all or part of such Office Holder's responsibility or liability for damages caused to the Company due to any breach of such Office Holder's duty of care towards the Company.

75. **INDEMNIFICATION**

75.1. Subject to the provisions of the Companies Law including the receipt of all approvals as required therein or under any applicable law, the Company may indemnify any Office Holder (as such term is defined in the Companies Law) to the fullest extent permitted by the Companies Law.

75.2. Subject to the provisions of the Companies Law including the receipt of all approvals as required therein or under any applicable law, the Board of Directors may resolve retroactively to indemnify an Office Holder with respect to the liabilities and expenses prescribed in the Companies Law, *provided* that such liabilities or expenses were incurred by such Office Holder in such person's capacity as an Office Holder of the Company.

75.3. Subject to the provisions of the Companies Law including the receipt of all approvals as required therein or under applicable law, the Board of Directors may resolve in advance to indemnify the Company's Office Holders for the following liabilities and expenses, *provided* that: (i) in the opinion of the Board of Directors such liabilities and expenses can be foreseen at the time the undertaking to indemnify is provided, and (ii) the Board of Directors shall set a reasonable limit to the amounts for such indemnification under the circumstances:

75.3.1. a monetary liability imposed on him in favor of a third party in any judgment, including any settlement confirmed as judgment and an arbitrator's award which has been confirmed by the court, in respect of an act performed by the Office Holder by virtue of the Office Holder being an Office Holder of the Company;

75.3.2. reasonable litigation expenses, including legal fees, paid for by the Office Holder, in an investigation or proceeding conducted against such Office Holder by an agency authorized to conduct such investigation or proceeding, and which investigation or proceeding (i) concluded without the filing of an indictment against such Office Holder and without there having been a financial obligation imposed against such Office Holder in lieu of a criminal proceeding, or (ii) concluded without the filing of an indictment against such Office Holder but with there having been a financial obligation imposed against such Office Holder in lieu of a criminal proceeding for an offense that does not require proof of criminal intent; all in respect of an act performed by the Office Holder by virtue of the Office Holder being an Office Holder of the Company; or

75.3.3. reasonable litigation expenses, including legal fees, paid for by the Office Holder, or which the Office Holder is obligated to pay under a court order, in a proceeding brought against the Office Holder by the Company, or on its behalf, or by a third party, or in a criminal proceeding in which the Office Holder is found innocent, or in a criminal proceeding in which the Office Holder was convicted of an offense that does not require proof of criminal intent, all in respect of an act performed by the Office Holder by virtue of the Office Holder being an Office Holder of the Company.

75.4. For purposes of Article 75.3.2 above:

75.4.1. the "*conclusion of a proceeding without the filing of an indictment*" regarding a matter in which a criminal proceeding was initiated, means the closing of a file pursuant to Section 62 of the Criminal Procedure Law [Consolidated Version], 5742-1982 (the "**Criminal Procedure Law**") or a stay of process by the Attorney General pursuant to Section 231 of the Criminal Procedure Law; and

75.4.2. a "*financial obligation imposed in lieu of a criminal proceeding*" means a financial obligation imposed by law as an alternative to a criminal proceeding, including an administrative fine pursuant to the Administrative Offenses Law, 5746-1982, a fine for committing an offense categorized as a finable offense pursuant to the provisions of the Criminal Procedure Law or a penalty.

76. **INSURANCE**

76.1. Subject to the provisions of the Companies Law (including the receipt of all approvals as required therein or under any applicable law), and to budget limitations, the Company may enter into an agreement to insure an Office Holder for any liability that may be imposed on such Office Holder in connection with an act performed by such Office Holder in such Office Holder's capacity as an Office Holder of the Company, with respect to the following:

76.1.1. a breach of the duty of care owed to the Company or any other person;

76.1.2. a breach of the fiduciary duty owed to the Company, *provided* that the Office Holder acted in good faith and had reasonable grounds to assume that the action would not injure the Company; or

76.1.3. a monetary liability imposed on an Office Holder in favor of a third party, in respect of an act performed by the Office Holder by virtue of the Office Holder being an Office Holder of the Company.

76.2. Notwithstanding the foregoing, the Company may not exempt Office Holders in advance from their responsibilities for damages due to their violation of their duty of care to the Company with respect to distributions.

76.3. Articles 75, 74 and 75.1 shall not apply under any of the following circumstances:

76.3.1. a breach of an Office Holder's fiduciary duty, in which the Office Holder did not act in good faith and with reasonable grounds to assume that the action in question was in the best interest of the Company;

76.3.2. a grossly negligent or intentional violation of an Office Holder's duty of care;

76.3.3. an intentional action by an Office Holder in which such Office Holder intended to reap a personal gain illegally; and

76.3.4. a fine or ransom levied on an Office Holder.

76.4. The Company may procure insurance for or indemnify any person who is not an Office Holder, including without limitation, any employee, agent, consultant or contractor, *provided*, *however*, that any such insurance or indemnification is in accordance with the provisions of the Articles and the Companies Law, and was duly approved by the Board of Directors.

WINDING UP

77. **WINDING UP**

If the Company be wound up, then, subject to applicable law the assets of the Company shall be distributed pursuant to Article 6.3 hereof.

CONFLICTING PROVISIONS

78. The Articles shall amend and supersede any previously adopted Articles of Association of the Company, and any such previous Articles of Association shall be null and void, and shall have no force and effect.

79. In the event that a Hebrew version of these Articles of Association is filed with any regulatory or governmental agency, including the Israeli Registrar of Companies, then whether or not such Hebrew version contains signatures of shareholders, such Hebrew

version shall be considered solely a convenience translation and shall have no binding effect, as between the shareholders of the Company and with respect to any third party. The English version shall be the only binding version of these Articles of Association, and in the event of any contradiction or inconsistency between the meaning of the English version and the meaning of the Hebrew version, the Hebrew version shall be disregarded, shall have no binding effect and shall have no impact on the interpretation of these Articles of Association.

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TheraCoat Ltd.

THE 2010 ISRAELI SHARE OPTION PLAN

(IN COMPLIANCE WITH AMENDMENT NO. 132 OF THE ISRAELI TAX ORDINANCE, 2002)

This plan, as amended from time to time, shall be known as TheraCoat Ltd. 2010 Israeli Share Option Plan (the "**ISOP**").

1. PURPOSE OF THE ISOP

The ISOP is intended to provide an incentive to retain, in the employ of the Company (as defined below) and its Affiliates (as defined below), persons of training, experience, and ability, to attract new employees, directors, consultants, service providers and any other entity which the Board shall decide their services are considered valuable to the Company (as defined below), to encourage the sense of proprietorship of such persons, and to stimulate the active interest of such persons in the development and financial success of the Company (as defined below) by providing them with opportunities to purchase shares in the Company (as defined below), pursuant to the ISOP.

2. DEFINITIONS

For purposes of the ISOP and related documents, including the Option Agreement, the following definitions shall apply:

2.1. "**Affiliate**" means any "employing company" within the meaning of Section 102(a) of the Ordinance.

2.2. "**Applicable Laws**" means the requirements relating to the administration of share option plans under applicable corporate laws, securities laws, any stock exchange or quotation system on which the Shares (as defined below) are listed or quoted and the applicable laws of any other country or jurisdiction where Options are granted under the ISOP.

2.3. "**Approved 102 Option**" means an Option granted pursuant to Section 102(b) of the Ordinance and held in trust by a Trustee for the benefit of the Optionee.

2.4. "**Board**" means the Board of Directors of the Company.

2.5. "**Capital Gain Option**" or "CGO" as defined in Section 5.4 below.

2.6. "**Cause**" means any of the following: (a) the Optionee's theft, dishonesty, or falsification of any Company documents or records; (b) the Optionee's improper use or disclosure of the Company's confidential or proprietary information; (c) any deliberate action by the Optionee which has a detrimental effect on the Company's reputation or business; (d) the Optionee's failure or inability to perform any reasonable assigned duties after written notice from the Company of, and a reasonable opportunity to cure, such failure or inability; (e) any material breach of the Optionee of any employment agreement between the Optionee and the Company, which breach is not cured pursuant to the terms of such agreement; or (f) the Optionee's conviction of any criminal act which impairs the Optionee's ability to perform his, her or its duties with the Company. For purposes of the definition of Cause, with respect to an Optionee employed by or providing services to an Affiliate of the Company, "Company" shall include Affiliate employing or engaging the services of the Optionee.

2.7. "**Chairman**" means the chairman of the Committee.

2.8. "**Committee**" means a share option compensation committee appointed by the Board, which shall consist of no fewer than two members of the Board.

2.9. "**Company**" means TheraCoat Ltd., an Israeli company.

2.10. "**Companies Law**" means the Israeli Companies Law 5759-1999.

2.11. "**Controlling Shareholder**" shall have the meaning ascribed to it in Section 32(9) of the Ordinance.

2.12. "**Date of Grant**" means, the date of grant of an Option, as determined by the Board and set forth in the Optionee's Option Agreement.

2.13. "**Director**" means a member of the Board of Directors of the Company, or any Affiliate.

2.14. "**Disability**" means physical or mental infirmity which impairs Optionee's ability to substantially perform his duties, which continues for a period of at least sixty (60) consecutive days.

2.15. "**Employee**" means a person who is employed by the Company or its Affiliates, including an individual who is serving as a director or an office holder, but excluding Controlling Shareholder. An Employee's employment shall not be deemed to have been terminated in the case of (i) any leave of absence approved by the Company (or by the Affiliate that employs the person) or (ii) transfers between locations of the Company (or Affiliate that employs the person) or between the Company, any of its Affiliates, or any successor. No such leave may exceed ninety days, unless reemployment upon expiration of such leave is guaranteed by statute or contract. Neither service as a Director nor payment of a director's fee shall be sufficient to constitute "employment".

2.16. "**Expiration date**" means the date upon which an Option shall expire, as set forth in Section 10.2 of the ISOP.

2.17. "**Fair Market Value**" means as of any date, the value of a Share determined at the sole discretion of the Board.

The Board may adopt, at its sole discretion, the following value determination mechanism:

2.17.1. If the Shares are listed on any established stock exchange or a national market system, the Fair Market Value shall be the closing sales price for such Shares (or the closing bid, if no sales were reported), as quoted on such exchange or system for the last market trading day prior to time of determination, as reported, or such other source as the Board deems reliable. Without derogating from the above, solely for the purpose of determining the tax liability pursuant to Section 102(b)(3) of the Ordinance, if at the Date of Grant the Company's shares are listed on any established' stock exchange or a national market system or if the Company's shares will be registered for trading within ninety (90) days following the Date of Grant, the Fair Market Value of a Share at the Date of Grant shall be determined in accordance with the average value of the Company's shares on the thirty (30) trading days preceding the Date of Grant or on the thirty (30) trading days following the date of registration for trading, as the case may be;

2.17.2. If the Shares are regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value shall be the mean between the high bid and low asked prices for the Shares on the last market trading day prior to the day of determination, or;

2.17.3. In the absence of an established market for the Shares, the Fair Market Value thereof shall be determined in good faith by the Board at its sole discretion.

2.18. "**IPO**" means the initial public offering of the Company's shares.

2.19. "**ISOP**" means this 2010 Israeli Share Option Plan.

2.20. "**ITA**" means the Israeli Tax Authorities.

2.21. "**Non-Employee**" means a consultant, adviser, service provider, Controlling Shareholder or any other person who is not an Employee.

2.22. "**Ordinary Income Option**" or "**OIO**" as defined in Section 5.5 below.

2.23. "**Option**" means an option to purchase one or more Shares of the Company pursuant to the ISOP.

2.24. "**102 Option**" means any Option granted to Employees pursuant to Section 102 of the Ordinance.

2.25. "**3(i) Option**" means an Option granted pursuant to Section 3(i) of the Ordinance to any person who is Non-Employee.

2.26. "**Optionee**" means a person who receives or holds an Option under the ISOP.

2.27. "**Option Agreement**" means the share option agreement between the Company and an Optionee that sets out the terms and conditions of an Option.

2.28. "**Ordinance**" means the Israeli Income Tax Ordinance [New Version] 1961 as now in effect or as hereafter amended.

2.29. "**Purchase Price**" means the price for each Share subject to an Option.

2.30. "**Section 102**" means Section 102 of the Ordinance as now in effect or as hereafter amended.

2.31. "**Share**" means the ordinary shares, NIS 0.01 par value each, of the Company.

2.32. "**Successor Company**" means any entity the Company is merged into or is acquired by, in which the Company is not the surviving entity.

2.33. "**Transaction**" means (i) merger, acquisition or reorganization of the Company with one or more other entities in which the Company is not the surviving entity, (ii) a sale of all or substantially all of the assets of the Company.

2.34. "**Trustee**" means any individual appointed by the Company to serve as a trustee and approved by the ITA, all in accordance with the provisions of Section 102(a) of the Ordinance.

2.35. "**Unapproved 102 Option**" means an Option granted pursuant to Section 102(c) of the Ordinance and not held in trust by a Trustee.

2.36. "**Vested Option**" means any Option, which has already been vested according to the Vesting Dates.

2.37. "**Vesting Dates**" means, as determined by the Board or by the Committee, the date as of which the Optionee shall be entitled to exercise the Options or part of the Options, as set forth in Section 11 of the ISOP.

3. ADMINISTRATION OF THE ISOP

3.1. The Board shall have the power to administer the ISOP either directly or upon the recommendation of the Committee, all as provided by applicable law and in the Company's Articles of Association. Notwithstanding the above, the Board shall automatically have residual authority if no Committee shall be constituted or if such Committee shall cease to operate for any reason.

3.2. The Committee shall select one of its members as its Chairman and shall hold its meetings at such times and places as the Chairman shall determine. The Committee shall make such rules and regulations for the conduct of its business as it shall deem advisable.

3.3. The Committee shall have the power to recommend to the Board and the Board shall have the full power and authority to: (i) designate participants; (ii) determine the terms and provisions of the respective Option Agreements, including, but not limited to, the number of Options to be granted to each Optionee, the number of Shares to be covered by each Option, provisions concerning the time and the extent to which the Options may be exercised and the nature and duration of restrictions as to the transferability or restrictions constituting substantial risk of forfeiture and to cancel or suspend awards, as necessary; (iii) determine the Fair Market Value of the Shares covered by each Option; (iv) make an election as to the type of Approved 102 Option; and (v) designate the type of Options(vi) alter any restrictions and conditions of any Options or Shares subject to any Options (vii) interpret the provisions and supervise the administration of the ISOP; (viii) accelerate

the right of an Optionee to exercise in whole or in part, any previously granted Option; (ix) determine the Purchase Price of the Option; (x) prescribe, amend and rescind rules and regulations relating to the ISOP; and (xi) make all other determinations deemed necessary or advisable for the administration of the ISOP.

3.4. Notwithstanding the above, the Committee shall not be entitled to grant Options to the Optionees, however, it will be authorized to issue Shares underlying Options which have been granted by the Board and duly exercised pursuant to the provisions herein in accordance with Section 112(a)(5) of the Companies Law.

3.5. The Board shall have the authority to grant, at its discretion, to the holder of an outstanding Option, in exchange for the surrender and cancellation of such Option, a new Option having a purchase price equal to, lower than or higher than the Purchase Price of the original Option so surrendered and canceled and containing such other terms and conditions as the Committee may prescribe in accordance with the provisions of the ISOP.

3.6. The interpretation and construction by the Committee of any provision of the ISOP or of any Option Agreement thereunder shall be final and conclusive unless otherwise determined by the Board.

4. DESIGNATION OF PARTICIPANTS

4.1. The persons eligible for participation in the ISOP as Optionees shall include any Employees and/or Non-Employees of the Company or of any Affiliate; provided, however, that (i) Employees may only be granted 102 Options; (ii) Non-Employees may only be granted 3(i) Options; and (iii) Controlling Shareholders may only be granted 3(i) Options.

4.2. The grant of an Option hereunder shall neither entitle the Optionee to participate nor disqualify the Optionee from participating in, any other grant of Options pursuant to the ISOP or any other option or share plan of the Company or any of its Affiliates.

4.3. Anything in the ISOP to the contrary notwithstanding, all grants of Options to directors and office holders shall be authorized and implemented in accordance with the provisions of the Companies Law or any successor act or regulation, as in effect from time to time.

5. DESIGNATION OF OPTIONS PURSUANT TO SECTION 102

5.1. The Company may designate Options granted to Employees pursuant to Section 102 as Unapproved 102 Options or Approved 102 Options.

5.2. The grant of Approved 102 Options shall be made under this ISOP adopted by the Board as described in Section 16 below, and shall be conditioned upon the approval of this ISOP by the ITA.

5.3. Approved 102 Option may either be classified as Capital Gain Option or Ordinary Income Option.

5.4. Approved 102 Option elected and designated by the Company to qualify under the capital gain tax treatment in accordance with the provisions of Section 102(b)(2) shall be referred to herein as CGO.

5.5. Approved 102 Option elected and designated by the Company to qualify under the ordinary income tax treatment in accordance with the provisions of Section 102(b)(1) shall be referred to herein as OIO.

5.6. The Company's election of the type of Approved 102 Options as CGO or OIO granted to Employees (the "Election"), shall be appropriately filed with the ITA before the Date of Grant of an Approved 102 Option. Such Election shall become effective beginning the first Date of

Grant of an Approved 102 Option under this ISOP and shall remain in effect until the end of the year following the year during which the Company first granted Approved 102 Options. The Election shall obligate the Company to grant only the type of Approved 102 Option it has elected, and shall apply to all Optionees who were granted Approved 102 Options during the period indicated herein, all in accordance with the provisions of Section 102(g) of the Ordinance. For the avoidance of doubt, such Election shall not prevent the Company from granting Unapproved 102 Options simultaneously.

5.7. All Approved 102 Options must be held in trust by a Trustee, as described in Section 6 below.

5.8. For the avoidance of doubt, the designation of Unapproved 102 Options and Approved 102 Options shall be subject to the terms and conditions set forth in Section 102 of the Ordinance and the regulations promulgated thereunder.

5.9. With regards to Approved 102 Options, the provisions of the ISOP and/or the Option Agreement shall be subject to the provisions of Section 102 and the Tax Assessing Officer's permit, and the said provisions and permit shall be deemed an integral part of the ISOP and of the Option Agreement. Any provision of Section 102 and/or the said permit which is necessary in order to receive and/or to keep any tax benefit pursuant to Section 102, which is not expressly specified in the ISOP or the Option Agreement, shall be considered binding upon the Company and the Optionees.

6. TRUSTEE

6.1. Approved 102 Options which shall be granted under the ISOP and/or any Shares allocated or issued upon exercise of such Approved 102 Options and/or other shares received subsequently following any realization of rights, including without limitation bonus shares, shall be allocated or issued to the Trustee and held for the benefit of the Optionees for such period of time as required by Section 102 or any regulations, rules or orders or procedures promulgated thereunder (the "**Holding Period**"). In the case the requirements for Approved 102 Options are not met, then the Approved 102 Options may be treated as Unapproved 102 Options, all in accordance with the provisions of Section 102 and regulations promulgated thereunder.

6.2. Notwithstanding anything to the contrary, the Trustee shall not release any Shares allocated or issued upon exercise of Approved 102 Options prior to the full payment of the Optionee's tax liabilities arising from Approved 102 Options which were granted to him and/or any Shares allocated or issued upon exercise of such Options.

6.3. With respect to any Approved 102 Option, subject to the provisions of Section 102 and any rules or regulation or orders or procedures promulgated thereunder, an Optionee shall not sell or release from trust any Share received upon the exercise of an Approved 102 Option and/or any share received subsequently following any realization of rights, including without limitation, bonus shares, until the lapse of the Holding Period required under Section 102 of the Ordinance. Notwithstanding the above, if any such sale or release occurs during the Holding Period, the sanctions under Section 102 of the Ordinance and under any rules or regulation or orders or procedures promulgated thereunder shall apply to and shall be borne by such Optionee.

6.4. Upon receipt of Approved 102 Option, the Optionee will sign an undertaking to release the Trustee from any liability in respect of any action or decision duly taken and bona fide executed in relation with the ISOP, or any Approved 102 Option or Share granted to him thereunder.

7. SHARES RESERVED FOR THE ISOP; RESTRICTION THEREON

7.1. The Company shall from time to time reserve, out of its authorized but unissued share capital, such number of Shares as the Board deems appropriate (subject to the Articles of Association) for the purposes of this ISOP and/or for the purposes of any other share option plans which have

previously been, or may in the future be, adopted by the Company, subject to adjustment as set forth in Section 9 below. Any Shares which remain unissued and which are not subject to then outstanding Options at the termination or expiration of this ISOP shall cease to be reserved for the purpose of this ISOP, but may continue to be reserved for other share option plans then in effect, and in any event, until termination of this ISOP the Company shall at all times reserve sufficient number of Shares to meet the requirements of any then outstanding Options. Should any Option for any reason expire or be canceled prior to its exercise or relinquishment in full, the Shares subject to such Option may again be subjected to a new Option under this ISOP or under the Company's other share option plans, provided, however, that Shares that have actually been issued under this ISOP shall not be returned to the pool under this ISOP and shall not become available for future distribution under this ISOP.

7.2. Each Option granted pursuant to the ISOP, shall be evidenced by a written Option Agreement between the Company and the Optionee, in such form as the Board or the Committee shall from time to time approve. Each Option Agreement shall state, among other matters, the number of Shares to which the Option relates, the type of Option granted thereunder (whether a CGO, OIO, Unapproved 102 Option or a 3(i) Option), the Vesting Dates, the Purchase Price per share, the Expiration Date and such other terms and conditions as the Committee or the Board in its discretion may prescribe, provided that they are consistent with this ISOP.

7.3. Until the consummation of an IPO, such Shares shall be voted by an irrevocable proxy (the "**Proxy**") pursuant to the directions of the Board, such Proxy to be assigned to the Trustee, who will abstain from any and all votes. The Trustee shall be indemnified and held harmless by the Company against any cost or expense (including counsel fees) reasonably incurred by him/her, or any liability (including any sum paid in settlement of a claim with the approval of the Company) arising out of any act or omission to act in connection with the voting of such Proxy unless arising out of such member's own fraud or bad faith, to the extent permitted by applicable law. Such indemnification shall be in addition to any rights of indemnification the person(s) may have as a director or otherwise under the Company's Articles of Association, any agreement, any vote of shareholders or disinterested directors, insurance policy or otherwise. Without derogating from the above, with respect to Approved 102 Options, such shares shall be voted in accordance with the provisions of Section 102 and any rules, regulations or orders promulgated thereunder.

8. PURCHASE PRICE

8.1. The Purchase Price of each Share subject to an Option shall be equal to the Share's Fair Market Value or as otherwise determined by the Board in its sole and absolute discretion in accordance with applicable law, subject to any guidelines as may be determined by the Board from time to time. Each Option Agreement will contain the Purchase Price determined for each Option covered thereby (but in any event, not less than the nominal value of the Share issuable upon exercise thereof).

8.2. The Purchase Price shall be payable upon the exercise of the Option in a form satisfactory to the Committee, including without limitation, by cash, check or wire transfer. The Committee shall have the authority to postpone the date of payment on such terms as it may determine.

8.3. The Purchase Price shall be denominated in the currency of the primary economic environment of, either the Company or the Optionee (that is the functional currency of the Company or the currency in which the Optionee is paid) as determined by the Company.

9. ADJUSTMENTS

Upon the occurrence of any of the following described events, Optionee's rights to purchase Shares under the ISOP shall be adjusted as hereafter provided:

9.1. In the event of a Transaction or an IPO, or if the Company is voluntarily liquidated or dissolved while unexercised Options remain outstanding under the ISOP, the Company shall immediately notify all unexercised Option holders of such event, and the Option holders shall then have twenty (20) days to exercise any unexercised Vested Option held by them at that time, in accordance with the exercise procedure set forth herein, or in the case of a merger or acquisition - to convert such Options into options in the acquiring or merging entity, all pursuant to the Board's determination and full discretion.. Notwithstanding the above and subject to any applicable law, the Board shall have full power and authority to determine different mechanisms with respect to unexercised Options outstanding under the ISOP.

9.2. If the outstanding shares of the Company shall at any time be changed or exchanged by declaration of a share dividend (bonus shares), share split, combination or exchange of shares, recapitalization, or any other like event by or of the Company, and as often as the same shall occur, then the number, class and kind of the Shares subject to the ISOP or subject to any Options therefore granted, and the Purchase Prices, shall be appropriately and equitably adjusted so as to maintain the proportionate number of Shares without changing the aggregate Purchase Price, provided, however, that no adjustment shall be made by reason of the distribution of subscription rights (rights offering) on outstanding shares. Upon happening of any of the foregoing, the class and aggregate number of Shares issuable pursuant to the ISOP (as set forth in Section 7 hereof), in respect of which Options have not yet been exercised, shall be appropriately adjusted, all as will be determined by the Board whose determination shall be final.

9.3. Anything herein to the contrary notwithstanding, if prior to the completion of the IPO all or substantially all of the shares of the Company are to be sold, or in case of a Transaction, all or substantially all of the shares of the Company are to be exchanged for securities of another Company, then each Optionee shall be obliged to sell or exchange, as the case may be, any Shares such Optionee purchased under the ISOP, in accordance with the instructions issued by the Board in connection with the Transaction, whose determination shall be final.

10. TERM AND EXERCISE OF OPTIONS

10.1. Options shall be exercised by the Optionee by giving written notice to the Company, in such form and method as may be determined by the Company and when applicable, by the Trustee in accordance with the requirements of Section 102, which exercise shall be effective upon receipt of such notice by the Company and the payment of the Purchase Price at the Company's principal office. The notice shall specify the number of Shares with respect to which the Option is being exercised.

10.2. Options, to the extent not previously exercised, shall terminate forthwith upon the earlier of: (i) the date set forth in the Option Agreement; (ii) the expiration of seven (7) years from the Date of Grant, or (iii) the expiration of any extended period in any of the events set forth in Section 10.5 below.

10.3. The Options may be exercised by the Optionee in whole at any time or in part from time to time, to the extent that the Options become vested and exercisable, prior to the Expiration Date, and provided that, subject to the provisions of section 10.5 below, the Optionee is employed by or providing services to the Company or any of its Affiliates, at all times during the period beginning with the granting of the Option and ending upon the date of exercise.

10.4. Subject to the provisions of Section 10.5 below, in the event of termination of Optionee's employment or services, with the Company or any of its Affiliates, all Options granted to such Optionee will immediately expire. A notice of termination of employment or service shall be deemed to constitute termination of employment or service. For the avoidance of doubt, in case of such termination of employment or service, the unvested portion of the Optionee's Option shall not vest and shall not become exercisable.

10.5. Notwithstanding anything to the contrary hereinabove and unless otherwise determined in the Optionee's Option Agreement, an Option may be exercised after the date of termination of Optionee's employment or service with the Company or any Affiliates during an additional period of time beyond the date of such termination, but only with respect to the number of Vested Options at the time of such termination according to the Vesting Dates, if:

10.5.1. termination is without Cause, in which event any Vested Option still in force and unexpired may be exercised within a period of ninety (90) days after the date of such termination; or-

10.5.2. termination is the result of death or Disability of the Optionee, in which event any Vested Option still in force and unexpired may be exercised within a period of twelve (12) months after the date of such termination; or -

10.5.3. prior to the date of such termination, the Committee shall authorize an extension of the terms of all or part of the Vested Options beyond the date of such termination for a period not to exceed the period during which the Options by their terms would otherwise have been exercisable.

10.5.4. For avoidance of any doubt, if termination of employment or service is for Cause, any outstanding unexercised Option (whether vested or non-vested), will immediately expire and terminate, and the Optionee shall not have any right in connection to such outstanding Options.

10.6. To avoid doubt, the Optionees shall not have any of the rights or privileges of shareholders of the Company in respect of any Shares purchasable upon the exercise of any Option, nor shall they be deemed to be a class of shareholders or creditors of the Company for purpose of the operation of Sections 350 and 351 of the Companies Law or any successor to such section, until registration of the Optionee as holder of such Shares in the Company's register of shareholders upon exercise of the Option in accordance with the provisions of the ISOP, but in case of Options and Shares held by the Trustee, subject to the provisions of Section 6 above.

10.7. Any form of Option Agreement authorized by the ISOP may contain such other provisions as the Committee may, from time to time, deem advisable.

10.8. With respect to Unapproved 102 Option, if the Optionee ceases to be employed by the Company or any Affiliate, the Optionee shall extend to the Company and/or its Affiliate a security or guarantee for the payment of tax due at the time of sale of Shares, all in accordance with the provisions of Section 102 and the rules, regulation or orders promulgated thereunder.

11. VESTING OF OPTIONS

11.1. Subject to the provisions of the ISOP, each Option shall vest following the Vesting Dates and for the number of Shares as shall be provided in the Option Agreement. However, no Option shall be exercisable after the Expiration Date. Unless the Committee provides otherwise, vesting of Options granted hereunder shall be tolled during any unpaid leave of absence.

11.2. Unless otherwise stated in the Optionee's Option Agreement, all Options granted pursuant to this ISOP, shall vest annually, in eight (4) equal portions, over a 4-year period from its Date of Grant, with twenty five percent (25%) of such Option becoming vested at the end of each twelve (12) month period following the Date of Grant.

11.3. An Option may be subject to such other terms and conditions on the time or times when it may be exercised, as the Board may deem appropriate. The vesting provisions of individual Options may vary.

12. SHARES SUBJECT TO RIGHT OF FIRST REFUSAL AND BRING ALONG

12.1. Notwithstanding anything to the contrary in the Articles of Association of the Company, none of the Optionees shall have a right of first refusal in relation with any sale of shares in the Company.

12.2. Unless otherwise determined by the Committee, until such time as the Company shall complete an IPO, an Optionee shall not have the right to sell Shares issued upon the exercise of an Option within six (6) months and one day of the date of exercise of such Option or issuance of such Shares. Unless otherwise determined by the Committee, until such, time as the Company shall complete an IPO, the sale of Shares issuable upon the exercise of an Option shall be subject to a right of first refusal on the part of the Repurchaser(s), in accordance with the applicable provision set forth in the Company Articles of Association, in effect at the pertinent time and as amended from time to time.

12.3. Repurchaser(s) means (i) the Company, if permitted by applicable law, (ii) if the Company is not permitted by applicable law, then any affiliate of the Company designated by the Committee; or (iii) if no decision is reached by the Committee, then the Company's existing shareholders (save, for avoidance of doubt, for other Optionees who already exercised their Options), pro rata in accordance with their shareholding.

12.4. Any sale of Shares issued under the ISOP by the Optionee that is not made in accordance with the ISOP or the Option Agreement or the Articles of Association of the Company, shall be null and void.

12.5. Prior to an IPO, and in addition to the right of first refusal, any transfer of Shares by an Optionee shall require the approval of the Board as to the identity of the transferee and as may be required under the Articles of Association. The Board may refuse to approve the transfer of Shares by an Optionee to any other person or entity the Board determined, in its discretion, may be detrimental to the Company, including without limitation to a competitor of the Company.

12.6. Notwithstanding anything herein to the contrary, the Optionee shall be bound by the "bring along" provisions of the Articles of Association and/or any agreement among the Company and all or substantially all of its shareholders, as in effect from time to time, to the effect that if, prior to the completion of the IPO, shareholders holding a certain percentage of the Company's share capital (as set forth in such agreement) ("**Proposing Holders**"), elect to sell all of their equity securities in the Company to a third party, or agree to merge or consolidate the Company with or into another entity, and such sale or merger is conditioned upon the sale of all remaining stock of the Company to such third party, or to the agreement of all of the shareholders, the Optionees shall be required, if so demanded by the Proposing Holders, to sell or transfer all of their equity securities in the Company to such third party as stipulated in the Articles of Association or such other shareholders agreement referred to herein. If no specific percentage of Proposing Holders is stipulated in the Articles of Association or such a shareholders agreement, then the percentage for the purposes of this Section and for the purposes of Section 341 of the Companies Law shall be seventy percent (70%).

13. DIVIDENDS

With respect to all Shares (but excluding, for avoidance of any doubt, any unexercised Options) allocated or issued upon the exercise of Options purchased by the Optionee and held by the Optionee or by the Trustee, as the case may be, the Optionee shall be entitled to receive dividends in accordance with the quantity of such Shares, subject to the provisions of the Company's Articles of Association (and all amendments thereto) and subject to any applicable taxation on distribution of dividends, and when applicable subject to the provisions of Section 102 and the rules, regulations or orders promulgated thereunder.

14. CONDITIONS UPON ISSUANCE OF SHARES

14.1. Legal Compliance. Shares shall not be issued pursuant to the exercise of an Option unless the exercise of such Option and the issuance and delivery of such Shares shall comply with Applicable Laws and shall be further subject to the approval of counsel for the Company with respect to such compliance.

14.2. Investment Representations. As a condition to the exercise of an Option, the Committee may require the person exercising such Option to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required.

14.3. Lock Up. As a condition to the exercise of an Option the Optionee will sign and execute a lock up agreement, prohibiting the Optionee from, pledging, selling, contracting to sell, or otherwise dispose of or transfer any with respect to the Shares for such a period, and on such terms and conditions, as determined by the Board at its sole and absolute discretion.

15. RESTRICTIONS ON ASSIGNABILITY AND SALE OF OPTIONS

15.1. Options may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Optionee, only by the Optionee, or by his guardian or legal representative to the extent provided for herein. An Optionee may file with the Board a written designation of the beneficiary on such form as may be prescribed by the Board and may from time to time amend or revoke such designation. If no designated beneficiary survives the Optionee, then the executor or administrator of the Optionee estate shall be deemed to be the Optionee's beneficiary.

15.2. As long as Options and/or Shares are held by the Trustee on behalf of the Optionee, all rights of the Optionee over the Shares are personal, can not be transferred, assigned, pledged or mortgaged, other than by will or pursuant to the laws of descent and distribution.

16. EFFECTIVE DATE AND DURATION OF THE ISOP

The ISOP shall be effective as of the day it was adopted by the Board and shall terminate at the end of ten (10) years from such day of adoption.

The Company shall obtain the approval of the Company's shareholders for the adoption of this ISOP or for any amendment to this ISOP, if shareholders' approval is necessary or desirable to comply with any applicable law, or if shareholders' approval is required by any authority or by any governmental agencies or national securities exchanges.

17. PURCHASE FOR INVESTMENT, REPRESENTATIONS

17.1. Upon the grant of Options to an Optionee or the issuance of Shares upon the exercise thereof, the Company shall obtain from the Optionee the representations and undertakings as follows, and any other representations and warranties that the Committee may deem advisable, and the giving of such representations and warranties by the Optionee shall be a condition precedent to Optionee's right to receive the Option and/or be issued the Shares upon exercise thereof:

(a) That the Optionee knows that there is no certainty that the exercise of the Options will be financially worthwhile. The Optionee thereby undertakes not to have any claim against the Company or any of its directors, employees, stockholders or advisors if it emerges, at the time of exercising the Options, that the Optionee's investment in the Company's Shares was not worthwhile, for any reason whatsoever.

(b) That the Optionee knows and understands that his rights regarding the Options and the Shares are subject for all intents and purposes to the instructions of the Company's documents of incorporation and to the agreements of the shareholders in the Company.

(c) That the Optionee knows that in addition to the allocations set forth above, the Company has allocated and/or is entitled to allocate Options and Shares to other employees and other people, and the Optionee shall have no claim regarding such allocations, their quantity, the relationship among them and between them and the other shareholders in the Company, exercising of the options or any matter related to or stemming from them.

(d) That the Optionee knows that neither this ISOP nor the grant of Option or Shares thereunder shall impose any obligation on the Company to continue the engagement of the Optionee, and nothing in this ISOP or in any Option or Shares granted pursuant thereto shall confer upon any Optionee any right to continue being engaged by the Company, or restrict the right of the Company to terminate such engagement at any time.

17.2. That the Optionee knows and agrees that it is possible that in the next future issuances by the Company of any additional share capital or other rights or securities convertible into or exchangeable for share capital of the Company, without consideration or for consideration, the price per share will be less than the price determined herein, and that in such event the Optionee will in no event be entitled to any right to full, ratchet anti-dilution protection.

18. INABILITY TO OBTAIN AUTHORITY

The inability of the Company to obtain authority from any regulatory body having jurisdiction, or corporate organ which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

19. AMENDMENTS OR TERMINATION

The Board may at any time, but when applicable, after consultation with the Trustee, amend, alter, suspend or terminate the ISOP. No amendment, alteration, suspension or termination of the ISOP shall impair the rights of any Optionee, unless mutually agreed otherwise between the Optionee and the Company, which agreement must be in writing and signed by the Optionee and the Company. Termination of the ISOP shall not affect the Committee's ability to exercise the powers granted to it hereunder with respect to Options granted under the ISOP prior to the date of such termination.

20. GOVERNMENT REGULATIONS

The ISOP, and the granting and exercise of Options hereunder, and the obligation of the Company to sell and deliver Shares under such Options, shall be subject to all applicable laws, rules, and regulations, whether of the State of Israel or any other state having jurisdiction over the Company and the Optionee, and the Ordinance and to such approvals by any governmental agencies or national securities exchanges as may be required. Nothing herein shall be deemed to require the Company to register the Shares under the securities laws of any jurisdiction.

21. CONTINUANCE OF EMPLOYMENT OR HIRED SERVICES

Neither the ISOP nor the Option Agreement with the Optionee shall impose any obligation on the Company or an Affiliate thereof, to continue any Optionee in its employ or service, and nothing in the ISOP or in any Option granted pursuant thereto shall confer upon any Optionee any right to continue in the employ or service of the Company or an Affiliate thereof or restrict the right of the Company or an Affiliate thereof to terminate such employment or service at any time.

22. GOVERNING LAW & JURISDICTION

The ISOP shall be governed by and construed and enforced in accordance with the laws of the State of Israel applicable to contracts made and to be performed therein, without giving effect to the principles of conflict of laws. The competent courts of Tel-Aviv, Israel shall have sole jurisdiction in any matters pertaining to the ISOP.

23. INTEGRATION OF SECTION 102 AND TAX COMMISSIONER'S PERMIT

23.1. With regards to Approved 102 Options, the provisions of this ISOP and the Option Agreement shall be subject to the provisions of Section 102 and the ITA's permit, and the said provisions and permit shall be deemed an integral part of this ISOP and of the individual Option Agreements with each Optionee.

23.2. Any provision of Section 102 and/or the said permit which is necessary in order to receive and/or to keep any tax benefit pursuant to Section 102, which is not expressly specified in this ISOP or the individual Option Agreement of the Optionees, shall be considered binding upon the Company and the Optionees.

24. TAX CONSEQUENCES

24.1. Any tax consequences arising from the grant or exercise of any Option, from the payment for Shares covered thereby or from any other event or act (of the Company and/or its Affiliates, the Trustee or the Optionee), hereunder, shall be borne solely by the Optionee. The Company and/or its Affiliates and/or the Trustee shall withhold taxes according to the requirements under the applicable laws, rules, and regulations, including withholding taxes at source. Furthermore, the Optionee shall agree to indemnify the Company and/or its Affiliates and/or the Trustee and hold them harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Optionee.

24.2. The Company and/or, when applicable, the Trustee shall not be required to release any Share certificate to an Optionee until all required payments have been fully made.

25. NON-EXCLUSIVITY OF THE ISOP

The adoption of the ISOP by the Board shall not be construed as amending, modifying or rescinding any previously approved incentive arrangements or as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of Options otherwise than under the ISOP, and such arrangements may be either applicable generally or only in specific cases.

For the avoidance of doubt, prior grant of options to Optionees of the Company under their employment agreements, and not in the framework of any previous option plan, shall not be deemed an approved incentive arrangement for the purpose of this Section 25.

26. MULTIPLE AGREEMENTS

The terms of each Option may differ from other Options granted under the ISOP at the same time, or at any other time. The Board may also grant more than one Option to a given Optionee during the term of the ISOP, either in addition to, or in substitution for, one or more Options previously granted to that Optionee.

Exhibit 10.3

INVESTORS' RIGHTS AGREEMENT

THIS INVESTORS' RIGHTS AGREEMENT (the "**Agreement**") is made as of September 18, 2014, by and among TheraCoat Ltd., a private company incorporated under the laws of the State of Israel of, 13 HaSadna St., P.O. Box 2397, Ra'anana 4365007, Israel (the "**Company**"), and each of the investors listed on Schedule A hereto, each of which is referred to in this Agreement as an "**Investor.**"

RECITALS

WHEREAS, pursuant to a Series A Share Purchase Agreement (the "**Purchase Agreement**"), of even date herewith, by and among the Company and the Investors, the Investors are purchasing Series A Preferred Shares of the Company (the "**Financing**"); and

WHEREAS, in order to induce the Company to enter into the Purchase Agreement and to induce the Investors to invest funds in the Company pursuant to the Purchase Agreement, the Investors and the Company hereby agree that this Agreement shall govern the rights of the Investors to cause the Company to register shares issuable to the Investors and to receive certain information from the Company, and shall govern certain other matters as set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are acknowledged, the Company and the Investors agree as follows:

1. Definitions. For purposes of this Agreement:

1.1 "**Amended Articles**" means the Company's Amended Articles of Association adopted pursuant to the Financing, as amended from time to time.

1.2 "**Affiliate**" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such specified Person, including without limitation any general partner, managing member, officer or director of such specified Person and any venture capital fund now or hereafter existing which is controlled by one or more general partners or managing members of, or shares the same management company with, such specified Person.

1.3 "**Board**" means the Board of Directors of the Company.

1.4 "**Certificate of Incorporation**" means the Company's Certificate of Incorporation, as the same may be amended or restated from time to time.

1.5 "**Ordinary Shares**" means the Ordinary Shares of the Company, par value NIS 0.01 per share.

1.6 "**Competitive Operating Entity**" means an operating corporation, partnership, limited liability company or similar entity actively engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the design, development, manufacture, marketing or sale of novel drug delivery systems, it being agreed however that Sol-Gel Ltd. is not a Competitive Operating Entity and that Arkin and Pontifax are active life science investors.

1.7 “**Damages**” means any loss, damage, or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other U.S. federal or state law, insofar as such loss, damage, or liability (or any action in respect thereof) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

1.8 “**Liquidation Event**” has the meaning assigned to such term in the Amended Articles.

1.9 “**Derivative Securities**” means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Ordinary Shares, including options and warrants.

1.10 “**Exchange Act**” means the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

1.11 “**Excluded Registration**” means (i) a registration relating to the sale of securities to employees of the Company or a subsidiary 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.

1.12 “**Form F-1**” means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

1.13 “**Form F-3**” means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.

1.14 “**GAAP**” means generally accepted accounting principles in US GAAP.

1.15 “**Holder**” means any holder of Registrable Securities who is a party to this Agreement or any assignee thereof in accordance with Section 2.12.

1.16 “**Immediate Family Member**” means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, of a natural person referred to herein.

1.17 "**Initiating Holders**" means, collectively, Holders who properly initiate a registration request under this Agreement.

1.18 "**IPO**" means the Company's first underwritten public offering of its Ordinary Shares under the Securities Act.

1.19 "**Major Investor**" means any Investor that, individually or together with such Investor's Affiliates, holds at least 25,000 Preferred Shares (or such number of Ordinary Shares issued upon conversion of 25,000 Preferred Shares) (as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof).

1.20 "**New Securities**" means equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible into or exchangeable into or exercisable for such equity securities. For the avoidance of doubt, "Excluded Securities" (as defined in the Amended Articles) shall be deemed not to be New Securities.

1.21 "**Person**" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.22 "**Preferred Shares**" means, the Series A Preferred Shares, par value NIS 0.01 per share.

1.23 **"Qualified Financing"** means any transaction involving the issuance or sale of New Securities by the Company.

1.24 "**Qualified Public Offering**" has the meaning assigned to such term in the Certificate of Incorporation.

1.25 "**Registrable Securities**" means (i) the Ordinary Shares issuable or issued upon conversion of the Preferred Shares now owned or hereafter acquired by the Investors; (ii) any other Ordinary Shares acquired by the Investors after the date hereof; and (iii) any Ordinary Shares issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (i) or (ii) of this Section 1.25, provided however, that (x) any shares sold by a Person in a transaction in which such Person's rights under Section 2 hereof are not assigned shall not be deemed Registrable Securities and (y) any shares for which registration rights have terminated pursuant to Section 2.13 of this Agreement shall not be deemed Registrable Securities.

1.26 "**Registrable Securities then outstanding**" means the number of shares determined by adding the number of Ordinary Shares that are Registrable Securities and the number of Ordinary Shares issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.

1.27 **"Requisite Investors"** means the holders of at least 50% of the Registrable Securities then outstanding.

1.28 "**Restricted Securities**" means the securities of the Company required to bear the legend set forth in Section 2.12(b) hereof.

1.29 "**SEC**" means the U.S. Securities and Exchange Commission.

1.30 "**SEC Rule 144**" means Rule 144 promulgated by the SEC under the Securities Act.

1.31 "**SEC Rule 145**" means Rule 145 promulgated by the SEC under the Securities Act.

1.32 "**Securities Act**" means the U.S. Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.33 "**Selling Expenses**" means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Section 2.6.

2. Additional Investors.

2.1 Each Additional Investor (as such term is defined under the Purchase Agreement) that joins the Purchase Agreement shall become a party to this Agreement upon executing a counterpart signature page to this Agreement in the form set forth as Schedule 2.1 attached hereto.

3. Registration Rights. The Company covenants and agrees as follows:

3.1 Demand Registration.

(a) Form F-1 Demand. If at any time after 180 days after the effective date of the registration statement for the IPO, the Company receives a request from Holders of at least 30% of the Registrable Securities then outstanding that the Company file a Form F-1 registration statement with respect to Registrable Securities then outstanding having an anticipated aggregate offering price of at least $5,000,000, then the Company shall (i) within 10 days after the date such request is given, give notice thereof (the "**Demand Notice**") to all Holders other than the Initiating Holders; and (ii) 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 F-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 the Company within 20 days of the date the Demand Notice is given, and in each case, subject to the limitations of Section 2.1(c) and Section 2.3.

(b) Form F-3 Demand. If at any time when it is eligible to use a Form F-3 registration statement, the Company receives a request from Holders of the Registrable Securities then outstanding that the Company file a Form F-3 registration statement with respect to outstanding Registrable Securities of such Holders having an anticipated aggregate offering price of at least $3,000,000, then the Company shall (i) within 10 days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders; and (ii) 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 F-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 the Company within 20 days of the date the Demand Notice is given, and in each case, subject to the limitations of Section 2.1(c) and Section 2.3.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this Section 2.1 a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Board it would be materially detrimental to the Company and its shareholders for such registration statement to either become effective or remain effective for as long as such registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than 60 days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than once in any 12-month period; and provided further that the Company shall not register any securities for its own account or that of any other shareholder during such 60-day period other than an Excluded Registration.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 2.1(a) (i) during the period that is 60 days before the Company's 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 the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two registrations pursuant to Section 2.1(a); or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form F-3 pursuant to a request made pursuant to Section 2.1(b). The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 2.1(b) (i) during the period that is 30 days before the Company's good faith estimate of the date of filing of, and ending on a date that is 90 days after the effective date of, a Company-initiated registration, provided, that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (ii) if the Company has effected two registrations pursuant to Section 2.1(b) within the 12-month period immediately preceding the date of such request. A registration shall not be counted as "effected" for purposes of this Section 2.1(d) 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 pursuant to Section 2.6, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Section 2.1(d).

3.2 Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for shareholders other than the Holders) any of its securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company 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 the Company, the Company shall, subject to the provisions of Section 2.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 2.2 before the effectiveness of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Section 2.6.

3.3 Underwriting Requirements.

(a) If, pursuant to Section 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Section 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Company and shall be reasonably acceptable to a majority in interest of the Initiating Holders. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Section 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this Section 2.3, if the managing underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares.

(b) In connection with any offering involving an underwriting of shares of the Company's shares pursuant to Section 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by shareholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as

practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares. Notwithstanding the foregoing, in no event shall the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering. For purposes of the provision in this Section 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, shareholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

(c) For purposes of Section 2.1, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provision in Section 2.3(a), fewer than 50% of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

3.4 Obligations of the Company. Whenever required under this Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to 120 days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such 120-day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Ordinary Shares (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form F-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such 120-day period shall be extended for up to 180 days in the aggregate, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue sky

laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on the New York Stock Exchange or the Nasdaq Global Market and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) promptly make available for inspection by the selling Holders, any underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

(i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and

(j) after such registration statement becomes effective, notify each Holder of Registrable Securities covered by such registration statement of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

3.5 Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as shall be reasonably required to effect the registration of such Holder's Registrable Securities.

3.6 Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers' and accounting fees; fees and disbursements of counsel for the Company; and the reasonable fees and disbursements, of one counsel for the selling Holders ("**Selling Holder Counsel**"), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Section 2.1 if the registration

request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Section 2.1(a) or Section 2.1(b), as the case may be; provided further, however, that if at the time of such withdrawal, the Holders have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information, then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Section 2.1(a) or Section 2.1(b), as the case may be. All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

3.7 Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.

3.8 Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company will indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and shareholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Section 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company (which consent shall not be unreasonably delayed, conditioned or withheld), nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished expressly for the use in connection with such registration by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, will indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based solely upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder

will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Section 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably delayed, conditioned or withheld; and provided further that in no event shall any indemnity or contribution under Sections 2.8(b) or 2.8(d) exceed the net proceeds from the offering received by such Holder, except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Section 2.8 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.8, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action. The failure to give notice to the indemnifying party within a reasonable time of the commencement of any such action shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.8, only if that such failure materially prejudices the indemnifying party's ability to defend such action. The failure to give notice to the indemnifying party will not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.8.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Section 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Section 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Section 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission;

provided, however, that, in any such case, (x) no such Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; and provided further that in no event shall a Holder's liability pursuant to this Section 2.8(d), when combined with the amounts paid or payable by such Holder pursuant to Section 2.8(b), exceed the net proceeds from the offering received by such Holder, except in the case of willful misconduct or fraud by such Holder.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this Section 2.8 shall survive the completion of any offering of Registrable Securities in a registration under this Section 2, and otherwise shall survive the termination of this Agreement.

3.9 Reports Under Exchange Act. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form F-3, the Company shall:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effectiveness of the registration statement filed by the Company for the IPO;

(b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after 90 days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form F-3 (at any time after the Company so qualifies); (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company; and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form F-3 (at any time after the Company so qualifies to use such form).

3.10 Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Requisite

Investors, enter into any agreement with any holder or prospective holder of any securities of the Company which would allow such holder or prospective holder to (a) include such securities in any registration unless under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the number of the Registrable Securities of the Holders that are included or (b) demand registration of any securities held by such holder or prospective holder.

3.11 "Market Stand off" Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the IPO and ending on the date specified by the Company and the managing underwriter (such period not to exceed 180 days, which period may be extended upon the request of the managing underwriter, to the extent required by any NASD or FINRA rules, for an additional period of up to 20 days if the Company issues or proposes to issue an earnings or other public release within 20 days of the expiration of the 180-day lockup period), (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Ordinary Shares held immediately prior to the effectiveness of the registration statement for the IPO, or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) of this Section 2.11 is to be settled by delivery of Ordinary Shares or other securities, in cash, or otherwise. The foregoing provisions of this Section 2.11 shall apply only to the IPO, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, and shall only be applicable to the Holders if all officers, directors and holders of more than one percent of the outstanding Ordinary Shares are subject to similar agreements. The underwriters in connection with the IPO are intended third-party beneficiaries of this Section 2.11 and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with the IPO that are consistent with this Section 2.11 or that are necessary to give further effect thereto.

3.12 Restrictions on Transfer.

(a) The Preferred Shares and the Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Shares and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate or instrument representing (i) the Preferred Shares, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Section 2.12(c)) be stamped or otherwise imprinted with a legend substantially in the following form:

THE SECURITIES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE SHAREHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this Section 2.12.

(c) The holder of each certificate representing Restricted Securities, by acceptance thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a "no action" letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or "no action" letter (x) in any transaction in compliance with SEC Rule 144 or (y) in any transaction in which such Holder distributes Restricted Securities to an Affiliate of such Holder for no consideration; provided that each transferee agrees in writing to be subject to the terms of this Section 2.12. Each certificate or instrument evidencing the Restricted Securities transferred as above provided shall bear, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Section 2.12(b), except that such certificate shall not bear such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act. Notwithstanding anything to the contrary herein, no Holder shall be permitted to transfer its Restricted Securities to a Competitive Operating Entity (other than in connection with a Purchase Offer made pursuant to the Amended Articles) without the prior written consent of the Company and the Requisite Investors; provided, however, that an

Investor may transfer its shares to a Competitive Operating Entity that is an Affiliate of such Investor without such consent, provided that such transferee will not be entitled to any rights provided pursuant to, or to obtain information under, Section 3 of this Agreement.

3.13 Termination of Registration Rights.

(a) No Holder shall be entitled to exercise any right provided for in this Section 2 after, and all such rights shall terminate upon the earlier to occur of (i) the closing of a Liquidation Event and (ii) the fifth anniversary of the IPO.

(b) The rights set forth in this Section 2 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 SEC Rule 144.

4. Information Rights.

4.1 Delivery of Financial Statements to Major Investors. The Company shall deliver to each Major Investor, provided that the Board has not reasonably determined that such Major Investor is a Competitive Operating Entity:

(a) as soon as practicable, but in any event (i) no later than 180 days following the end of each fiscal year of the Company (beginning with the fiscal year ended December 31, 2014), (a) a balance sheet as of the end of such year, (b) statements of income and of cash flows for such year and a comparison between (x) the actual amounts as of and for such fiscal year and (y) the comparable amounts for the prior year and as included in the Budget (as defined in Section 3.1(e)) for such year, with an explanation of any material differences between such amounts and a schedule as to the sources and applications of funds for such year, and (c) a statement of shareholders' equity as of the end of such year, all such financial statements, comparisons and explanations to be in reasonable detail, prepared in accordance with GAAP and such financial statements audited and certified by independent public accountants of nationally or regionally recognized standing selected by the Company;

(b) as soon as practicable, but in any event within 45 days after the end of each of the first three quarters of each fiscal year of the Company, unaudited statements of income and of cash flows for such fiscal quarter, and an unaudited balance sheet and a statement of shareholders' equity as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c) as soon as practicable, but in any event within 45 days after the end of each of the first three quarters of each fiscal year of the Company, a statement showing the number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the period, the Ordinary Shares issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Ordinary Shares and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit such Major Investor to calculate its respective percentage equity ownership in the Company, and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct;

(d) as soon as practicable, but in any event 30 days before the end of each fiscal year, a budget and business plan for the next fiscal year (collectively, the "**Budget**"), approved by the Board, prepared on a monthly basis, including balance sheets, income statements, and statements of cash flow for such months and, promptly after prepared, any other budgets or revised budgets prepared by the Company;

(e) with respect to the financial statements called for in Section 3.1(a), Section 3.1(b) and Section 3.1(d), an instrument executed by the chief financial officer and chief executive officer of the Company certifying that such financial statements were prepared in accordance with GAAP consistently applied with prior practice for earlier periods (except as otherwise set forth in Section 3.1(b) and Section 3.1(d)) and fairly present the financial condition of the Company and its results of operation for the periods specified therein; and

(f) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Major Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Section 3.1 to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in a form acceptable to the Company) or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

Notwithstanding anything else in this Section 3.1 to the contrary, the Company may cease providing the information set forth in this Section 3.1 during the 60-day period before the Company's good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided that the Company's covenants under this Section 3.1 shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

4.2 Inspection. The Company shall permit each Major Investor (provided that the Board has not reasonably determined that such Major Investor is a Competitive Operating Entity), at such Major Investor's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Major Investor; provided, however, that the Company shall not be obligated pursuant to this Section 3.2 to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in a form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

4.3 Termination of Information and Inspection Covenants. The covenants set forth in Section 3.1 and Section 3.2 shall terminate and be of no further force or effect (i) immediately prior to the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon the closing of a Liquidation Event, whichever event occurs first.

4.4 Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Section 3.4 by such Investor), (b) as evidenced by written documents is or has been independently developed or conceived by the Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to the Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities from such Investor, provided that (y) such prospective purchaser agrees to be bound by the provisions of this Section 3.4 and (z) the Board has not reasonably determined that such prospective purchaser is a Competitive Operating Entity; (iii) to any existing or prospective Affiliate, partner, member, shareholder, or wholly owned subsidiary of such Investor in the ordinary course of business, provided that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law, provided that the Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure.

5. Additional Covenants.

5.1 Insurance. The Company shall maintain, from financially sound and reputable insurers Directors and Officers liability insurance in an amount US$3,000,000 (three million United States Dollars) and on terms and conditions satisfactory to the Board. The Company will use commercially reasonable efforts to cause such insurance policies to be maintained until such time as the Board determines that such insurance should be discontinued.

5.2 Board Matters. Unless otherwise provided for in the Amended Articles or determined by the vote of a majority of the directors then in office, the Board shall meet at least quarterly in accordance with an agreed-upon schedule. The Company shall reimburse the directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company's travel policy) in connection with attending meetings of the Board.

5.3 Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary, proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board as in effect immediately before such transaction, whether such obligations are contained in the Company's Amended Articles, separate agreement, or elsewhere, as the case may be.

5.4 Termination of Covenants. The covenants set forth in this Section 5, except for Section 5.4, shall terminate and be of no further force or effect upon the earliest of (a) immediately prior to the consummation of the IPO, (b) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, and (c) upon the closing of a Liquidation Event.

6. Miscellaneous.

6.1 Successors and Assigns. Except as provided in Section 2.12(c), the rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (i) is an Affiliate of a Holder; (ii) is a Holder's Immediate Family Member or trust for the benefit of an individual Holder or one or more of such Holder's Immediate Family Members; or (iii) after such transfer, holds at least 500,000 shares of Registrable Securities (subject to appropriate adjustment for stock splits, stock dividends, combinations, and other recapitalizations); provided, however, that (x) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; (y) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Section 2.11; and (z) such transfer occurs in compliance with Section 2.12(c). For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or shareholder of a Holder; (2) who is a Holder's Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such Holder's Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided further that all transferees who would not qualify individually for assignment of rights shall have a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.

6.2 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Israel, regardless of the laws that might otherwise govern under applicable principles of conflicts of law.

6.3 Counterparts; Facsimile. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may also be executed and delivered by facsimile signature and in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

6.4 Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

6.5 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given and received upon the earliest of (a) actual receipt, (b) personal delivery to the party to be notified, (c)

when sent, if sent by electronic mail or confirmed facsimile during normal business hours of the recipient, and if not sent during normal business hours, then on the recipient's next business day, (d) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, and (e) four business days after deposit with an internationally recognized overnight courier (it being agreed that DHL and FedEx are internationally recognized overnight couriers), freight prepaid, specifying next business day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their facsimile number or address (and with such copies, which shall not constitute notice) as set forth herein, on a signature page hereto or on Schedule A hereto, as the case may be, or to such facsimile number or address as subsequently modified by written notice given in accordance with this Section 6.5. If notice is given to the Company, it shall be sent to TheraCoat Ltd., 13 HaSadna St., P.O. Box 2397, Ra'anana 4365007, Israel; fax: +972-77-4171410; e-mail: gil.hakim@theracoat.com, with a copy to: Yaron Sobol, Adv., Hamburger Evron & Co., The Museum Tower, 4 Berkowitz St., Tel Aviv 6423806, Israel; fax: +972-3-607-4004; e-mail: yaron.sobol@evronlaw.com.

6.6 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the Requisite Investors; provided, that the Company may in its sole discretion waive compliance with Section 2.12(c); and provided further that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Any amendment or waiver effected in accordance with this paragraph shall be binding upon each holder of any Registrable Securities then outstanding, each future holder of all such Registrable Securities, the Company, and all of their respective successors and permitted assigns. Notwithstanding the foregoing, this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination, or waiver applies to all Investors in the same fashion, including, for the avoidance of doubt, that this sentence may not be amended, terminated or waived as to such Investor without the written consent of such Investor. The Company shall give prompt notice of any amendment or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, termination, or waiver. Any amendment, termination, or waiver effected in accordance with this Section 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

6.7 Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.8 Aggregation of Shares. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

6.9 Entire Agreement. This Agreement (including any exhibits and schedules hereto), the Amended Articles and the other Transaction Agreements (as defined in the Purchase Agreement) and the agreements, documents and instruments referenced therein constitute the full and entire understanding and agreement between the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties are expressly canceled.

6.10 Submission to Jurisdiction. The parties hereto (a) hereby irrevocably and unconditionally submit to the jurisdiction of the appropriate courts in the Tel Aviv Jaffa District for the purpose of any suit, action or other proceeding arising out of or based upon this Agreement, (b) agree not to commence any suit, action or other proceeding arising out of or based upon this Agreement except in the appropriate courts in the Tel Aviv Jaffa District, and (c) hereby waive, and agree not to assert, by way of motion, as a defense, or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that this Agreement or the subject matter hereof may not be enforced in or by such court. Each of the parties to this Agreement consents to personal jurisdiction for any equitable action sought in the appropriate courts in the Tel Aviv Jaffa District having subject matter jurisdiction.

6.11 Delays or Omissions. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

6.12 Acknowledgment. The Company acknowledges that at least some of the Investors are in the business of venture capital and private equity investing and therefore review the business plans and related proprietary information of many enterprises, including enterprises which may have products or services which are adverse to or compete directly or indirectly with those of the Company. Nothing in this Agreement shall otherwise preclude or in any way restrict any Investor or any Affiliate thereof from investing or participating in any particular enterprise whether or not such enterprise has products or services which are adverse to or compete, directly or indirectly, with those of the Company. Notwithstanding, the preceding sentence shall not release or relieve any Investor from its obligations and undertaking pursuant to Section 4.4 above.

[signature page follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first written above.

COMPANY:

THERACOAT LTD.

By: /s/ Gil Hakim
Name: Gil Hakim
Title: Chief Executive Officer

By: /s/ Yossi Yavin
Name: Yossi Yavin
Title: Director

THE INVESTORS:

M. ARKIN (1999) LTD.

By: /s/ Nir Arkin
Name: Nir Arkin
Title: Director

PONTIFAX (ISRAEL) III L.P.

By: Pontifax Ltd., its General Partner

By: /s/ Ran Nussbaum

Title: Director

PONTIFAX (CAYMAN) III L.P.

By: Pontifax Ltd., its General Partner

By: /s/ Ran Nussbaum

Title: Director

SCHEDULE A

M. ARKIN (1999) LTD.

PONTIFAX (ISRAEL) III L.P.

PONTIFAX (CAYMAN) III L.P.

AMENDMENT TO INVESTORS' RIGHTS AGREEMENT

THIS AMENDMENT TO INVESTORS' RIGHTS AGREEMENT (this "Amendment") is entered into effective as of October 1st, 2015 ("Effective Date"), by and among TheraCoat Ltd. ("Company"), Arkin Communications Ltd. ("Arkin"), Pontifax (Israel) III Limited Partnership ("Pontifax IL") and Pontifax Cayman III Limited Partnership ("Pontifax CM").

WHEREAS, on September 18, 2014, the Company entered into that certain Investors' Right Agreement with each of the investors listed on Schedule A thereto ("IRA); and

WHEREAS, Arkin, Pontifax IL and Pontifax CM hold at least 50% (fifty percent) of the Registrable Securities outstanding and qualify as Requisite Investors; and

WHEREAS, pursuant to Section 6.6 of the IRA any term of the IRA may be amended and the observance of any term of the IRA may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the Requisite Investors; and

WHEREAS, the Company and the Requisite Investors desire to amend the IRA as provided herein;

NOW, THEREFORE, in consideration of the premises and the mutual promises herein made, and in consideration of the representations, warranties, and covenants herein contained, and intending to be legally bound hereby, the parties hereby agree as follows:

1. Capitalized terms used herein (including in the preamble to the Amendment) and not otherwise defined shall have the respective meaning ascribed to them in the IRA.

2. As of the Effective Date Section 1.6 of the IRA shall be deleted and replaced by the following section:

"1.6 "**Competitive Operating Entity**" means an operating corporation, partnership, limited liability company or similar entity actively engaged, directly or indirectly (including through any partnership, limited liability company, corporation, joint venture or similar arrangement (whether now existing or formed hereafter)), in the design, development, manufacture, marketing or sale of novel drug delivery systems, it being agreed however that Sol-Gel Ltd. is not a Competitive Operating Entity and that Arkin, Pontifax and ProQuest Investments IV, L.P. are active life science investors."

3. As of the Effective Date Section 3.12(a) of the IRA shall be deleted and replaced by the following section:

"(a) The Preferred Shares and the Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. It is clarified that a transfer made in accordance with Rule 144 shall not be restricted and shall be deemed to be made in accordance with the conditions specified in this Agreement. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Shares and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement."

4. All references in Section 3 of the IRA to various Sub-Sections in Section 2 of the IRA, or references to Section 2 of the IRA itself should be references to the corresponding Sub-Section in Section 3 of the IRA, or to Section 3 of the IRA itself.

5. Except as specifically provided herein, there are no other amendments to the IRA. The IRA, as amended hereby, shall continue in full force and effect and is hereby ratified and affirmed by the parties thereto. In the event of contradiction between any provision of the IRA and an amendment thereto as set forth herein, such amendment shall prevail.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Amendment, as of the date first stated above.

/s/ Ron Bentsur
TheraCoat Ltd.
By: Ron Bentsur
Title: CEO

/s/ Nir Arkin
Arkin Communications Ltd.
By: Nir Arkin
Title: Director

/s/ Ran Nussbaum
Pontifax (Israel) III Limited Partnership
By: Ran Nussbaum
Title: Managing Partner

/s/ Ran Nussbaum
Pontifax Cayman III Limited Partnership
By: Ran Nussbaum
Title: Managing Partner

AMENDMENT No. 2 TO INVESTORS' RIGHTS AGREEMENT

THIS AMENDMENT No. 2 TO INVESTORS' RIGHTS AGREEMENT ("Amendment No. 2") is entered into effective as of April 12, 2016 ("Effective Date"), by and among UroGen Pharma Ltd. ("Company"), Arkin Communications Ltd. ("Arkin"), Pontifax (Israel) III Limited Partnership ("Pontifax IL"), Pontifax Cayman III Limited Partnership ("Pontifax CM") and ProQuest Investments IV, L.P. ("ProQuest").

WHEREAS, on September 18, 2014, the Company entered into that certain Investors' Right Agreement with each of the investors listed on Schedule A thereto ("IRA"); and

WHEREAS, on October 1, 2015, the Company and the Requisite Investors (as such term is define under the IRA) entered into that certain Amendment to Investors' Right Agreement ("Amendment No. 1"); and

WHEREAS, Arkin, Pontifax IL, Pontifax CM and ProQuest hold at least 50% (fifty percent) of the Registrable Securities outstanding and qualify as Requisite Investors; and

WHEREAS, pursuant to Section 6.6 of the IRA any term of the IRA may be amended and the observance of any term of the IRA may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the Requisite Investors; and

WHEREAS, the Company and the Requisite Investors desire to amend the IRA as provided herein;

NOW, THEREFORE, in consideration of the premises and the mutual promises herein made, and in consideration of the representations, warranties, and covenants herein contained, and intending to be legally bound hereby, the parties hereby agree as follows:

1. Capitalized terms used herein (including in the preamble to the Amendment No. 2) and not otherwise defined shall have the respective meaning ascribed to them in the IRA and Amendment No. 1.

2. As of the Effective Date Section 3.2 of the IRA shall be deleted and replaced by the following section:

"3.2 Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for shareholders other than the Holders) any of its securities under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company 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 the Company, the Company shall, subject to the provisions of Section 3.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 3.2 before the effectiveness of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Section 3.6.

This Section 3.2 shall not apply in the event of an IPO."

3. All references in Section 4 of the IRA to various Sub-Sections in Section 3 of the IRA, or references to Section 3 of the IRA itself should be references to the corresponding Sub-Section in Section 4 of the IRA, or to Section 4 of the IRA itself.

4. Except as specifically provided herein, there are no other amendments to the IRA and Amendment No. 1. The IRA and Amendment No. 1, as amended hereby, shall continue in full force and effect and is hereby ratified and affirmed by the parties thereto. In the event of contradiction between any provision of the IRA and an amendment thereto as set forth herein, such amendment shall prevail.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Amendment, as of the date first stated above.

UroGen Pharma Ltd.

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

Arkin Communications Ltd.

By: /s/ Moshe Arkin
Title: Director

Pontifax (Israel) III Limited Partnership

By: /s/ Ran Nussbaum
Title: Managing Partner

Pontifax Cayman III Limited Partnership

By: /s/ Ran Nussbaum
Title: Managing Partner

ProQuest Investments IV, L.P.

By: /s/ Pasquale DeAngelis
Title: Managing Member of the General Partner

Exhibit 10.4

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (the "Agreement") is made and entered into as of October 1st, 2015 ("Effective Date"), by and between TheraCoat Ltd., a limited liability company, incorporated under the laws of the State of Israel (the "Purchaser"), of the first party; and Telormedix SA, a company incorporated under the laws of Switzerland ("Seller"), of the second party (Purchaser and Seller shall be referred to as a "Party" or "Parties", as applicable).

WHEREAS, the Purchaser is engaged in the development, testing and commercialization of a novel drug delivery system which may be used for various therapeutic purposes, including the treatment of bladder and upper tract cancers and other urology related diseases; and

WHEREAS, the Seller is a biopharmaceutical company focused on targeted immunity and the role of the innate immune system in treating bladder cancer and related diseases; and

WHEREAS, Purchaser desires to purchase, acquire and assume from the Seller, and the Seller desires to sell, transfer and assign to the Purchaser, the Proprietary Information (as defined below), subject to the terms and conditions in this Agreement; and proprietary information

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises, representations, warranties and covenants hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, intending to be legally bound hereby, the Parties hereto agree as follows:

1. Definitions

1.1. "Authorizations" means all franchises, grants, authorizations, licenses, permits, easements, consents, certificates and orders of any governmental authority or self-regulatory body required for the utilization of the Proprietary Information.

1.2. "Clinical Studies" means all studies, tests and preclinical and clinical trials conducted by or on behalf of Seller were and, if still pending, are, and in all material respects, being conducted in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all Laws and Authorizations.

1.3. "EMA" means the European Medicine Agency, a decentralized agency of the European Union and any successor agency having substantially the same functions.

1.4. "Escrow Agreement" means the share escrow agreement with respect to Escrow Shares to which said Seller is entitled at Initial Closing.

1.5. "Escrow Shares" means 54,000 (fifty four thousand) Preferred Shares constituting 25% (twenty five percent) of the Initial Closing Shares.

1.6. "FDA" means United States of America Food and Drug Administration and any successor agency having substantially the same functions.

1.7. “Goodwill” means any reference to the name “Vesimune” “TMX-{xxx}”, any service marks, trademarks, trade names, identifying symbols, logos, emblems, signs or insignia related thereto or containing or comprising the foregoing to their brand names and trademarks whether registered or not, including any name or mark confusingly similar thereto, and applications for trademarks and service marks, trade names, logos, trade dress and other proprietary indicia and all goodwill associated therewith.

1.8. “Initial Closing” means the consummation the transactions contemplated in Section 2.1 herein as contemplated by this Agreement.

1.9. “Initial Closing Date” shall have the meaning set forth in Section 3.1 below.

1.10. “Initial Closing Shares” means 216,000 (two hundred sixteen thousand) Preferred Shares.

1.11. “Intellectual Property” means (i) inventions (whether or not patentable), trade secrets, technical data, databases, customer lists, designs, tools, methods, processes, technology, ideas, know-how and other confidential or proprietary information and materials; (ii) trademarks and service marks (whether or not registered), applications for trademarks and service marks, trade names, logos, trade dress and other proprietary indicia and all goodwill associated therewith; (iii) documentation, advertising copy, marketing materials, specifications, mask works, drawings, graphics, databases, recordings and other works of authorship, whether or not protected by copyright; (iv) source code, object code, data and operating files, user manuals, documentation, flow charts, algorithms, compilers, development tools, maintenance records and other materials related to computer programs; (v) internet websites and domain names; and (vi) all forms of legal rights and protections that may be obtained for, or may pertain to, the Intellectual Property set forth in clauses (i) through (v) in any country of the world, including, without limitation, all issued patents, letters patent, patent applications, provisional patents, design patents, Patent Cooperation Treaty (PCT) filings and other rights to inventions or designs, all registered and unregistered copyrights in both published and unpublished works, trade secret rights, mask works, moral rights or other literary property or authors rights, rights regarding trademarks and other proprietary indicia, and all applications, registrations, issuances, divisions, continuations, renewals, reissuances and extensions of the foregoing.

1.12. “IPO” means an underwritten public offering of the securities of the Purchaser.

1.13. “IPO Shares” means that certain class of shares of the Purchaser offered pursuant to the IPO.

1.14. “Laws” means all laws, statutes, regulations, rules, ordinances or orders to which it is subject or which are applicable to the Proprietary Information.

1.15. “Licenses” means any exclusive or non-exclusive worldwide or territory limited license, including the right to grant sublicenses on terms set forth herein, to research, develop, import, offer for sale, market, commercialize, distribute and sell product incorporating the Intellectual Property.

1.16. “Liens” means any and all mortgages, claims, demands, liens, security interests, pledges, escrows, charges (whether fixed or floating), hypothecations, options, right of preemption, right of retention of title or any other form of security interest or any obligation (including any conditional obligation) to create any of the same, restrictions, or encumbrances of any kind whatsoever.

1.17. “Milestone Closing” or “Milestone Closings” means the 1st Milestone Closing, the 2nd Milestone Closing and the 3rd Milestone Closing, as applicable.

1.18. “Milestone Shares” means the 1st Milestone Shares, the 2nd Milestone Shares and the 3rd Milestone Shares, as applicable.

1.19. “Regulatory Agency” means FDA, EMA and any similar, corresponding or successor regulatory authority if the context so indicates.

1.20. “Preferred Shares” means Preferred A Shares of the Purchaser par value NIS 0.01 each.

1.21. “Product” means Seller’s proprietary Vesimune (TMX-101) product for the local treatment of various forms of bladder cancer as monotherapy only.

1.22. “Proprietary Information” means any and all owned knowledge or data of the Seller, whether registered or not, including but not limited to, the Intellectual Property, Goodwill, Clinical Studies and Licenses.

1.23. “Third Party Rights” means any loans, options and third party rights, claims, restrictions or interests of any kind, contractual or otherwise.

1.24. “Transaction Shares” means the Initial Closing Shares, 1st Milestone Shares, 2nd Milestone Shares and 3rd Milestone Shares.

1.25. “1st Milestone Closing” means the enrolment of the 1st (first) patient to a Phase III Clinical Study or study intended to provide evidence for FDA drug marketing approval for the Product (protocol TMX-101-004 presented by Seller to the FDA).

1.26. “1st Milestone Shares” means 29,000 (twenty nine thousand) Preferred Shares or IPO Shares, as the case may be.

1.27. “2nd Milestone Closing” means receipt of a FDA drug marketing approval for the Product.

1.28. “2nd Milestone Shares” means 29,000 (twenty nine thousand) Preferred Shares or IPO Shares, as the case may be.

1.29. “3rd Milestone Closing” means the end of Purchaser’s financial reporting period when sales of the Product as monotherapy only shall generate “*net sales*” of US$50,000,000 (fifty million U.S. Dollars) in the aggregate. For the purpose of the 3rd Milestone Closing “*net sales*” shall mean the total amount actually received by the Purchaser in connection with sales of the Product, in a bona fide at arm’s length transactions, after deduction of all of the following to the extent applicable to such sales: (a) all trade, cash and quantity credits, discounts, refunds or rebates; (b) allowances or credits for returns; (c) actual and recorded sales commissions; and (d) sales taxes (including value added tax),

1.30. “3rd Milestone Shares” means 29,000 (twenty nine thousand) Preferred Shares or IPO Shares, as the case may be.

2. The Transaction

2.1. Proprietary Information Being Purchased; Closing. At the Initial Closing, the Seller shall sell to the Purchaser, and the Purchaser shall purchase from the Seller, the Proprietary Information by selling to the Purchaser all of Seller's right, title and interest, in the Proprietary Information, "as is" and free and clear of any Liens and Third Party Rights.

2.2. Consideration at the Initial Closing. Subject to the terms and conditions hereof, at the Initial Closing in consideration to the Proprietary Information the Purchaser shall issue, allot and deliver to Seller, and Seller shall purchase and receive from the Purchaser, the Initial Closing Shares.

2.3. Issue and Purchase of Shares at the Milestone Closings. Subject to the terms and conditions herein below, at the First Milestone Closing (as defined below), Second Milestone Closing (as defined below) and Third Milestone Closing (as defined below) the Purchaser shall issue and allot to Seller, and Seller shall receive from the Purchaser, as additional consideration for the Proprietary Information, the 1st Milestone Shares, 2nd Milestone Shares and 3rd Milestone Shares, respectively.

3. Closing, Delivery and Transfer of Proprietary Information.

3.1. Initial Closing. The Initial Closing to be held as described in Section 3.2 below remotely via the exchange of documents and signatures, within three (3) business days following satisfaction (or waiver by the relevant party) of the conditions set forth in Sections 3.3 below, at 11:00 a.m., local time, or at such other time or place as the Purchaser and the Seller shall mutually agree upon. Notwithstanding the foregoing, if the Initial Closing does not take place within fifteen (15) days following the execution hereof, this Agreement shall terminate and shall be of no force and effect, unless otherwise agreed between the Purchaser and the Seller.

3.2. Deliveries and Transactions at the Initial Closing. At the Initial Closing, the following transactions shall occur, which transactions shall be deemed to take place simultaneously and no transaction shall be deemed to have been completed or any document delivered until all such transactions have been completed and all required documents delivered:

3.2.1. The Seller shall deliver to the Purchaser the following documents or cause the following actions to be completed:

(i) Board Resolutions. Duly executed resolution of the board of directors of Seller, substantially in the form attached as Schedule 3.2.1(i) hereto;

(ii) Shareholders Resolutions. Duly executed resolutions of the shareholders of the Seller, substantially in the form attached as Schedule 3.2.1(ii) hereto, pursuant to which the Seller's shareholder shall have approved all transactions contemplated hereby and taken all corporate actions related to such transactions;

(iii) Shares Escrow. Duly executed Escrow Agreement;

(iv) "Market Stand-off" Undertaking. Duly executed "Market Standoff" Undertaking, attached hereto as Exhibit A, or any other lock-up agreement/undertaking requested by underwriters in its stead; and

(v) Proprietary Information Assignment. Seller shall deliver to Purchaser dully executed assignment and transfer deeds, as the case may be, necessary to effect the transfer of the Proprietary Information to the Purchaser, substantially in the form attached as Schedule 3.2.1(iv) hereto ("Deeds"),

3.2.2. The Purchaser shall deliver to the Seller the following documents or cause the following actions to be completed:

(i) Board Resolutions. Duly executed resolutions of the board of directors of the Purchaser, substantially in the form attached as Schedule 3.2.2(i) hereto;

(ii) Share Certificates. Validly executed share certificates, dated as of the Initial Closing date, covering the Initial Closing Shares issued to Seller as of the Initial Closing; and

(iii) Shareholder Register. A copy, duly certified by an officer of the Purchaser dated as of the Initial Closing date, of the Purchaser's shareholders register, reflecting the registration by the Purchaser of the issue of the Initial Closing Shares to the Seller.

3.3. Conditions of the Purchaser to Initial Closing. The obligations of the Purchaser to purchase the Proprietary Information and to issue the Initial Closing Shares, are subject to the fulfillment at or before such Initial Closing of the following conditions precedent (to the extent indicated below), any one or more of which may be waived in whole or in part by the Purchaser:

3.3.1. Representations and Warranties. The representations and warranties made by the Seller in this Agreement shall have been true and correct as if made on the Initial Closing date.

3.3.2. Consents, etc. The Seller shall have secured all permits, consents and authorizations that shall be necessary or required lawfully to consummate this Agreement and to transfer the Proprietary Information to the Purchaser at the Initial Closing.

3.3.3. Escrow Agreement. The Seller shall have delivered to the Purchaser a duly executed copies of the Escrow agreement.

3.3.4. "Market Stand-off" Undertaking. The Seller shall have delivered to the Purchaser a duly executed copy of the "Market Stand-off" Undertaking, Exhibit A.

3.3.5. Deeds. The Seller shall have delivered to the Purchaser dully executed Deeds.

3.4. Milestone Closing: Transactions at Milestone Closings.

3.4.1. The closings of the transactions contemplated in Section 2.3 above will take place at closings to be held remotely via the exchange of documents and signatures within thirty (30) business days following the occurrence of any of the Milestone Closings.

3.4.2. At each Milestone Closing, the following transactions shall occur, which transactions shall be deemed to take place simultaneously and no transaction shall be deemed to have been completed or any document delivered until all such transactions have been completed and all required documents delivered:

3.4.2.1. Validly executed share certificates dated as of the respective Milestone Closing date covering the respective Milestone Closing Shares; and

3.4.2.2. A copy, duly certified by an officer of the Purchaser dated as of the Milestone Closing date, of the Purchaser's shareholders register, reflecting the registration by the Purchaser of the issue of the respective Milestone Closing Shares.

3.4.2.3. Seller, or the liquidator of the Seller, shall advise Purchaser in writing to whom to distribute the Milestone Shares.

3 .4.2.4. All Milestone Shares issued shall, to the extent upon their issuance Purchaser is listed on a stock exchange and subject to underwriters' standard lock-up requirement, be automatically registered by the Purchaser.

4. Representations and Warranties of Seller. The Seller hereby represents and warrants to the Purchaser that, except as set forth on the Schedule of Exceptions attached as Schedule 4 to this Agreement, which exceptions shall be deemed to be part of the representations and warranties made hereunder, the following representations are true and complete on the date hereof and as of the date of the Initial Closing, except as otherwise specifically indicated. The Schedule of Exceptions shall be arranged in sections corresponding to the numbered and lettered sections and subsections contained in this Section 4, and the disclosures in any section or subsection of the Schedule of Exceptions shall not qualify other sections and subsections in this Section 4.

4.1. Requisite Power and Authority. The Seller has all requisite corporate power and authority to execute and deliver this Agreement, to consummate the transactions and perform its obligations contemplated hereby and thereby, and to carry out the provisions of this Agreement. Upon its execution and delivery, this Agreement to which it is a party will be valid and binding obligations of the Seller, enforceable in accordance with their respective terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights and (b) as limited by general principles of equity that restrict the availability of equitable remedies.

4.2. Authorization; Binding Obligations. All corporate action on the part of each of Seller, its officers, directors and shareholders necessary for the authorization of the transfer of the Proprietary Information and the performance of all obligations of Seller hereunder and thereunder at the Initial Closing has been taken. This Agreement has been duly executed and delivered by Seller and constitute valid and binding obligations of Seller enforceable in accordance with their respective terms.

4.3. Consents. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any governmental authority is required on the part of Seller in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement.

4.4. No Conflicts. The execution and delivery of this Agreement, and the consummation by Seller of the transactions contemplated hereby and thereby do not, and will not result in a violation of any Laws or Authorizations to which Seller is subject.

4.5. Proprietary Information. Seller is the sole owner, or is exclusively licensed to use, free and clear of any Liens or Third Party Rights, all Proprietary Information used in or necessary for the conduct of its business as so far conducted. There are no claims or demands pending by any other person pertaining to any of such Proprietary Information nor is there a claim or demand threatened, and no proceedings have been instituted or threatened which challenge the rights of Seller with respect to such Proprietary Information and Seller there is no basis for such claim.

4.6. Intellectual Property.

4.6.1. Schedule 4.6.1(i) lists all Intellectual Property currently owned or licensed to use by Seller. With respect to Intellectual Property that is owned by Seller, all such Intellectual Property is owned free and clear of Liens or Third Party Rights. Seller does not own any patents, patent applications, trademarks, trademark applications, trademark registrations, service marks, service work applications, service mark registrations, or registered copyrights related to the Intellectual Property not included in this Agreement. Seller does not owe by way of royalties, fees or otherwise to any owner or licensor of, or other claimant to, any item of Intellectual Property.

4.6.2. Other than for “off the shelf” products used by Seller in its day to day operations, there are no licenses or other agreements or shared ownership interests of any kind, under which Seller is or may be, granted rights in Intellectual Property of any third person.

4.6.3. There are no licenses or other agreements or shared ownership interests of any kind, under which Seller has granted rights to others in its Intellectual Property.

4.6.4. Seller has taken all commercially reasonable measures required to establish and preserve ownership of all Intellectual Property developed by, or on behalf of, Seller, including the maintenance and renewal of all registered Intellectual Property. Seller has required all current and former employees and inventors and all consultants and independent contractors having, or who have had, access to, or who were involved in the development of, any of the Intellectual Property owned, licensed to, or developed by Seller, to execute enforceable agreements that provide valid written assignment of all right, title and interest in and to inventions and other Intellectual Property resulting from their employment or services, and all such persons are in compliance with such agreements. Any and all Intellectual Property of any kind which has been developed or is currently being developed by any employee or service provider of Seller in the course of their employment or engagement by Seller shall be the sole and exclusive property of Seller. No third party has infringed, misappropriated, or otherwise violated or conflicted with any of Seller’s Intellectual Property. Seller does not use any inventions of any of its employees or consultants (or persons it intends to hire) made prior to their engagement by Seller. All current and former employees and all consultants and independent contractors hired by Seiler have agreed to maintain the confidentiality of all confidential and proprietary information of Seller and of any information of third parties received by Seller under an obligation of confidentiality.

4.6.5. The conduct of the business of Seller, as conducted so far, including Seller’ products or services developed, produced or supplied by Seller and its Intellectual Property does not infringe misappropriate, or otherwise violate or conflict with any of the Intellectual Property of any third party. No proceeding charging Seller with infringement of any Intellectual Property of any third person has been filed or is threatened to be filed.

4.6.6. Seller is not making unauthorized use of any confidential information or trade secrets or other Intellectual Property of any person, including without limitation any former employer of any past or present employee or consultant of Seller. Neither Seller nor any employee or consultant of Seller is obligated under any duty or agreement (including any license, confidentiality agreement, covenant or commitment of any nature), or subject to any judgment, decree or order of any court or authorized administrative agency, that would interfere in any manner with the use of their best efforts to promote the interests of Seller or that would conflict with Seller' business as conducted so far. Each former and current employee, officer, consultant and independent contractor of Seller has executed a proprietary information and assignment of inventions undertaking towards Seller, pertaining to all right, title and interest in and to all Intellectual Property resulting from his/her/its employment with or services to Seller. No employee, officer, consultant or independent contractor is in violation of any proprietary information or assignment of inventions agreement, or in any such similar agreement, with any former employer or contractor, and the conduct of Seller' business as conducted so far will not conflict with or result in a breach of the terms, conditions or provisions of, or constitute a default under, such agreements.

4.6.7. The Intellectual Property (i) is and at all times has been in material compliance with the Laws; (ii) is in compliance in all material respects with all the Authorizations, and Seller has not received any notice (a) of adverse finding, untitled letter or other correspondence or notice from any governmental authority alleging or asserting noncompliance with any Laws or Authorizations with respect to the Intellectual Property, including any warning letter from a Regulatory Agency containing any unresolved issues concerning noncompliance with any Laws or Authorizations, (b) of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that the Intellectual Property is in violation of any Laws or Authorizations, and no such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; and (c) that any governmental authority has taken, is taking, or intends to take action to limit, suspend, modify or revoke any Authorizations with respect to the Intellectual Property and it has no knowledge that such governmental authority is considering such action.

4.7. Clinical Studies. All Clinical Studies were and, if still pending, are in all material respects, being conducted in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all Laws and Authorizations. Schedule 4.7 sets forth a detailed description of the Clinical Studies conducted by Seller prior to the execution hereof. The descriptions of the results of such studies, tests and trials contained in Schedule 4.7 are accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; Seller is not aware of any studies, tests or trials the results of which call into question the Clinical Studies set forth in Schedule 4.7 when viewed in the context in which such results are described and the clinical state of development; and Seller has not received any notices or correspondence from any Regulatory Agency or any other governmental authority requiring the termination, suspension or material modification of any Clinical Studies conducted by or on behalf of Seller.

4.8. Disclosure. The representations and warranties made or contained in this Agreement, the schedules and exhibits hereto, and the certificates and statements executed or delivered in connection herewith, when taken together, do not contain any untrue statement of a material fact and do not omit to state a material fact required to be stated therein or necessary in order to make such representations, warranties, or other material not misleading in light of

the circumstances in which they were made or delivered. There is no material fact or information individually or in the aggregate relating to the Proprietary Information, existing as of the date hereof, that has not been expressly disclosed to Purchaser by Seller and which: (i) is reasonably necessary to enable Purchaser to decide to enter into the transactions contemplated in this Agreement; or (ii) have or could reasonably be expected to have a material adverse effect on the Proprietary Information. The Purchaser have the right to rely fully upon the representations, warranties, covenants and agreements of Seller contained in this Agreement (including, inter alia, any Schedule or Exhibit hereto) or in any certificate made or delivered in connection herewith.

5. Representations and Warranties of the Purchaser. The Purchaser hereby represents and warrants to the Purchaser that as of the Initial Closing date:

5.1. Requisite Power and Authority. The Purchaser has all requisite corporate power and authority to execute and deliver this Agreement, to consummate the transactions and perform its obligations contemplated hereby and thereby, and to carry out the provisions of this Agreement. Upon its execution and delivery, this Agreement to which it is a party will be valid and binding obligations of the Purchaser, enforceable in accordance with their respective terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights and (b) as limited by general principles of equity that restrict the availability of equitable remedies.

5.2. Authorization: Binding Obligations. All corporate action on the part of each of Purchaser, its officers, directors and shareholders necessary for the performance of all obligations of Purchaser hereunder and thereunder at the Initial Closing has been taken. This Agreement has been duly executed and delivered by Purchaser and constitute valid and binding obligations of Purchaser enforceable in accordance with their respective terms.

5.3. Consents. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any governmental authority is required on the part of Purchaser in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement.

5.4. Transaction Shares. At the Initial Closing the Transaction Shares shall be duly issued and the Purchaser shall have the right and capacity to tissue and deliver them, free and clear of any Lien or Third Party Rights.

5.5. Seller Representations. Without derogating from any representations, warranties or covenants of the Seller hereinabove, Purchaser, in making its decision to purchase the Proprietary Information, has neither conducted independent due diligence inquiries nor ask questions of, and receive answers from, Seller and its representatives concerning the Proprietary Information sufficient to enable it to evaluate the transaction contemplated under the Agreement, and that it is relying solely upon any examination or inquiry performed by the Seller. Nothing set forth in this Section 5 shall be deemed to detract from or otherwise prejudice Purchaser's reliance on the Seller' representations and warranties set forth in this Agreement. Further, neither any inquiries nor any other investigation conducted by or on behalf of Purchaser or its representatives or counsel, if any, shall modify, amend or affect Purchaser's right to rely on the truth, accuracy and completeness of the Seller' representations and warranties contained in this Agreement.

6. Liability and Escrow

6.1. The representations, warranties, covenants and agreements made in this Agreement, or any other agreement, certificate, document or instrument furnished pursuant hereto shall survive any investigation made by Purchaser and shall be true and accurate as of the Initial Closing.

6.2. Seller shall reimburse Purchaser for any and all damages, liabilities, losses, costs and expenses (including attorneys' fees and expenses), whether or not arising out of third-party claims, based upon, or arising out of, or relating to the Intellectual Property.

6.3. Seller's liability under this Agreement, or any other agreement, certificate, document or instrument furnished pursuant hereto shall be limited to claims raised by Purchaser within the earlier of (a) 12 (twelve) months as of Initial Closing Date and (b) the consummation of the IPO. Any claim not raised within such date shall be time barred and there shall be no liability of Sellers under any title thereafter.

6.4. Seller's liability under this Agreement, or any other agreement, certificate, document or instrument furnished pursuant hereto shall be payable in Escrow Shares only, and shall be limited to an aggregate amount of the Escrow Shares.

6.5. To fully secure Seller's undertaking under Section 6.2 above, Seller undertakes that the Escrow Shares shall be subject to the terms and provisions of the Escrow Agreement. The Escrow Shares shall be automatically released to Seller on the earlier of (a) 12 (twelve) months after the Initial Closing Date, and (b) the consummation of the IPO, unless Purchaser has validly raised a claim before.

7. Confidentiality. Seller and any person acting on its behalf shall, and shall procure that Seller shall, keep the existence of this Agreement and its terms, as well as the representation and warranties included herein in strict confidence, and shall not disclose or issue any public statement or press release concerning this transaction without the prior written approval of Purchaser of the substance and form of any such statement or release, except as, and only to the extent required, (a) to exercise any of its rights or fulfill any of its obligations under the Agreement, (b) to their attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with making or monitoring the contemplated transaction herein, provided such professionals are obligated to the Seller to keep any such information confidential pursuant to a written agreement or by nature, or (c) as may be required under applicable law.

8. Miscellaneous

8.1. Governing Law. This Agreement shall be governed, construed and interpreted in accordance with the laws of the State of Israel, without giving effect to principles of conflicts of law or choice of law that would cause the substantive laws of any other jurisdiction to apply.

8.2. Arbitration. Any dispute, controversy or claim arising in relation to this Agreement, including with regard to its validity, invalidity, breach, enforcement or termination, will be referred to a single arbitrator, who shall be appointed by the Parties and if they are unable to agree on the identity of an arbitrator within 30 (thirty) days of the first written request of a party, the arbitrator shall be appointed by the Head of the Israeli Bar Association. Arbitration proceedings shall take place in Tel Aviv, Israel and shall be conducted according

to the substantive law. The arbitrator will not be bound by rules of evidence or procedure and will give the reasons for his judgment. The arbitrator's decision shall be final and enforceable in any court. This paragraph shall constitute an arbitration agreement between the parties.

8.3. Amendment and Waiver. Any provision of this Agreement may be amended and the observance thereof may be waived (either generally or in a particular instance and either retroactively or prospectively), only by the written consent of Purchaser and the Seller. Any amendment or waiver effected in accordance with this Section 8.3 shall be binding upon Purchaser and the Seller, and their respective successors and assigns.

8.4. Entire Agreement. This Agreement, the exhibits and schedules hereto, the certificates and the other documents delivered pursuant hereto constitute the entire agreement among the parties relative to the specific subject matter hereof and thereof.

8.5. Notices. All notices required or permitted hereunder shall be in writing and shall be deemed effectively given: (i) upon personal delivery to the party to be notified; (ii) when sent by facsimile with confirmation of transmission if sent during normal business hours of the recipient, if not, then on the next business day; or (iii) 5 (five) days after having been sent by registered or certified mail, return receipt requested, postage prepaid. All communications shall be sent to Purchaser and Seller at the respective address or facsimile number set forth below or at such other address as Purchaser, or the Seller, may designate by 10 (ten) days' advance written notice to the other Party.

If to Purchaser:
Address: TheraCoat Ltd.
9 Ha' Taasiya St.
P.O. Box 2397
Ra'anana 4365007
Israel
Attn: Ron Bentsur, CEO
Fax: +972-77-4171410
E-mail: ron.bentsur@theracoat.com

with a copy to: Yaron Sobol, Adv.
Hamburger Evron & Co.
The Museum Tower
4 Berkowitz St.
Tel Aviv 6423806
Israel
Fax: +972-3-6074004
Email: yaron.sobol@evronlaw.com

If to Seller:
Address: Telormedix SA
Via della Posta 10
H-6934 Bioggio
Switzerland
Attn: Jean-Philippe Tripet
Fax: +41-91-610-7031
E-mail: jean-philippe@aravis.ch

with a copy to: Marco A. Rizzi, Attorney at Law
FRORIEP
Bellerivestrasse 201
P.O. Box 385
8034 Zurich
Switzerland
Fax: +41-44-3836050
E-mail: mrizzi@froriep.ch

8.6. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable under applicable law, then such provision shall be excluded from this Agreement and the remainder of this Agreement shall be interpreted as if such provision was so excluded and shall be enforceable in accordance with its terms; provided, however, that in such event this Agreement shall be interpreted so as to give effect, to the greatest extent consistent with and permitted by applicable law, to the meaning and intention of the excluded provision as determined by such court of competent jurisdiction.

8.7. Expenses. Each party shall pay all costs and expenses that it incurs with respect to the negotiation, due diligence investigation, execution, delivery and performance of the Agreement.

8.8. Broker's Fees. Each party represents and warrants that no agent, broker, investment banker, person or firm acting on behalf of or under the authority of such party is or will be entitled to any broker's or finder's fee or any other commission directly or indirectly in connection with the transactions contemplated herein.

8.9. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each counterpart signed by a Party and delivered by or PDF (Portable Document Format) transmission via electronic mail or facsimile transmission shall have the same force and effect as the delivery of original signatures shall be binding as evidence of such Party's agreement hereto and acceptance hereof, and signatures obtained in this manner shall be considered original.

8.10. Successors and Assigns. Except as otherwise limited herein, this Agreement and the provisions hereof shall be binding upon and inure to the benefit of and be enforceable by the parties and their respective successors and assigns. None of the rights, privileges, or obligations set forth in, arising under, or created by this Agreement may be assigned or transferred without the prior consent in writing of Purchaser and the Seller, except that Purchaser may freely assign this Agreement to a successor in interest.

8.11. Titles and Subtitles. The titles of the sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement.

[Remainder of Page Intentionally Left Blank]

Asset Purchase Agreement - Signature Page

IN WITNESS WHEREOF, the parties hereto have executed this Share Purchase Agreement as of the date set forth in the first paragraph hereof.

PURCHASER	SELLER
TheraCoat Ltd.	Telormedix SA
By: /s/ Ron Bentsur	By: /s/ Jean-Philippe Tripet
Title: CEO	Title: Director
By:	By:
Title:	Title:

Exhibit A

"Market Stand-off" Undertaking

Telormedix SA ("TMX") hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to an underwritten public offering ("IPO") of the securities of TheraCoat Ltd. ("Company") and ending on the date specified by the Company and the managing underwriter (such period not to exceed 180 days, which period may be extended upon the request of the managing underwriter, to the extent required by any NASD or FINRA rules, for an additional period of up to 20 days if the Company issues or proposes to issue an earnings or other public release within 20 days of the expiration of the 180-day lockup period), (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Ordinary Shares held immediately prior to the effectiveness of the registration statement for the IPO, or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) of this undertaking is to be settled by delivery of Ordinary Shares or other securities, in cash, or otherwise. The foregoing provisions of this undertaking shall apply only to the IPO, shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, and shall only be applicable to TMX if all officers, directors and holders of more than one percent of the outstanding Ordinary Shares are subject to similar agreements. The underwriters in connection with the IPO are intended third-party beneficiaries of this undertaking and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. TMX further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with the IPO that are consistent with this undertaking or that are necessary to give further effect thereto.

To the extent TMX shall assign and transfer its securities to its shareholders, such transfer shall be contingent upon each such assignee and transferee execution of similar undertaking.

IN WITNESS WHEREOF, the parties hereto have executed this Share Purchase Agreement as of the date set forth in the first paragraph hereof.

Telormedix SA

By: /s/ Jean-Philippe Tripet

Title: Director

By: _____

Title: _____

Exhibit 21.1

UroGen Pharma Ltd.
Subsidiary of the Registrant
(as of December 31, 2015)

Urogen Pharma, Inc., a Delaware corporation.

Exhibit 99.1

April 14, 2016

CONSENT OF DR. J. GREGORY WIRTH

United States Securities and Exchange Commission

In connection with UroGen Pharma Ltd.'s (the "Company") Registration Statement on Form F-1 (the "Registration Statement"), I, Dr. J. Gregory Wirth, hereby consent to the inclusion in the Company's Registration Statement of the following:

1. Images showing pre-treatment and post-MitoGel treatment results from one low-grade UTUC patient in the Compassionate Use program.

Yours truly,

/s/ Dr. J. Gregory Wirth

Dr. J. Gregory Wirth