# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## AMENDMENT NO. 3
to

FORM S-1

REGISTRATION STATEMENT
UNDER

THE SECURITIES ACT OF 1933

Urovant Sciences Ltd.
(Exact name of registrant as specified in its charter)

<table>
<thead>
<tr>
<th>Bermuda</th>
<th>2834</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>(State or other jurisdiction of incorporation or organization)</td>
<td>(Primary Standard Industrial Classification Code Number)</td>
<td>(I.R.S. Employer Identification Number)</td>
</tr>
<tr>
<td>Suite 1, 3rd Floor</td>
<td>11-12 St. James’s Square</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>11-12 St. James’s Square</td>
<td>London SW1Y 4LB</td>
<td>+44 203 318 9709</td>
</tr>
<tr>
<td>(Address, including zip code, and telephone number, including area code, of registrant’s principal executive offices)</td>
<td></td>
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</tbody>
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Corporation Service Company
2711 Centerville Road
Wilmington, DE 19808
(866) 846-8765

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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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 number of the earlier effective registration statement for the same offering. ☐

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

Large accelerated filer ☐
Accelerated filer ☐
Non-accelerated filer ☑ (Do not check if a smaller reporting company)
Smaller reporting company ☐
Emerging growth company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☑

## CALCULATION OF REGISTRATION FEE

<table>
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<th>Proposed maximum aggregate offering price(1)(2)</th>
<th>Amount of registration fee(2)(3)</th>
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<tr>
<td>Common shares, $0.00001 par value per common share</td>
<td>$150,000,000</td>
<td>$18,675</td>
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</tbody>
</table>

(1) Includes common shares that the underwriters have the option to purchase.

(2) Estimated solely for purposes of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act.

(3) The registrant previously paid $18,675 in connection with the original filing of this Registration Statement on July 13, 2018.
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 that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(e), may determine.
Subject to completion, dated August 30, 2018

Prospectus

Common shares
This is the initial public offering of our common shares. We are selling common shares. We currently expect the initial public offering price to be between $ and $ per common share.

Prior to this offering, there has been no market for our common shares. We have applied to list our common shares on The Nasdaq Global Market under the symbol “UROV.”

Upon the closing of this offering, we expect to be a “controlled company” within the meaning of applicable listing rules of The Nasdaq Global Market. In addition, Roivant Sciences Ltd., our controlling shareholder, will have the right to appoint two directors to our board of directors, each of whom will have three votes on all matters presented to the board of directors. Upon the closing of this offering, such directors will hold a majority of the voting power on all matters presented to the board of directors. See “Description of share capital—Election and removal of directors.”

We are an “emerging growth company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

<table>
<thead>
<tr>
<th>Per share</th>
<th>Total</th>
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<tbody>
<tr>
<td>Initial public offering price</td>
<td>$</td>
</tr>
<tr>
<td>Underwriting discounts and commissions(1)</td>
<td>$</td>
</tr>
<tr>
<td>Proceeds to Urovant Sciences Ltd., before expenses</td>
<td>$</td>
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</tbody>
</table>

(1) See “Underwriting” for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to additional common shares.

Investing in our common shares involves risks. See “Risk factors” beginning on page 15.

Consent under the Exchange Control Act 1972 (and its related regulations) has been obtained from the Bermuda Monetary Authority for the issue and transfer of our common shares to and between residents and non-residents of Bermuda for exchange control purposes provided our common shares remain listed on an appointed stock exchange, which includes The Nasdaq Global Market. In granting such consent the Bermuda Monetary Authority does not accept any responsibility for our financial soundness or the correctness of any of the statements made or opinions expressed in 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.

The underwriters expect to deliver the common shares to purchasers on or about , 2018.

J.P. Morgan

Jefferies

Cowen

Prospectus dated , 2018
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We are responsible for the information contained in this prospectus and in any free writing prospectus we prepare or authorize. We have not, and the underwriters have not, authorized anyone to provide you with different information, and we and the underwriters take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the cover of this prospectus.

Persons who come into possession of this prospectus and any applicable free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.
Prospectus Summary

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common shares, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth in the sections titled “Risk factors” and “Management’s discussion and analysis of financial condition and results of operations.” Unless the context otherwise requires, we use the terms “company,” “we,” “us” and “our” in this prospectus to refer to Urovant Sciences Ltd. and our wholly owned subsidiaries. Our fiscal year ends on March 31.

Company overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Our lead product candidate, vibegron, is an oral, once-daily, small molecule beta-3 agonist. We are currently evaluating vibegron in our 1,400 patient, international pivotal Phase 3 EMPOWUR trial for the treatment of overactive bladder, or OAB. We expect to report top-line results from this clinical trial in the first or second quarter of 2019, and if these results are positive, we plan to submit a new drug application to the U.S. Food and Drug Administration, or FDA, by early 2020. OAB is a highly prevalent condition, with more than 30 million Americans over the age of 40 suffering from bothersome symptoms. In large, randomized, placebo-controlled, international Phase 2b and Japanese Phase 3 clinical trials in a total of over 2,600 OAB patients, vibegron 50 mg and 100 mg met all primary and secondary efficacy endpoints compared to placebo at week 8 and week 12, respectively. Our ongoing Phase 3 EMPOWUR trial has a design similar to these clinical trials. We believe vibegron, if successful in meeting the efficacy endpoints in our pivotal Phase 3 EMPOWUR trial, and if approved by the FDA, may offer a differentiated profile compared to current OAB therapies, including the potential for broader efficacy claims if the FDA approves the inclusion of urgency data, rapid onset of action data, and a single convenient once-daily dose in the label. Vibegron has been well tolerated in all clinical trials to date, has not been associated with clinically relevant drug-drug interactions, such as the inhibition of CYP2D6, and has not demonstrated a QTc signal at any of the human doses tested. In addition to OAB, we are developing vibegron for two additional potential indications, the treatment of OAB in men with benign prostatic hyperplasia, or BPH, and the treatment of pain associated with irritable bowel syndrome, or IBS. By the end of 2018, we expect to commence a Phase 3 clinical trial for OAB in men with BPH and a Phase 2a clinical trial for IBS-associated pain. Our second product candidate, hMaxi-K, is a novel gene therapy that we are developing for patients with OAB who have failed oral pharmacological therapy. There are no currently available FDA-approved gene therapy treatments for OAB. Subject to feedback from the FDA, we intend to initiate a proof-of-concept Phase 2a clinical trial in 2019 to evaluate the safety and efficacy of hMaxi-K. We intend to continue to expand our pipeline with the goal of creating a leading urology company by developing, commercializing and acquiring innovative therapies.
Our development programs and upcoming milestones are summarized in the following figure:

<table>
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<tr>
<th>Drug Candidate</th>
<th>Indication</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Upcoming Milestone</th>
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<tr>
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<td>OAB</td>
<td></td>
<td></td>
<td></td>
<td>Phase 2a Initiation 2019³</td>
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</tbody>
</table>

1. Subject to feedback from the FDA.
2. Pending submission of an investigational new drug application to the FDA in this indication.

We received an exclusive license to develop, manufacture and commercialize vibegron worldwide, excluding Japan and certain other Asian territories, pursuant to our license agreement with Merck Sharp & Dohme Corp., or Merck, which we entered into in February 2017. Vibegron is also being developed by Kyorin Pharmaceutical Co., Ltd., or Kyorin, for the treatment of OAB in Japan and certain other Asian territories. We received an exclusive license to develop, manufacture and commercialize hMaxi-K worldwide, pursuant to our license agreement with Ion Channel Innovations, LLC, or ICI, which we entered into in August 2018.

Our experienced management team is led by our Chief Executive Officer, Keith A. Katkin, who previously served as President and Chief Executive Officer of Avanir Pharmaceuticals, Inc. through its acquisition by Otsuka Pharmaceutical Co., Ltd. in 2015. Together, the members of our management team have helped launch over 20 prescription drugs.

**Vibegron for the treatment of overactive bladder**

**Overactive bladder overview**

OAB is a clinical condition characterized by the sudden urge to urinate that is difficult to control, referred to as urgency, with or without accidental urinary leakage, and usually with increased frequency of urination. Accidental urinary leakage resulting from urgency is referred to as urge urinary incontinence, or UUI. Symptoms of OAB can have a debilitating impact on psychosocial functioning and quality of life, profoundly impacting normal social and occupational activities and leading to depression, anxiety and decreased sexual function and marital satisfaction. More than 30 million Americans over the age of 40 suffer from bothersome symptoms of OAB. Approximately 46% of this population, or 14 million people, talk to their physicians about their symptoms. In 2017, over 19 million prescriptions for oral OAB medications were written for an estimated 3.3 million patients in the United States.

Behavioral therapies such as bladder training, pelvic floor muscle training and fluid management are recommended as first-line treatment for OAB. Second-line treatment consists of prescription pharmacological...
therapy with an anticholinergic drug or a beta-3 agonist. Third-line treatment includes procedural therapy using either intradetrusor onabotulinumtoxinA (BOTOX) or neuromodulation.

Anticholinergic drugs have been the standard of pharmacologic care for OAB for decades; however, these drugs are associated with poor tolerability and increasing safety concerns. While approximately 86% of OAB patients treated with oral prescription therapy in the United States are initially prescribed anticholinergic drugs, 71% of those patients fail treatment within six months. Anticholinergic side effects include dry mouth, constipation and blurred vision. Further, there is a growing body of evidence associating anticholinergic use with cognitive impairment and dementia. Anticholinergics have also been associated with increased use of healthcare resources.

**Beta-3 agonists**

Beta-3 adrenergic receptor agonists, or beta-3 agonists, constitute the newest class of oral prescription therapy for OAB. The beta-3 adrenergic receptor is the most prevalent beta-adrenergic receptor subtype on the smooth muscle around the bladder. Bladder filling involves the relaxation of this muscle and the contraction of the urethral smooth muscle, while voiding involves contracting the bladder muscle and relaxation of the urethral muscle. Beta-3 stimulation has been shown to relax the smooth muscle around the bladder, which increases bladder capacity and reduces the symptoms of OAB. In 2012, mirabegron (Myrbetriq), a beta-3 agonist, became the first drug other than an anticholinergic approved by the FDA for the treatment of OAB. Mirabegron remains the sole beta-3 agonist on the market for OAB, and since its approval, has continued to take U.S. OAB prescription share from anticholinergics, primarily due to its safety and tolerability advantages. In the first three months of 2018, mirabegron’s share of the oral OAB prescription market in the United States grew 20% from the comparable period in 2017, from 13.7% to 16.5%.

Despite its success, mirabegron requires dose titration that results in a slow onset of action and is associated with frequent drug-drug interactions and QTc prolongation. Mirabegron’s onset of action is eight weeks at the starting dose. Further, mirabegron’s U.S. label has a note in the warnings and precautions section about drug-drug interaction risk related to its known inhibition of the CYP2D6 enzyme, an important enzyme involved in the metabolism of numerous drugs. Approximately 37% of patients taking mirabegron are taking other drugs that are metabolized via the CYP2D6 pathway, presenting an increased risk of exacerbated adverse events. In addition, in a thorough QTc study, mirabegron demonstrated QTc prolongation in women at a dose greater than the maximum approved dose, or a supratherapeutic dose, which is noted in the pharmacodynamic section of its U.S. label. QTc prolongation refers to the lengthening of the QT interval in an electrocardiogram, during which interval, the heart recovers from one heartbeat and is preparing for the next heartbeat. The QT interval is a very vulnerable phase in the electric cycle of the heart, and prolongation of this interval may lead to serious and potentially life-threatening tachyarrythmias, or very fast and irregular heartbeats that are not sufficient to support the function of the heart.

**Our solution**

Vibegron is an oral, once-daily, small molecule that was observed to be highly selective for the human beta-3 adrenergic receptor in in vitro assays. We are developing vibegron for the treatment of OAB. In large, randomized, placebo-controlled international Phase 2b and Japanese Phase 3 clinical trials, vibegron 50 mg and 100 mg met all primary and secondary efficacy endpoints compared to placebo at week 8 and week 12, respectively. These endpoints included reductions per day in number of urinations, or micturitions, urgency episodes, UUI episodes and total incontinence episodes.
We believe vibegron, if successful in meeting the efficacy endpoints in our pivotal Phase 3 EMPOWUR trial, and if approved by the FDA, has the potential to address the limitations of both anticholinergics and mirabegron and become a differentiated beta-3 agonist based on the following potential advantages:

- Met primary and secondary efficacy endpoints and was well tolerated in large, randomized, placebo-controlled international Phase 2b and Japanese Phase 3 clinical trials
- Observed to be highly selective for the human beta-3 adrenergic receptor in \textit{in vitro} assays
- No known dementia risk
- Potential for broader efficacy claims, including urgency data, if successful in meeting the efficacy endpoints in our pivotal Phase 3 EMPOWUR trial
- Rapid onset of action
- Single, convenient dose
- No CYP2D6 drug-drug-interactions
- No QTc signal
- Crushable dose formulation

Based on a third-party market research study we commissioned, which surveyed 120 OAB patients and 150 physicians, including urologists, primary care physicians and OB/GYNs, we believe each of the above factors could represent a meaningful advantage over mirabegron. Specifically, both patients and prescribers identified the potential for no CYP2D6 drug-drug interactions and no QTc signal, as well as the potential for rapid onset of action and single-crushable dose formulation, as highly motivating differentiators. Furthermore, based on vibegron’s potential product profile, approximately 50% of surveyed physicians indicated that they would be attracted to, or willing to use, vibegron if approved with such a profile. Among OAB patients currently taking an anticholinergic, approximately 62% indicated that they would be attracted to, or willing to ask their physician to replace their current treatment with, vibegron based on its potential product profile. We believe there is a significant opportunity for a new OAB treatment as approximately 86% of OAB patients treated with oral prescription therapy in the United States are initially prescribed anticholinergic drugs.

\textbf{Potential vibegron coverage and reimbursement in the United States}

Access to oral OAB therapy is managed primarily by differential co-payments, or co-pays. Payors generally charge the lowest co-pays for generic drugs and higher co-pays for branded agents such as Vesicare or Myrbetriq. In 2017, 92% of commercial plans and 93% of Medicare plans covered Myrbetriq, the only currently marketed beta-3 agonist. According to IMS PayerTrak, in 2017, the U.S payor mix for the oral OAB prescription market was approximately 52% Medicare D, 37% commercial or cash and 10% other payors.

In May 2018, we commissioned a third-party market research study to assess how vibegron would be covered, if approved. The research firm interviewed representatives of payors, who are involved with, but not solely responsible for, access and reimbursement decisions. Such interviewees represented payors covering over 80 million U.S. commercial and Medicare Part D lives.

Based on this study and our analysis of the current coverage of OAB therapies, we believe the OAB pharmacologic category is not highly managed by payors. The payor representatives interviewed expect that vibegron would be managed at a preferred or non-preferred branded tier, without prior authorization, allowing physicians and patients to make the choice of whether to pay a higher co-pay for a branded product or a lower
co-pay for a generic. In addition, these payor representatives anticipate that vibegron’s coverage would not change following Myrbetriq’s loss of marketing exclusivity, which we expect to occur in 2023 or 2024. Based on this study, we also believe that access to vibegron, if approved, will not be restricted to patients who first fail any other oral therapies for OAB.

In June 2018, we commissioned a second market research study, conducted by a separate third-party market research firm, to further assess how vibegron would be covered, if approved. The research firm interviewed representatives of payors who are involved with, but not solely responsible for, access and reimbursement decisions. Such interviewees represented payors covering over 160 million U.S. commercial and Medicare Part D lives.

The results of this additional study reinforced the results of the May 2018 study with regard to vibegron’s potential coverage. In addition, the payors interviewed indicated that they believe the OAB pharmacologic category is not highly managed and is instead primarily controlled through differential co-pays for branded OAB drugs as compared to generic OAB drugs. They expect the OAB pharmacologic category will continue to be managed this way.

**Our ongoing Phase 3 program**

In March 2018, we enrolled the first patients in our international pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. Our Phase 3 EMPOWUR trial is a randomized, double-blind, placebo- and active comparator-controlled trial in men and women with OAB wet, meaning symptoms include at least one UUI episode per day, or OAB dry. The trial is expected to enroll approximately 1,400 patients and has a design similar to the completed Phase 2b and Japanese Phase 3 clinical trials. We expect to report top-line results from our Phase 3 EMPOWUR trial in the first or second quarter of 2019 and, if the results are positive, we plan to submit a new drug application, or NDA, to the FDA by early 2020.

**Clinical data for vibegron for the treatment of overactive bladder**

**Merck Phase 2b clinical trial**

In 2013, Merck completed a large, international, randomized, double-blind, placebo-controlled Phase 2b dose-ranging clinical trial conducted to evaluate the efficacy, safety and tolerability of once-daily vibegron in 1,395 patients with OAB, administered alone and concomitantly with extended release tolterodine, a commonly prescribed anticholinergic for OAB. In this trial, the 50 mg and 100 mg doses of vibegron demonstrated improvements compared to placebo on all primary and secondary efficacy endpoints at week 8, including reductions per day in number of micturitions, urgency episodes, UUI episodes and total incontinence episodes. Vibegron was observed to be well tolerated in this trial.

**Kyorin Phase 3 program in Japan**

In 2016, Kyorin completed a large, randomized, double-blind, placebo-controlled Phase 3 clinical trial of vibegron in patients with OAB in Japan. In this trial, a total of 1,232 patients were randomized to vibegron 50 mg or 100 mg once-daily, imidafenacin (a commonly prescribed anticholinergic in Japan for OAB) twice-daily or placebo, each administered for 12 weeks. Both doses of vibegron demonstrated improvements compared to placebo on all of the primary and secondary efficacy endpoints, including reductions per day of micturitions, urgency episodes, UUI episodes and total incontinence episodes, as well as an increase in volume voided per micturition. Vibegron was observed to be well tolerated in this trial. In 2016, Kyorin also completed a 52-week multicenter, open-label, non-controlled clinical trial in Japan to evaluate the long-term safety and efficacy of vibegron 50 mg and 100 mg in OAB patients. The primary endpoint of this trial was safety. Vibegron was
observed to be well tolerated in this trial, with one reported treatment-related serious adverse event, cerebral infarction, for which a causal relationship was not ruled out by the investigator. There were no other treatment-related serious adverse events reported.

In September 2017, Kyorin submitted a marketing application for vibegron to the Japan Pharmaceuticals and Medical Devices Agency.

**Vibegron for the treatment of overactive bladder in men with benign prostatic hyperplasia**

BPH is characterized by prostate enlargement, which can block the urethra and prevent normal urine flow, and is progressive with age. There are approximately 40 million men between the ages of 50 and 80 in the United States with BPH, approximately 4.5 million of whom are treated for their BPH symptoms. Approximately 50% of BPH patients also suffer from OAB. Currently, there are no FDA-approved therapies specifically for the treatment of OAB in men with BPH.

We believe that developing vibegron specifically for the treatment of OAB in men with BPH would be highly complementary to our overall OAB program. BPH patients, similar to OAB patients, are generally treated by urologists and primary care physicians. Further, due to historical concerns with acute urinary retention, a potential side-effect of anticholinergics, there has been hesitancy among doctors to prescribe anticholinergics for the treatment of OAB in men with BPH. As a result, a majority of men with BPH and OAB are not treated for their OAB symptoms, and this remains an area of high unmet medical need.

We intend to initiate a Phase 3 clinical trial of vibegron for the treatment of OAB in men with BPH by the end of 2018, subject to feedback from the FDA.

**Vibegron for the treatment of pain associated with irritable bowel syndrome**

IBS is characterized by recurrent abdominal pain associated with two or more of the following: defecation, a change in frequency of stool, or a change in form or appearance of stool. Additionally, IBS presents a significant health care burden and can severely impair the patient’s quality of life. While there are currently approved therapies for IBS with constipation and IBS with diarrhea, these drugs do not adequately address IBS-associated pain, and there are no currently marketed drugs indicated specifically for IBS-associated pain.

There are approximately 30 million to 40 million Americans with IBS symptoms, 30% of whom consult with their physician. Approximately 80% of these patients identify pain as a symptom contributing to the severity of their IBS. Based on this data, we estimate that there is an addressable market in the United States of approximately 7.2 to 9.6 million patients who suffer from IBS-associated pain.

In a randomized, placebo-controlled Phase 2 clinical trial conducted by GlaxoSmithKline plc in 99 IBS patients, treatment with solabegron, a clinical-stage beta-3 agonist, led to an increase of adequate relief of pain and discomfort associated with IBS compared to placebo at six weeks.

We intend to initiate a Phase 2a trial of vibegron for the treatment of IBS-associated pain by the end of 2018, pending the submission of an investigational new drug application, or IND, to the FDA in this indication.

**hMaxi-K for the treatment of overactive bladder**

hMaxi-K is a novel gene therapy product candidate that we are developing for patients with OAB who have failed oral pharmacological therapy. hMaxi-K is under development as a potential injectable treatment option for smooth muscle-based disorders such as OAB. hMaxi-K is a plasmid vector containing human DNA encoding the pore-forming
component of the Maxi-K ion channel. Expression of this protein in muscle cells increases potassium ion flow across the cell membrane, reducing excitability of smooth muscle cells. We believe this mechanism could normalize the heightened detrusor smooth muscle tone in OAB, thereby reducing the symptoms of OAB.

There are no currently available FDA-approved gene therapy treatments for OAB. Development of hMaxi-K was initiated by ICI and, to date, has been studied in four early stage clinical trials, including a total of 22 women for the treatment of OAB and 38 men for the treatment of erectile dysfunction. In ICI’s Phase 1b trial for OAB, completed in 2017, hMaxi-K was observed to be generally well tolerated and showed dose-dependent improvements in urinary urgency and frequency.

Subject to feedback from the FDA, we intend to initiate a proof-of-concept Phase 2a clinical trial in 2019 to evaluate the safety and efficacy of hMaxi-K for the treatment of OAB in patients who have not responded to oral pharmacological therapies.

Our strategy
Our goal is to be a leading urology company by developing, commercializing and acquiring innovative therapies. The key elements of our strategy to achieve this goal include:

• Complete the development and obtain FDA approval of vibegron for the treatment of OAB.
• Expand the clinical development of vibegron for additional indications.
• Maximize the commercial potential of vibegron.
• Advance the clinical development of hMaxi-K as a novel treatment for OAB patients who have not responded to oral pharmacological therapies.
• Acquire or in-license additional clinical- or commercial-stage product candidates for the treatment of urologic conditions in a capital-efficient manner.

Relationships with Roivant Sciences Ltd., Roivant Sciences, Inc. and Roivant Sciences GmbH

Roivant Sciences Ltd. will be our controlling shareholder
We are a wholly owned subsidiary of Roivant Sciences Ltd., or RSL, a biopharmaceutical company focused on realizing the full value of promising late-stage drug candidates to improve the lives of patients and their families. Upon the closing of this offering, we expect to be a “controlled company” within the meaning of the applicable listing rules of The Nasdaq Global Market, or Nasdaq. Assuming we sell the number of the common shares set forth on the cover page of this prospectus, RSL will own, in the aggregate, approximately % of our outstanding common shares, or approximately % if the underwriters exercise their option to purchase additional common shares in full. RSL will be able to exercise control over all matters requiring shareholder approval, including the election of our directors and approval of significant corporate transactions. In addition, RSL will have the right to appoint two directors to our board of directors, each of whom will have three votes on all matters presented to the board of directors. Upon the closing of this offering, such directors will hold a majority of the voting power on all matters presented to the board of directors. See the section titled “Description of share capital—Election and removal of directors.”
Services agreements with Roivant Sciences, Inc. and Roivant Sciences GmbH

We have received, and will continue to receive, various services provided by our affiliates, Roivant Sciences, Inc., or RSI, and Roivant Sciences GmbH, or RSG, each a wholly owned subsidiary of RSL. These services include, but are not limited to, the identification of potential additional product candidates, assistance with clinical trials and other development, administrative and financial activities. Following the closing of this offering, we expect that our reliance on RSI and RSG will decrease over time as we continue to hire the necessary personnel to manage the development and potential commercialization of vibegron and any future product candidate. For a description of the services agreements pursuant to which these services are provided, see the section titled “Certain relationships and related party transactions—Affiliate services agreements.”

Risks associated with our business

Our business is subject to a number of risks that you should be aware of before making a decision to invest in our common shares. These risks are discussed more fully in the section titled “Risk factors” and include, among others:

- We have a limited operating history and have never generated any product revenue. Our operations to date have been limited to organizing and staffing our company, acquiring rights to vibegron and initiating our Phase 3 EMPOWUR trial.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. We will require additional capital to fund our operations, and our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- We are heavily dependent on the success of our lead product candidate, vibegron, and if vibegron does not successfully complete clinical development or receive regulatory approval, or is not successfully commercialized, our business may be harmed.
- We have a limited number of dedicated employees and we rely on our affiliates, RSI and RSG, to provide us with various administrative, business development and other services.
- Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes.
- Our gene therapy product candidate, hMaxi-K, is based on a novel technology and the regulatory landscape that governs gene therapy products is uncertain and may change, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.
- We were not involved in the development of vibegron or hMaxi-K prior to our acquisition of the rights to either product candidate and, as a result, we are dependent on Merck and ICI having accurately reported the results and correctly collected and interpreted the data from all preclinical studies and clinical trials conducted to date.
- We rely on our agreements with Merck and ICI to provide rights to the core intellectual property relating to vibegron and hMaxi-K, respectively, and any termination or loss of significant rights under either agreement would adversely affect our development or commercialization of these product candidates.
- We are reliant on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.
We do not have our own manufacturing capabilities and will rely on third parties to produce additional clinical supplies, if needed, and commercial supplies of vibegron and any future product candidates.

We currently rely on a single supplier for the enzyme used to manufacture vibegron, and if we encounter any difficulties in procuring such enzyme, it may harm our business.

If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. We are aware of several companies that are working to develop drugs that we believe would compete against vibegron and hMaxi-K for the treatment of OAB, including another beta-3 agonist, which is currently in Phase 2 clinical development.

Even if one of our product candidates receives marketing approval, it may fail to achieve the market acceptance necessary for commercial success, or coverage and adequate reimbursement may not be available, which could make it difficult for us to sell our product candidate profitably.

RSL will continue to own a significant percentage of our common shares after this offering, and we will be a “controlled company” within the meaning of applicable Nasdaq listing rules. In addition, RSL will have the right to appoint two directors to our board of directors, each of whom will have three votes on all matters presented to the board of directors, and upon the closing of this offering, such directors will hold a majority of the voting power on all matters presented to the board of directors.

We may be classified as a passive foreign investment company, or PFIC, with respect to the current taxable year. U.S. holders of our common shares may suffer adverse tax consequences if we are characterized as a PFIC.

If we are unable to adequately address these and other risks we face, our business, financial condition, operating results and prospects may be adversely affected.

Implications of being an emerging growth company

In addition, we are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012, and therefore we intend to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive and director compensation in this prospectus, our periodic reports and our proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive and director compensation and any golden parachute payments not previously approved. We may take advantage of these exemptions until March 31, 2024, or until we are no longer an “emerging growth company.”

Corporate information

We are an exempted limited company incorporated under the laws of Bermuda on January 27, 2016 under the name Roivant PPS Holdings Ltd. We changed our name to Thalavant Sciences Ltd. on November 14, 2016 and to Urovant Sciences Ltd. on January 13, 2017, when we commenced operations. Our principal office is located at Suite 1, 3rd Floor, 11-12 St. James’s Square, London SW1Y 4LB, United Kingdom, and our registered office is located in...
Bermuda at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. We also have business operations at 5151 California Avenue, Suite 250, Irvine, California 92617. Our telephone number is +44 203 318 9709. Our website address is www.urovant.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common shares.

We have three wholly owned subsidiaries: Urovant Sciences, Inc., or USI, a Delaware corporation; Urovant Holdings Limited, a private limited company incorporated under the laws of England and Wales; and Urovant Sciences GmbH, or USG, a company with limited liability formed under the laws of Switzerland. USG is the principal operating company for conducting our business and the entity that holds our intellectual property rights in vibegron.

Our affiliate, RSG, has applied for a trademark registration in the United States for UROVANT. This prospectus contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or ™ symbols.
# The offering

**Common shares offered by us**  
common shares

**Common shares to be outstanding immediately after this offering**  
common shares (or common shares if the underwriters exercise their option to purchase additional common shares in full)

**Option to purchase additional shares**  
We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional common shares.

**Use of proceeds**  
We estimate that the net proceeds to us from this offering, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, will be approximately $ million, assuming an initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus.

We intend to use the net proceeds from this offering primarily to fund the clinical development of vibegron. The remaining proceeds will be used for working capital and general corporate purposes. See the section titled “Use of proceeds” for additional information.

**Controlled company**  
Upon the closing of this offering, RSL will beneficially own a controlling interest in us and we expect to be a “controlled company” under applicable Nasdaq listing rules. As a controlled company, we intend to avail ourselves of the controlled company exemptions under such rules. See the section titled “Management—Director independence and controlled company exemptions” for further information.

**Risk factors**  
You should read the section titled “Risk factors” for a discussion of factors to consider carefully before deciding to invest in our common shares.

**Proposed Nasdaq symbol**  
“UROV”

The number of common shares that will be outstanding immediately after this offering is based on 75,000,000 common shares outstanding as of June 30, 2018, and excludes:

- 9,071,750 common shares issuable upon the exercise of stock options outstanding as of June 30, 2018, with a weighted-average exercise price of $1.26 per share; and
- 2,428,250 common shares reserved for future issuance under our 2017 Equity Incentive Plan, as amended, as of June 30, 2018, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.

Except as otherwise indicated herein, all information in this prospectus, including the number of common shares that will be outstanding after this offering, assumes or gives effect to:

- a 100,000-for-1 stock split effected on June 1, 2017;
• a 1-for- reverse stock split to be effected on , 2018; and
• no exercise by the underwriters of their option to purchase additional common shares.
## Summary consolidated financial data

The following tables set forth our summary consolidated statement of operations data for the periods indicated. We derived the consolidated statement of operations data for the years ended March 31, 2017 and 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. We derived the consolidated statement of operations data for the three months ended June 30, 2018 and the consolidated balance sheet data as of June 30, 2018 from our unaudited condensed consolidated financial statements appearing elsewhere in this prospectus. We have prepared the unaudited condensed consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the years ended March 31, 2017 and 2018 and for the three months ended June 30, 2018 are not indicative of the results that may be expected for a full fiscal year or any other future period. You should read this summary consolidated financial data below, together with our consolidated financial statements and related notes thereto appearing elsewhere in this prospectus, as well as the sections titled “Selected consolidated financial data” and “Management’s discussion and analysis of financial condition and results of operations.” Our fiscal year ends on March 31.

<table>
<thead>
<tr>
<th></th>
<th>Year ended March 31, 2017</th>
<th>Year ended March 31, 2018</th>
<th>Three months ended June 30, 2017</th>
<th>Three months ended June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>$26,047,370</td>
<td>$32,359,078</td>
<td>$3,131,553</td>
<td>$27,964,780</td>
</tr>
<tr>
<td>General and administrative</td>
<td>1,016,166</td>
<td>4,639,900</td>
<td>334,125</td>
<td>3,504,256</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>27,063,536</td>
<td>36,998,978</td>
<td>3,465,678</td>
<td>31,469,036</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td>93,454</td>
<td>(37,467)</td>
<td>(146,711)</td>
<td>229,361</td>
</tr>
<tr>
<td>Loss before provision for income taxes</td>
<td>(26,970,082)</td>
<td>(37,036,445)</td>
<td>(3,612,389)</td>
<td>(31,239,675)</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>2,103</td>
<td>2,103</td>
<td>55,429</td>
<td>55,429</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(26,970,082)</td>
<td>$(37,073,674)</td>
<td>$(3,614,492)</td>
<td>$(31,295,104)</td>
</tr>
<tr>
<td>Net loss per common share—basic and diluted(1)</td>
<td>$ (2.70)</td>
<td>$ (0.58)</td>
<td>$ (0.12)</td>
<td>$ (0.42)</td>
</tr>
<tr>
<td>Weighted-average common shares outstanding—basic and diluted(1)</td>
<td>10,000,000</td>
<td>64,136,986</td>
<td>31,428,571</td>
<td>75,000,000</td>
</tr>
</tbody>
</table>

(1) See Note 2[L] to our consolidated financial statements for an explanation of the method used to compute basic and diluted net loss per common share.
## Consolidated balance sheet data:

<table>
<thead>
<tr>
<th></th>
<th>Actual</th>
<th>As adjusted (1) (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cash</strong></td>
<td>$ 4,252,962</td>
<td>$</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>11,662,384</td>
<td></td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td>16,797,509</td>
<td></td>
</tr>
<tr>
<td><strong>Additional paid-in capital</strong></td>
<td>91,867,863</td>
<td></td>
</tr>
<tr>
<td><strong>Accumulated deficit</strong></td>
<td>95,480,252</td>
<td></td>
</tr>
<tr>
<td><strong>Total shareholder’s (deficit) equity</strong></td>
<td>(5,135,125)</td>
<td></td>
</tr>
</tbody>
</table>

(1) The as adjusted balance sheet data gives effect to our sale of common shares in this offering at an assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(2) Each $1.00 increase or decrease in the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease each of cash, total assets and total shareholder’s equity on an as adjusted basis by approximately $ million, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase or decrease of 1.0 million common shares offered by us at the assumed initial public offering price, would increase or decrease each of cash, total assets and total shareholder’s equity on an as adjusted basis by approximately $ million, after deducting underwriting discounts and commissions. The as adjusted information is illustrative only, and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.
Risk factors

Investing in our common shares involves a high degree of risk. You should carefully consider the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before making your decision to invest in our common shares. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and cash flows and if so our future prospects would likely be materially and adversely affected. If any of such events were to happen, the trading price of our common shares could decline, and you could lose all or part of your investment.

Risks related to our business, financial position and capital requirements

We have a limited operating history and have never generated any product revenue.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were incorporated in January 2016, and our operations to date have been limited to organizing and staffing our company, acquiring rights to vibegron and hMaxi-K, and initiating our pivotal Phase 3 EMPOWUR trial of vibegron for the treatment of OAB. We have not yet demonstrated an ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, vibegron for the treatment of OAB or our other targeted indications, OAB in men with BPH and IBS-associated pain, as well as hMaxi-K for the treatment of OAB. We have never been profitable, have no products approved for commercial sale, and have not generated any product revenue.

Even if we receive regulatory approval for one of our product candidates, we do not know when or if it will generate product revenue. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete clinical trials and obtain regulatory approval for the marketing of our product candidates;
- add operational, financial and management information systems personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- initiate and continue relationships with third-party manufacturers and have commercial quantities of our product candidates manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- attract and retain experienced management and advisory teams;
- launch commercial sales of our products, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems for our product candidates;
- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
achieve broad market acceptance of our products in the medical community and with third-party payors and consumers; and
maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA or comparable non-U.S. regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if one of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with its commercial launch. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be negatively impacted.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. We have never generated any product revenue, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. Our net loss was $27.0 million and $37.1 million for the years ended March 31, 2017 and 2018, respectively, and $31.3 million for the three months ended June 30, 2018. As of June 30, 2018, we had an accumulated deficit of $95.5 million.

We expect to continue to incur substantial and increasing losses through the commercialization of our product candidates, if approved. Our product candidates have not been approved for marketing anywhere in the world, and they may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of, obtain necessary regulatory approvals for, and manufacture and successfully market our product candidates alone or in collaboration with others. We cannot assure you that we will be profitable even if we successfully commercialize our product candidates. If we do successfully obtain regulatory approval to market our product candidates, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, the accepted price for our product candidates and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common shares and our ability to raise capital and continue operations.

We expect our research and development expenses in connection with our development programs for our product candidates to continue to be significant. In addition, as we prepare for and if we obtain regulatory approval for our product candidates, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses had and will continue to have an adverse effect on our results of operations, financial position and working capital.

Our auditors have issued a going concern opinion on our consolidated financial statements as of March 31, 2017 and 2018, expressing substantial doubt that we can continue as an ongoing business due to insufficient capital.
We are heavily dependent on the success of our lead product candidate, vibegron, and if vibegron does not successfully complete clinical development or receive regulatory approval, or is not successfully commercialized, our business may be harmed.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the advancement of vibegron, through clinical trials and the regulatory approval process, as well as the commercialization of vibegron following regulatory approval, if received. Accordingly, our business currently depends heavily on the successful completion of our Phase 3 EMPOWUR trial and subsequent regulatory approval and commercialization of vibegron.

We cannot be certain that vibegron will receive regulatory approval, or be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market vibegron in the United States until we receive approval of an NDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization.

We have not yet demonstrated our ability to complete later-stage or pivotal clinical trials, and there can be no assurance that our Phase 3 EMPOWUR trial of vibegron for OAB will produce results sufficient for us to submit an NDA or differentiate our product from currently available OAB therapies. Our ongoing Phase 3 EMPOWUR trial may not demonstrate a statistically significant difference for the active 75 mg vibegron dose compared to placebo for the co-primary endpoints, which are reductions in frequency of micturitions and UUI episodes. Any failure to demonstrate a statistically significant change from baseline would adversely impact the potential for regulatory approval, if any, of vibegron in the United States. Furthermore, even if the statistical difference compared to placebo is achieved for these co-primary endpoints, we may not be able to demonstrate such differences for our secondary endpoints, such as changes in the frequency of urinary urgency episodes and total incontinence episodes and self-reported quality of life scores. As such, even if we were able to obtain approval for vibegron, these key secondary endpoints would not be mentioned in the U.S. label, which could potentially adversely affect product differentiation.

We have not submitted an NDA for vibegron, a Biologics License Application, or BLA, for hMaxi-K, or any other marketing authorizing application for any other product candidates to the FDA or any comparable application to any other regulatory authority. Obtaining approval of an NDA, BLA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of any of our current or future product candidates for many reasons, including:

• we may not be able to demonstrate that our product candidates are effective as treatments for any of our targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
• the relevant regulatory authorities may require additional pre-approval studies or clinical trials, which would increase our costs and prolong our development timelines;
• the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
• the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;

• the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that materially adversely impact our clinical trials and ability to obtain market approvals;

• the FDA or other relevant regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;

• the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of our product candidates, or may require that we conduct additional studies;

• the FDA or other relevant regulatory authorities may not accept data generated from our clinical trial sites;

• if our NDA or other foreign application is reviewed by an advisory committee, the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

• the FDA or other relevant regulatory authorities may require development of a risk evaluation and mitigation strategy, or REMS, or its equivalent, as a condition of approval;

• the FDA or other relevant regulatory authorities may require additional post-marketing studies, which would be costly;

• the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data insufficient to support the quality of our product candidates;

• the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or

• the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of vibegron.

We expect to spend substantial capital to complete the development of, seek regulatory approvals for and commercialize our product candidates. These expenditures will include costs associated with our license agreements with Merck and ICI pursuant to which we are obligated to cover the development and commercialization costs of vibegron and hMaxi-K, respectively, make payments in connection with the achievement of certain regulatory milestones prior to generating any product sales, make further payments upon the achievement of certain sales milestones and make tiered royalty payments in connection with the sale of approved products, if any.

Even with the net proceeds from this offering, we will require additional capital to complete the development and potential commercialization of our product candidates. Because the length of time and activities associated with successful development of our product candidates are highly uncertain, we are unable to estimate with
certainty the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the timing, costs and results of our Phase 3 EMPOWUR trial of vibegron for the treatment of OAB;
- the initiation, timing, costs and results of our proposed Phase 3 clinical trial of vibegron for the treatment of OAB in men with BPH and our proposed Phase 2a clinical trial of vibegron for the treatment of IBS-associated pain;
- the timing, costs and results of our proposed Phase 2a clinical trial for hMaxi-K for the treatment of OAB in patients who have not responded to oral pharmacological therapies;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for our products in regions where we choose to commercialize our products on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

We believe our existing cash, together with the net proceeds from this offering, will be sufficient for us to fund our operating expenses and capital expenditure requirements through at least . This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We do not have any committed external source of funds. We cannot be certain that additional capital will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our current and any future product candidates, or potentially discontinue operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current product development programs.

Raising additional funds by issuing securities may cause dilution to existing shareholders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities,
our existing shareholders’ ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of a common shareholder. Additionally, any agreements for future debt or preferred equity financings, if available, may involve covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds 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 develop and market ourselves.

We rely on our license agreements with Merck and ICI to provide rights to the core intellectual property relating to vibegron and hMaxi-K, respectively. Any termination or loss of significant rights under either agreement, would adversely affect our development or commercialization of these product candidates.

We have licensed our core intellectual property relating to vibegron and hMaxi-K from Merck and ICI, respectively. If, for any reason, our license agreement with Merck or ICI is terminated or we otherwise lose those rights, it would adversely affect our business. Our license agreements impose on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages to Merck or ICI, and Merck or ICI may have the right to terminate our license, which would result in us being unable to develop, manufacture and sell our product candidates.

Pursuant to our license agreement with Merck, Merck agreed to provide a supply of the vibegron compound to support the development of vibegron. Under this agreement, we may only use such material in preclinical and clinical work. The agreement also provides for Merck to reasonably assist us during a specified period of time with a technical transfer of the manufacturing process from Merck to us or our designee for production of vibegron. Although Merck has already transferred the manufacturing process for vibegron to us, we may still need additional assistance during scale-up of vibegron if we experience any setbacks with the manufacturing at a larger scale. If Merck fails to fulfill its continuing obligations under this agreement, if needed, or if we require additional assistance after their obligation to assist us expires, our development of vibegron could be significantly delayed or otherwise adversely affected.

Under our license agreement with ICI, ICI agreed to reasonably assist us during a specified period of time with a technical transfer of the manufacturing process from ICI to us or our designee for production of hMaxi-K. If ICI fails to fulfill its obligations under this agreement, or if we require additional assistance after their obligation to assist us expires, our manufacture and development of hMaxi-K could be significantly delayed or otherwise adversely affected.

We may be required to make significant payments to third parties under our licensing and collaboration agreements for our current product candidates.

Under our agreements with Merck, Kyorin and ICI, we are subject to significant obligations, including payment obligations upon the achievement of specified milestones and payments based on product sales, as well as other material obligations. Certain of the milestone payments payable by us under these agreements are due upon events that will occur prior to our planned commercialization of our product candidates. Accordingly, we will be required to make such payments prior to the time at which we are able to generate any revenue, if any, from sales of our product candidates. There can be no assurance that we will have the funds necessary to make
such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. Furthermore, if we are forced to raise additional funds, 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 develop and market ourselves.

**We currently have a limited number of employees who are employed by our wholly owned subsidiaries and we rely on RSI and RSG to provide various administrative, business development, clinical development and other services.**

As of June 30, 2018, we had no employees, and our wholly owned subsidiary, USI, had 26 employees. We rely on the administrative support, business development, clinical development and other services provided by RSI and RSG, wholly owned subsidiaries of RSL, which provide services to us pursuant to services agreements, or the Services Agreements, as further described under the section titled “Certain relationships and related party transactions—Affiliate services agreements.” For example, we currently rely and expect to continue to rely on RSI to support our Phase 3 EMPOWUR trial of vibegron for the treatment of OAB through its completion. Personnel and support staff that provide services to us under the Services Agreements are not required to, and we do not expect that they will, have the management and administration of our business as their primary responsibility, or act exclusively for us. RSI and RSG have limited finance, accounting, clinical development and other resources. Furthermore, RSI and RSG engage in other business activities and provide support for other of our affiliates and subsidiaries of RSL. If their focus is diverted or their limited resources are otherwise employed, we could face potential delays or disruptions in the conduct of our clinical development programs and the commercialization of our product candidates, if approved, which could harm our business.

In the event of a default under or termination of the Services Agreements, we may be unable to contract with substitute service providers on similar terms, in a timely fashion, or at all, and the costs of substituting service providers may be substantial. In addition, a substitute service provider may not be able to provide the same level of services due to lack of pre-existing knowledge or synergies. Any termination of our relationship with RSI or RSG, or decrease in provision of services by RSI and RSG, and any delay in appointing or finding a suitable replacement provider, if one exists, could make it difficult for us to operate our business and continue the clinical development and potential commercialization of our current or future product candidates.

**We may not be able to manage our business effectively if we are unable to attract and retain key personnel.**

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategies.

We are highly dependent on the skills and leadership of our senior management team and key employees. Our senior management and key employees may terminate their positions with us at any time. If we lose one or more members of our senior management team or key employees, our ability to successfully implement our business strategies could be adversely affected. Replacing these individuals may be difficult, cause disruption and may take an extended period of time due to the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel. We do not maintain “key person” insurance for any members of our senior management team or other employees.
We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to hire, either directly, or through any current or future subsidiaries of ours, additional employees for our managerial, finance and accounting, clinical, scientific and engineering, regulatory, operational, manufacturing, medical affairs and sales and marketing teams. We may have difficulties identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations across our entities, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of vibegron, hMaxi-K and any future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate or grow revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future product candidates and compete effectively will partly depend on our ability to effectively manage any future growth.

Many of the other pharmaceutical companies we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these opportunities may be more appealing to high-quality candidates and consultants than what we have to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can develop product candidates and our business will be harmed.

Our or our affiliates’ employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our or our affiliates’ employees and contractors, including principal investigators, CROs, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA or other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing and the FDA’s Good Clinical Practice, or GCP, or current Good Manufacturing Practice, or cGMP, standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee or third-party misconduct, 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

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investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person, including any person who may have engaged in any fraud or misconduct, or government agency could allege such fraud or other misconduct, even if none occurred. Furthermore, we rely on our CROs and clinical trial sites to adequately report data from our ongoing clinical trials. For example, any failure by such parties to adequately report safety signals to us in a timely manner from any such trials may also affect the approvability of our product candidates or cause delays and disruptions for the approval of our product candidates, if any. If our or our affiliates’ employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers or other vendors are alleged or found to be in violation of any such regulatory standards or requirements, or become subject to a corporate integrity agreement or similar agreement and curtailment of our operations, it could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, suspension or delay in our clinical trials, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and additional reporting requirements and oversight, any of which could adversely affect our ability to operate our business and our results of operations.

We may not be successful in our efforts to identify and acquire or in-license additional product candidates, or to enter into collaborations or strategic alliances for the development and commercialization of any such future product candidates.

Part of our strategy involves identifying and acquiring or in-licensing novel product candidates. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

• the process by which identify and decide to acquire product candidates may not be successful, including through the business development support we receive from RSL and its subsidiaries pursuant to the Services Agreements;

• potential product candidates may, upon further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;

• potential product candidates may not be effective in treating their targeted diseases; or

• the acquisition or in-licensing transactions can entail numerous operational and functional risks, including exposure to unknown liabilities, disruption of our business, or incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected acquisition or integration costs.

We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. We also cannot be certain that, following an acquisition or in-licensing transaction, we will achieve the revenue or specific net income that justifies such transaction. Further, time and resources spent identifying, acquiring and developing potential product candidates may distract management’s attention from our primary business or other development programs. If we are unable to identify and acquire suitable product candidates for clinical development, this would adversely impact our business strategy, our financial position and share price.

In the future, we may also decide to collaborate with other pharmaceutical companies for the development and potential commercialization of our product candidates in the United States or other countries or territories of the world. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates.
because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

**International expansion of our business exposes us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business outside of the United States.**

Part of our business strategy involves international expansion, including establishing and maintaining operations outside of the United States and establishing and maintaining relationships with health care providers, payors, government officials, distributors and manufacturers globally. Conducting business internationally involves a number of risks, including:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the United States Foreign Corrupt Practices Act, or FCPA, including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010, or UK Bribery Act, and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors’ activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, negatively impact our financial condition, results of operations and cash flows.

**Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.**

Our computer systems, as well as those of various third parties on which we rely, including RSL and its affiliates, our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally
increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an 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 nonclinical or clinical trial data from completed, ongoing or planned 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 were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our current or future product candidates could be delayed.

**The failure to successfully implement an enterprise resource planning system could adversely impact our business and results of operations.**

RSI and RSG commenced the implementation of a company-wide enterprise resource planning, or ERP, system to upgrade certain existing business, operational and financial processes, on which we rely. ERP implementations are complex and time-consuming projects that require transformations of business and financial processes in order to reap the benefits of the ERP system; any such transformation involves risk inherent in the conversion to a new computer system, including loss of information and potential disruption to normal operations. Additionally, if the ERP system is not effectively implemented as planned, or the system does not operate as intended, the effectiveness of our internal controls over financial reporting could be adversely affected or our ability to assess those controls adequately could be delayed. Significant delays in documenting, reviewing and testing our internal control could cause us to fail to comply with our U.S. Securities and Exchange Commission, or SEC, reporting obligations related to our management’s assessment of our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business during or following the implementation of the ERP, our business and results of operations could be harmed.

**Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.**

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, other pharmaceutical companies or others taking or otherwise coming into contact with our products. On occasion, large monetary judgments have been awarded in class action lawsuits where drugs have had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our current or future product candidates, if approved;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our current or future product candidates, if approved; and
- loss of revenue.
The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and 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 due to liability. If we obtain marketing approval for our product candidates, we intend to acquire insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of our current or future product candidates, if approved.

**Risks related to development, regulatory approval and commercialization**

*Clinical trials are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes.*

Our product candidates are still in development and will require extensive clinical testing before we are prepared to submit an NDA or other similar application for regulatory approval. We cannot provide you any assurance that we will submit an NDA for regulatory approval for our product candidates within our projected timeframes or whether any such applications will be approved by the relevant regulatory authorities. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA or other regulatory authorities may not agree with our proposed analysis plans for any clinical trials of our product candidates, and during any such review, may identify unexpected efficacy or safety concerns, which may delay the approval of an NDA or similar application. The FDA may also find that the benefits of our product candidates do not outweigh their risks in a manner sufficient to grant regulatory approval. The clinical trial process is also time-consuming and costly and relies on the collaboration with many CROs and clinical trial sites.

Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development or submission of an NDA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit safety signals in later stage clinical trials that they did not exhibit in preclinical or earlier-stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in or the discontinuation of advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Likewise, the results of nonclinical testing or early clinical trials may not be predictive of the results of our planned development programs, and there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future trial results. In particular, our gene therapy product candidate, hMaxi-K, is in early stages of development. The outcome of nonclinical testing and early clinical trials may not be predictive of the success of later stage clinical trials. The Phase 1b clinical trial conducted by ICI for hMaxi-K for the treatment of OAB and detrusor overactivity in women studied a small patient population, which makes it difficult to predict whether the favorable results observed in such clinical trial will be repeated in larger and more advanced clinical trials.

The commencement and completion of clinical trials may be delayed by several factors, including:

- failure to obtain regulatory approval to commence a trial;
- unforeseen safety issues;
occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;

lack of effectiveness during clinical trials;

determination of dosing issues;

inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

slower than expected rates of patient recruitment or failure to recruit suitable patients to participate in a trial;

failure to add a sufficient number of clinical trial sites;

unanticipated impact from changes in or modifications to protocols or clinical trial design;

inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols or applicable regulatory requirements;

an institutional review board, or IRB, refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;

premature discontinuation of study participants from clinical trials or missing data;

failure to manufacture or release sufficient quantities of a product candidate or placebo, or failure to obtain sufficient quantities of active comparator medications for our clinical trials, if applicable, that in each case meet our quality standards, for use in clinical trials;

inability to monitor patients adequately during or after treatment; or

inappropriate unblinding of trial results.

Further, we, the FDA or other regulatory authority may suspend our clinical trials in an entire country at any time, or an IRB may suspend its clinical trial sites within any country, if it appears that we or our collaborators are failing to conduct a trial in accordance with regulatory requirements, including cGMP regulations, that we are exposing participants to unacceptable health risks, or if the FDA or other regulatory authority, as the case may be, finds deficiencies in our IND or equivalent applications for other countries or the manner in which the clinical trials are conducted. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue may be delayed. In addition, any delays in our clinical trials could increase our costs, cause a decline in our share price, slow down the approval process, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and results of operations. 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.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the
utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, prior to our acquisition of the rights to vibegron and hMaxi-K, we had no involvement with or control over the nonclinical or clinical development of these product candidates. Additionally, pursuant to our collaboration agreement with Kyorin, who retains exclusive rights from Merck to develop and commercialize vibegron in Japan and certain other Asian territories, we may rely on data generated by Kyorin in connection with seeking regulatory approval of vibegron in the territories in which we have rights to develop and commercialize vibegron. We are dependent on Merck, Kyorin and ICI having conducted such research and development in accordance with the applicable protocols and legal, regulatory and scientific standards, having accurately reported the results of all clinical trials and other research they conducted prior to our acquisition of the rights to our current product candidates, having correctly collected and interpreted the data from these trials and other research, and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of these assets. Problems related to predecessors could result in increased costs and delays in the development of our product candidates, which could adversely affect our ability to generate any future revenue from sales of our product candidates, if approved.

Our gene therapy product candidate, hMaxi-K, is based on a novel technology and the regulatory landscape that governs gene therapy products is uncertain and may change, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval.

The use of gene therapy in the treatment of OAB is novel. There can be no assurance that we will not experience problems or delays in developing our product candidate and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process from ICI, which may prevent us from completing our clinical studies or commercializing hMaxi-K on a timely or profitable basis, if at all.

In addition, the clinical trial requirements and the criteria used by the FDA and other foreign regulatory authorities to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidate. The regulatory approval process for novel product candidates such as hMaxi-K can be more expensive and take longer than for other, better known or more extensively studied product candidates. To date, only a limited number of gene therapies have received marketing authorization from the FDA or foreign regulatory authorities. Until August 2017, the FDA had never approved a gene therapy product. Since that time, the FDA has only approved a small number of gene therapy product candidates, including Kymriah by Novartis International AG, for pediatric and young adult patients with a form of acute lymphoblastic leukemia, Yescarta by Kite Pharma, Inc., for adult patients with certain forms of non-Hodgkin lymphoma, and Luxturna by Spark Therapeutics, Inc. for patients with an inherited form of vision loss. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for hMaxi-K in either the United States, or other major markets or how long it will take to commercialize hMaxi-K, if approved. Approvals by foreign regulatory authorities may not be indicative of what the FDA may require for approval, and vice versa.

The FDA recently released a series of draft guidance documents regarding certain gene therapy product candidates, including gene therapies for rare diseases, and other clinical and manufacturing issues related to gene therapy product candidates. We cannot be certain when additional guidance will be released that could be relevant to, or have an impact on, our gene therapy product candidate or the duration or expense of any applicable regulatory review processes.
Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Tissues and Advanced Therapies within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise the CBER in its review. In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials for cell therapy products and gene therapy had historically been subject to review by the Recombinant DNA Advisory Committee, or the RAC, of the National Institutes of Health, or NIH, Office of Biotechnology Activities, or OBA, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH Guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment on its proposed modifications. During the public comment period, which closes October 16, 2018, the NIH has announced that it will no longer accept new human gene transfer protocols for review as a part of the protocol registration process or convene the RAC to review individual clinical protocols. These trials will remain subject to the FDA’s oversight and other clinical trial regulations, and oversight at the local level will continue as set forth in the NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Even though we may not be required to submit a protocol for our gene therapy product candidates through the NIH for RAC review, we will still be subject to significant regulatory oversight by the FDA, and in addition to the government regulators, the applicable IBC and institutional review board, or IRB, of each institution at which we or our collaborators conduct clinical trials of our product candidates, or a central IRB if appropriate, would need to review and approve the proposed clinical trial. Similarly, foreign regulatory authorities may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines.

The FDA, NIH and the European Medicines Agency, or EMA, have each expressed interest in further regulating biotechnology, including gene therapy and genetic testing. For example, the EMA advocates a risk-based approach to the development of a gene therapy product candidate. Agencies at both the federal and state level in the United States, as well as the U.S. congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such actions may delay or prevent development and, if approved, commercialization of hMaxi-K.

These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional testing, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of hMaxi-K or lead to significant post-approval limitations or restrictions. As we advance our gene therapy product candidate, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of hMaxi-K. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects would be adversely affected.
Negative public opinion of gene therapy and increased regulatory scrutiny of gene therapy and genetic research may adversely impact public perception of our current and future product candidates.

Our gene therapy product candidate, hMaxi-K, involves introducing genetic material into patients’ cells. The clinical and commercial success of hMaxi-K and any future gene therapy product candidates will depend in part on public acceptance of the use of gene therapy and gene regulation for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy and gene regulation are unsafe, unethical or immoral and, consequently, any gene therapy product candidates that we may develop may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll patients in our clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of gene therapy product candidates that we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of hMaxi-K. For example, in 2003, clinical trials using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell’s DNA, have led to several well publicized adverse events, including reported cases of leukemia. Adverse events in our clinical trials, even if not ultimately attributable to our gene therapy product candidate, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of hMaxi-K or any future gene therapy product candidates, stricter labeling requirements for such product candidates if approved and a decrease in demand for any such product candidates. The risk of cancer remains a concern for gene therapy and we cannot assure that it will not occur in any of our planned or future clinical trials. In addition, there is the potential risk of delayed adverse events following exposure to gene therapy due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. If any such adverse events occur, our clinical trials and, if approved, commercialization of hMaxi-K or any future product candidates could be halted or delayed, which would have a negative impact on our business and operations.

Reported data or other clinical development announcements by Kyorin or other third parties may adversely affect our clinical development plan.

Kyorin is developing vibegron for the treatment of OAB in Japan. Kyorin recently reported positive results from its Phase 3 clinical trial in Japan for the treatment of OAB. See “Business—Vibegron for the treatment of overactive bladder—Clinical data for vibegron in overactive bladder—Kyorin Phase 3 program in Japan.” However, favorable announcements by Kyorin regarding these trials do not guarantee that the results of our clinical trials will also be favorable as the design of our international Phase 3 EMPOWUR trial differs from that of Kyorin’s Phase 3 trial. Further, if subsequent announcements by Kyorin regarding its development of vibegron are unfavorable, or post-marketing or Phase 4 clinical trials conducted by Kyorin are unfavorable or result in new safety signals in Japan during any such post-marketing or Phase 4 clinical trial, it could negatively impact our clinical development plans and potential approval for vibegron in the United States. Any unexpected measure by the Japanese regulatory agencies following approval of vibegron in Japan, including any measures due to unexpected post-marketing safety signals, will also affect the potential approval for vibegron in the United States. In addition, we face similar risks to the extent that third parties develop vibegron in other Asian territories.

The results of our clinical trials may not support our proposed claims for our product candidates, or regulatory approval at all.

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior nonclinical testing.
and clinical trials. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical trial as a whole will be successful. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after promising results in earlier nonclinical studies or clinical trials. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical and initial clinical trials. For example, we may not succeed in demonstrating that vibegron offers a differentiated profile compared to current OAB therapies, including the potential for broader efficacy claims if the FDA approves the inclusion of urgency data, rapid onset of action data, and a single, convenient once-daily dose in the label. A future failure of a clinical trial to meet its pre-specified endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates.

Any delay in, or termination of, our clinical trials will delay the submission of our NDA to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize vibegron and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support these claims for differentiation or the effectiveness or safety of vibegron. The FDA has substantial discretion in the review and approval process and may disagree that our studies support the differentiated claims we propose. We cannot guarantee that we will obtain approval for the differentiated claims we propose, if at all.

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

From time to time, we may publicly disclose preliminary or “top-line” data from our clinical trials, which is based on a preliminary analysis of then-available top-line data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the top-line data that we report differ from actual results, or if others, including
Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate, leading to delays in our development timelines. For example, we may face difficulty enrolling or maintaining a sufficient number of patients in our clinical trials due to the existing alternative treatments approved for the treatment of OAB as patients may decline to enroll or decide to withdraw from our clinical trials due to the risk of receiving placebo or the perceived risks of gene therapy as compared to more traditional treatment options. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, and the risk that patients enrolled in clinical trials will drop out of the trials before completion. For example, our Phase 3 EMPOWUR trial has over 300 planned clinical sites in the United States and Europe. The trial is being conducted by a large multinational CRO and will require close collaboration with, and oversight over, the CRO and the clinical sites. The ability for our Phase 3 EMPOWUR trial to be conducted and completed on our current timelines, or at all, could also be adversely impacted by our CRO facing a loss of key personnel or business challenges, as well as changes in the political situation or in the legislation of the countries of our participating clinical sites.

Furthermore, any negative results or new safety signals we or third parties may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in our clinical trials. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing us from completing recruitment of one or more of our trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

Drug development is highly competitive and subject to rapid and significant technological advancements. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for OAB. Further, it is likely that additional drugs will become available in the future for the treatment of OAB and our other target indications.

We are aware of several companies that are working to develop drugs that would compete against vibegron and hMaxi-K for the treatment of OAB. For example, Velicept Therapeutics, Inc. is advancing solabegron, a beta-3 receptor agonist for the treatment of OAB.
agonist initially developed by GlaxoSmithKline plc, as a twice-daily and once-daily formulation into Phase 2b clinical trials. In addition to solabegron, there are several other product candidates under development for the treatment of OAB. Taiho Pharmaceutical Co., Ltd., is developing TAC-302, a novel neurite outgrowth enhancer, currently in Phase 2 clinical trials in Japan. Dong-A ST Co., Ltd., is developing DA-8010, a novel anticholinergic, currently in a Phase 1 clinical trial. Taris Biomedical LLC is developing TAR-302, an intravesicular drug-delivery system for trospium, an anticholinergic drug, currently in Phase 1 clinical trials. Outpost Medicine, LLC's IND for OP-687 for OAB was accepted by the FDA in late 2017. In addition, a number of companies are developing injectable neurotoxins (biosimilar onabotulinumtoxinA, abobotulinumtoxinA, and nivobotulinumtoxinA) for OAB.

We also face competition from other drugs and therapies currently approved for the treatment of OAB. Anticholinergic drugs have been the standard of pharmacologic care for OAB since the approval of flavoxate in 1970 and oxybutynin in 1975. Anticholinergics continue to account for the largest share of prescriptions written for the treatment of OAB in the United States. There are a number of widely prescribed anticholinergics approved for sale in the United States, including solifenacin, tolterodine and oxybutynin. In addition, we will face competition from mirabegron (Myrbetriq, marketed by Astellas) and Allergan’s BOTOX, each of which are FDA-approved therapies used for the treatment of OAB. Furthermore, we expect to face additional competition from a generic version of mirabegron following Myrbetriq’s loss of marketing exclusivity, which we expect to occur in 2023 or 2024. Any such competition from generics could adversely affect the market size and opportunity for vibegron, and there can be no assurance that generic competition will not reach the market even sooner than we expect.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any product candidate that we may develop.

Our ability to compete successfully will depend largely on our ability to:

- develop and commercialize therapies that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our technologies and product;
- obtain required regulatory approvals, including approvals to market our product candidates in ways that are differentiated from existing and future therapies;
- successfully commercialize our product candidates, if approved;
• obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
• successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapies.

The availability of our competitors’ products could limit the demand and the price we are able to charge for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA or other regulatory authority approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate product revenue will be impaired.

Activities associated with the development and commercialization of our product candidates, including the design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution of our product candidates are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by similar regulatory authorities outside the United States. Failure to obtain marketing approval for, and thus commercialize our product candidates, could negatively impact our ability to generate any revenue from product sales.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that none of our product candidates will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Neither we nor any current or future collaborator, is permitted to market any of our product candidates in the United States or any other jurisdiction until we receive regulatory approval of an NDA from the FDA or similar regulatory authorities outside of the United States.

The time required to obtain approval of an NDA by the FDA or similar regulatory authorities outside of the United States is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authority. For example, prior to submitting an NDA to the FDA or any comparable application to any other foreign regulatory authorities for approval of vibegron, we will need to complete our ongoing Phase 3 EMPOWUR trial of vibegron for the treatment of OAB and receive favorable results from this trial. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions.

Securing marketing approvals requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the safety and efficacy of the product candidate for that indication. We expect to rely on third-party CROs, consultants and personnel from RSI and RSG to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Delays or errors in the submission of applications for marketing approval or issues, including those related to gathering the appropriate data and the inspection process, may ultimately delay or affect our ability to obtain regulatory approval, commercialize our product candidates and generate product revenue.
Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events caused by our product candidates or that of adjuncts, could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials, and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events or new safety signals are reported in our clinical trials for our current or future product candidates, our ability to obtain regulatory approval for such product candidates may be negatively impacted. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects.

In particular, there have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia in trials using earlier generation viral vectors. While hMaxi-K uses a plasmid vector, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. Possible adverse side effects that may occur with treatment with gene therapy products include an immunologic reaction early after administration that could substantially limit the effectiveness of the treatment or represent safety risks for patients. Many times, side effects are only detectable after investigational products are tested in larger scale, pivotal clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If any of our current or future product candidates are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or require a REMS (or equivalent outside the United States) to impose restrictions on its distribution or other risk management measures;
- we may be required to recall a product;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications, or require other labeling changes;
- we may be required to change the way the product is administered or to conduct additional clinical trials;
- we may be required to repeat a preclinical study or clinical trial or terminate a program, even if other studies or trials related to the program are ongoing or have been successfully completed;
- we could be sued and held liable for harm caused to patients;
- we could elect to discontinue the sale of our product;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our current or future product candidates, if approved.
The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for any of our current or future product candidates, we will still face extensive regulatory requirements and our product may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment of registration and drug listing requirements, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of drug product samples to physicians, recordkeeping and GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or the FDA or other regulatory authorities may require that contraindications, warnings or precautions-including in some cases, a boxed warning be included in the product labeling, which could limit sales of the product.

Regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Regulatory authorities impose stringent restrictions on manufacturers’ communications regarding off-label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the United States and other comparable regulations in foreign jurisdictions relating to the promotion of prescription drugs may lead to enforcement actions and investigations by the FDA, Department of Justice, State Attorneys General and other...
foreign regulatory agencies alleging violations of United States federal and state health care fraud and abuse laws, as well as state consumer protection laws and comparable laws in foreign jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements may yield various results, including:

- restrictions on the manufacture of such products;
- restrictions on the labeling or marketing of such products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials, or any regulatory holds on our clinical trials;
- requirement of a REMS (or equivalent outside the United States);
- Warning or Untitled Letters;
- withdrawal of the products from the market;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA and other regulatory authorities’ policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 abroad. If we are slow or unable to adapt to changes in existing requirements or to 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.

For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders will be implemented, and the extent to which they will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Even if any of our current or future product candidates receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

Even if any of our current or future product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community.
community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenue or become profitable. The degree of market acceptance of a product candidate, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the content of the approved product label;
- product label differentiation from other OAB therapies;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- utilization controls imposed by third-party payors, such as prior authorizations and step edits; and
- any restrictions on the use of our product, if approved, together with other medications.

Because we expect sales of vibegron, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of vibegron to find market acceptance would harm our business and could require us to seek additional financing. **If we are unable to establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we may not be successful in commercializing any of our current or future product candidate, if approved.**

We do not currently have any infrastructure for the sales, marketing, or distribution of any product, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any product that may be approved, we must build our sales, distribution, marketing, managerial and other nontechnical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization.

We expect to build a focused sales, distribution and marketing infrastructure to market our product candidate in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage geographically dispersed sales and marketing teams. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact its commercialization. For example, if we recruit a sales force and establish marketing capabilities in anticipation of the commercial launch of our lead product candidate, vibegron, and such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.
Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs;
- the inability to negotiate with payors regarding reimbursement for our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator’s strategic interest in our products, and that collaborator’s ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sales and marketing of our product candidates, if approved, for certain markets overseas; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenue we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of our product candidates, we may be forced to delay potential commercialization or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring any current or future product candidates to market or generate product revenue. We could enter into arrangements with collaborative partners at an earlier stage than otherwise would be ideal and we may be required to relinquish certain rights to any current or future product candidate or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any current or future product candidate and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

*If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could adversely affect our business.*

If our product candidates are approved for commercialization outside of the United States, we intend to enter into agreements with third parties to market in certain jurisdictions in which we have exclusive commercialization rights. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced or no protection of intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
economic weakness, including inflation, or political instability in particular foreign economies and markets;

• compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

• foreign reimbursement, pricing and insurance regimes;

• foreign taxes;

• any foreign partners or collaborators not fulfilling their respective regulatory reporting requirements and any foreign regulatory authorities taking actions with respect to such failures, which would be reportable to the FDA;

• any foreign partners or collaborators not informing us of any new post-marketing safety signals in a timely manner;

• foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

• workforce uncertainty in countries where labor unrest is more common than in the United States;

• potential noncompliance with the FCPA, the UK Bribery Act or similar antibribery and anticorruption laws in other jurisdictions;

• production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

• business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in commercializing any product, and many biopharmaceutical companies have found the process of marketing their products in foreign countries to be very challenging.

**Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.**

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support, charitable organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval. Such laws include, among others:

• the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. Although 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. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity does not need to have actual knowledge of the federal Anti-
Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $74,792 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

• the federal false claims laws, including the False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

• the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

• HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information on health plans, health care clearing houses, and most providers and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity;

• the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other “transfers of value” made to physicians and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other “transfers of value” to such physician owners (covered manufacturers are required to submit reports to the government by the 90th day of each calendar year); and

• analogous state and foreign laws and regulations, such as state antikickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and 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 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; and state and foreign laws governing the privacy and security of health information
in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price and other harm to our business, financial condition and results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The Patient Protection and Affordable Care Act and future legislative changes may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the healthcare industry, and impose additional healthcare policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry’s regulatory burdens and operating costs. Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts (increasing to 70% commencing January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries under 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 individuals enrolled in Medicaid managed care organizations;

• expansion of eligibility criteria for Medicaid programs in certain states;

• expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

• a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; 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.

We cannot predict the full impact of the Affordable Care Act on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred. For example, in January 2016, the Centers for Medicare and Medicaid Services issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the “average manufacturer price” is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President of the United States signed into law the Budget Control Act of 2011, which, among other things, included further reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2027 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years. Further, there have been several recent United States Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs.

Moreover, the Drug Supply Chain Security Act, which was enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act, imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidate or additional pricing pressures.

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Coverage and adequate reimbursement may not be available for our product candidate, which could make it difficult for us to sell it profitably, if approved.

Market acceptance and sales of any approved product that we develop will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities and private health insurers. For example, in May 2018, we commissioned a third-party market research study to assess how vibegron would be covered, if approved. The research firm interviewed representatives of payors, who are involved with, but not solely responsible for, access and reimbursement decisions. Such interviewees represented payors covering over 80 million U.S. commercial and Medicare Part D lives. The payor representatives interviewed expect that vibegron would be managed at a preferred or non-preferred branded tier, without prior authorization, allowing physicians and patients to make the choice of whether to pay a higher co-pay for a branded product or a lower co-pay for a generic. This market research study has no bearing on the payors, and any assumptions or interpretations based on the results of this study, may ultimately be inaccurate. There is no assurance that vibegron, if approved, would achieve adequate coverage and reimbursement levels.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Third-party payors decide which drugs they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop through approval will be made on a plan-by-plan basis. One payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. Additionally, a third-party payor’s decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay the manufacturer for the drug, on what tier of its formulary the drug will be placed and whether to require step therapy. The position of a drug on a formulary generally determines the co-payment that a patient will need to make to obtain the drug and can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Further, from time to time, typically on an annual basis, payment rates are updated and revised by third-party payors. Such updates could impact the demand for our products, to the extent that patients who are prescribed our products, if approved, are not separately reimbursed for the cost of the product. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula and provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule through 2019, but no annual update from 2020 through 2025. MACRA also introduced a merit based incentive bonus program for Medicare physicians beginning in 2019. At this time, it is unclear how the introduction of the merit based incentive program will impact overall physician reimbursement under the Medicare program. Any resulting decrease in payment under the merit based reimbursement system may adversely affect our business, financial condition and prospects. In addition, the Medicare physician fee schedule has been adapted by some private payors into their plan-specific physician payment schedule. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our product candidates or lowers reimbursement for procedures using our products could harm our business.
The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, products. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. 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. Inadequate coverage or reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Additionally, there have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. There can be no assurance that any of our current or future product candidates, if approved, will be considered medically reasonable and necessary, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

Risks related to our dependence on third parties

We do not have our own manufacturing capabilities and will rely on third parties to produce additional clinical supplies, if needed, and commercial supplies of our current and future product candidates.

We have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution or testing. Both Merck and ICI are obligated to reasonably assist us during a specified time-period with a technical transfer of the manufacturing process to us or our designee for production of vibegron and hMaxi-K, respectively. Although Merck has already transferred the manufacturing process of vibegron to us, we may still need additional assistance during scale-up of vibegron if we experience any setbacks with the manufacturing on the larger scale. If Merck or ICI fail to fulfill their respective obligations, as applicable, or if we require additional assistance after their obligation to assist us expires, our development of our product candidates could be significantly delayed or otherwise adversely affected.

Pursuant to our agreement with Merck, Merck provided us with a supply of vibegron, which we may only utilize in preclinical and clinical work. We expect that the vibegron drug substance transferred to us under our agreement with Merck will be sufficient for us to complete our Phase 3 EMPOWUR trial and our other currently planned clinical trials for the treatment of OAB in men with BPH and IBS-associated pain. Additionally, while, pursuant to our agreement with ICI, ICI is obligated to transfer adequate manufacturing technical package for the clinical development and manufacture of hMaxi-K, we do not currently have any clinical supply of hMaxi-K for any proposed and future nonclinical studies and clinical trials. We intend to rely on third-party manufacturers, as needed, to supply us with sufficient quantities of vibegron and hMaxi-K to be used for the development and subsequent commercialization of these product candidates, if approved.

If we are unable to initiate or continue our relationship with one or more of these third-party manufacturers, we could experience delays in our development efforts and subsequent commercialization if any of our product candidates are approved, as we locate and qualify new or additional manufacturers.
Third-party vendors may be difficult to identify for process and formulation development and manufacturing for our product candidates due to special capabilities required, and they may not be able to meet our quality standards. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements for manufacture of drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

• failure of the drug substance transferred from Merck to meet our product specifications and quality requirements;
• inability to meet our product specifications and quality requirements consistently;
• delay or inability to procure or expand sufficient manufacturing capacity;
• manufacturing and product quality issues related to scale-up of manufacturing;
• costs and validation of new equipment and facilities required for scale-up;
• failure to comply with applicable laws, regulations and standards, including cGMP and similar foreign standards;
• deficient or improper record-keeping;
• inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
• termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
• reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates, if approved, or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
• lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
• operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or other regulatory sanctions related to the manufacture of another company’s products;
• carrier disruptions or increased costs that are beyond our control; and
• failure to deliver our products under specified storage conditions and in a timely manner.

In addition, the process for manufacturing gene therapy product candidates, such as hMaxi-K, is more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, characterization and testing of a gene therapy product candidate such as ours generally can be challenging. The complexity of these processes, as well as strict government standards for the manufacture and storage of gene therapy product candidates, subjects us to increased manufacturing risks for hMaxi-K. If supply from a third-party manufacturing facility is interrupted, there could be a significant disruption in supply of hMaxi-K. Any of these events could lead to clinical trial delays, cost overruns, delay or failure to obtain regulatory approval or impact our ability to successfully commercialize our product candidates, if approved, as well as potential product liability litigation, product recalls or product withdrawals. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production of our product candidates.

We currently rely on a single supplier for the enzyme used to manufacture vibegron, and if we encounter any difficulties in procuring such enzyme, it may harm our business.

Currently, we rely on a single supplier, Codexis, for its proprietary enzyme that we use to manufacture vibegron, and we have agreed to purchase from Codexis all of our requirements for such enzyme for use in our clinical and commercial production of vibegron for the first six years after the first approval in either the United States, Europe or Canada. However, if following the first six years after such approval, if any, we are unable to continue to obtain the proprietary enzyme from Codexis, or make arrangements for an alternative source for such enzyme, we may encounter difficulties or delays in continuing to produce vibegron on a commercial scale. Furthermore, there can be no assurance that Codexis will be able to meet our commercial needs, if any, for the enzyme used to manufacture vibegron. Any business or economic challenges our supplier faces, including compliance with regulatory authorities, whether in the ordinary course or not, could impair its ability to meet our needs. Accordingly, there is a risk that supplies of our product may be significantly delayed by or may become unavailable as a result of any issues affecting our supplier's production of its proprietary enzyme.

Changes in methods of product manufacturing or formulation may result in additional costs or delays.

It is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our products to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate any revenue.

We are reliant on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We currently do not have the ability to independently conduct nonclinical studies that comply with Good Laboratory Practice, or GLP, requirements. We also do not currently have the ability to independently conduct any
clinical trials. We rely exclusively on CROs and clinical trial sites, which need to comply with GCP, to ensure the proper and timely conduct of our clinical trials, and we have limited influence over their actual performance.

We rely upon CROs to monitor and manage data for our clinical programs, as well as for the execution of nonclinical studies. We control only certain aspects of our CROs’ activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with GLP and GCP regulations and guidelines enforced by the FDA, and are also required by the competent authorities of the member states of the European Economic Area and other comparable foreign regulatory authorities to comply with the International Council for Harmonization guidelines for any of our product candidates that are in nonclinical and clinical development. The regulatory authorities enforce GCP regulations through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical trials before approving our marketing applications. Accordingly, if we or our CROs fail to comply with these regulations or other applicable laws, regulations or standards, or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the relevant regulatory approval process. Failure by our CROs to properly execute study protocols in accordance with applicable law could also create product liability and healthcare regulatory risks for us as sponsors of those studies.

While we will have agreements governing their activities, our CROs are not our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our (or their own) clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop could be harmed, our costs could increase and our ability to generate revenue could be delayed.

If our relationships with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms or in a timely manner. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can adversely impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.
Risks related to our intellectual property

If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely, and will continue to rely, upon a combination of patents, trademarks, trade secret protection and confidentiality agreements with employees, consultants, collaborators, advisors and other third parties to protect the intellectual property related to our current and future drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future drug development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and any future product candidates in the United States or in other foreign countries. We may also inadvertently make statements to regulatory agencies during the regulatory approval process that may be inconsistent with positions that have been taken during prosecution of our patents, which may result in such patents being narrowed, invalidated or held unenforceable.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our current and any future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may obtain. Even if patents do successfully issue based on our patent applications, and even if such patents cover vibegron and hMaxi-K, uses of vibegron and hMaxi-K, or other aspects related to vibegron, hMaxi-K or any future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us in the future could deprive us of rights necessary for the successful commercialization of any of our current or future product candidates, if approved. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed may fail to result in issued patents with claims that protect our current and any future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may obtain. Even if patents do successfully issue based on our patent applications, and even if such patents cover vibegron and hMaxi-K, uses of vibegron and hMaxi-K, or other aspects related to vibegron, hMaxi-K or any future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us in the future could deprive us of rights necessary for the successful commercialization of any of our current or future product candidates, if approved. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any of our current or future product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drugs. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any such outcome could have an adverse effect on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and
patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act made a number of significant changes to United States patent laws. These include provisions that affect the way patent applications are prosecuted and challenged at the U.S. Patent and Trademark Office, or the USPTO, and may also affect patent litigation. The USPTO has developed and continues to develop new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act, subsequent rulemaking, and judicial interpretation of the Leahy-Smith Act and regulations will have on the operation of our business. However, the Leahy-Smith Act 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 have an adverse effect on our business and financial condition.

The inventorship and ownership rights for patents that we own or in-license may be challenged by third parties. Such challenges could result in loss of exclusive rights to such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or require us to obtain a license from such third parties on commercially reasonable terms to secure exclusive rights. If any such challenges to inventorship or ownership were asserted, there is no assurance that a court would find in our favor or that, if we choose to seek a license, such license would be available to us on acceptable terms or at all.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Moreover, 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 current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents
protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

*If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term and obtaining data exclusivity for our product candidates, our business may be harmed.*

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, product candidates and our target indications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). This extension is limited to only one patent that covers the approved product, the approved use of the product, or a method of manufacturing the product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time-period or the scope of patent protection afforded could be less than we request.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

*The validity, scope and enforceability of any patents listed in the Orange Book that cover our product candidates can be challenged by third parties.*

If one of our product candidates is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug containing vibegron, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA’s Orange Book with respect to our NDA for the applicable approved product candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party’s generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved product candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party’s ANDA is accepted for filing by the FDA. We may then initiate a lawsuit.
to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party’s ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party’s ANDA will not be subject to the 30-month stay of FDA approval.

Moreover, a third party may challenge the current patents, or patents that may issue in the future, within our portfolio, which could result in the invalidation of some or all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products. If a third party successfully challenges all of the patents that might otherwise be eligible for listing in the Orange Book for one of our products, we will not be entitled to the 30-month stay of FDA approval upon the filing of an ANDA for a generic drug containing, for example, vibegron, and relies in whole or in part on studies conducted by or for us.

Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management’s attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our product candidates.

The validity, scope and enforceability of any patents that cover our biologic product candidates can be challenged by third parties.

For biologics, such as hMaxi-K, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell a biosimilar or interchangeable versions of brand name biological products. Due to the large size and complexity of biological products, as compared to small molecules, a biosimilar must be “highly similar” to the reference product with “no clinically meaningful differences between the two.” The BPCIA also provides reference product sponsors with 12 years of market exclusivity, but unlike the Hatch-Waxman Act, it does not require reference product sponsors to list patents in an Orange Book and does not include an automatic 30-month stay of FDA approval upon the timely filing of a lawsuit. The BPCIA, however, does require a formal pre-litigation process which includes the exchange of information between a biosimilar applicant and a reference biologic sponsor that includes the identification of relevant patents and each parties’ basis for infringement and invalidity. After the exchange of this information, we may then initiate a lawsuit within 30 days to defend the patents identified in the exchange. If the biosimilar applicant successfully challenges the asserted patent claims it could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or result in a finding of non-infringement.

There is a risk that our current or any future gene therapy product candidate approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated.

Moreover, the extent to which a biosimilar, once approved, will be substituted for our current or any future reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, the biosimilar regulatory framework is still being implemented by the FDA and is subject to ongoing litigation disputes to interpret the laws and implementing regulations. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing biosimilars could change in unpredictable ways that would weaken our ability to obtain or maintain approval as a biologic and 12 years of market exclusivity.
If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidate.

We have licensed certain intellectual property rights covering vibegron from Merck and hMaXi-K from ICI. If, for any reason, our license agreement with either of these licensors is terminated or we otherwise lose those rights, it could adversely affect our business. These license agreements impose, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering any of our current or future product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our product candidates, including for example, a use for a patented or proprietary DNA delivery-related technology to manufacture and commercialize hMaXi-K. If we are unable to obtain licenses from such third parties when needed or on commercially reasonable terms, our ability to commercialize our product candidates, if approved, would likely be delayed.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.
Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate patents or other proprietary rights, may delay or prevent the development and commercialization of any of our current or future product candidates.

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization. For example, we have conducted searches for information in support of patent protection and otherwise evaluating the patent landscape for vibegron, and based on these searches and evaluations to date, we do not believe that there are valid patents that contain granted claims that could be asserted with respect to vibegron. However, we may be incorrect.

There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent was to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms.
terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

**We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.**

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counterclaims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and
perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to detect or 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. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

**Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.**

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

**Changes in United States patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.**

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening 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. Depending on actions by the United States 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 patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights”. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself.
We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering our current and any future product candidates throughout the world would be prohibitively expensive. 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 may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents 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.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license 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 develop or license.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties to manufacture our current and any future product candidates, and we expect to continue to collaborate with third parties on the development of our current and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our collaboration or similar agreements. For example, under our collaboration agreement with Kyorin, we are obligated to share with Kyorin certain information relating to the development of vibegron including reports from nonclinical studies and clinical trials. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Further, adequate remedies may not exist in the event of
Unauthorized use or disclosure. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor’s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Policing unauthorized use of our or our licensors’ intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Moreover, enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor’s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees’ former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we or our licensors fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

*Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.*

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their...
normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials and internal research programs, or in-license needed technology or other product candidates. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our product candidates, if approved.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our current and any future product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.
Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

• others may be able to make formulations or compositions that are the same as or similar to our product candidates, but that are not covered by the claims of the patents that we own;
• others may be able to make product that is similar to product candidates we intend to commercialize that is not covered by the patents that we exclusively licensed and have the right to enforce;
• we, our licensor or any collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
• we or our licensor might not have been the first to file patent applications covering certain of our inventions;
• others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
• it is possible that our pending patent applications will not lead to issued patents;
• issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
• our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
• we may not develop additional proprietary technologies that are patentable.

Risks related to this offering and our common shares

No public market for our common shares currently exists, and a public market may not develop or be liquid enough for you to sell your shares quickly or at market price.

Prior to this offering, there has not been a public market for our common shares. If an active trading market for our common shares does not develop following this offering, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration. The initial public offering price of our common shares has been determined by negotiations between us and representatives of the underwriters, and it may not be indicative of the market prices of our common shares that will prevail in the trading market.

In addition, our common shares are held by a relatively small number of holders. Our officers and directors have the potential to acquire shares through any equity awards granted to them, subject to vesting conditions. Consequently, our common shares may have a limited public float and low average daily trading volume, which could affect a holder’s ability to sell common shares or the price at which they can be sold. In addition, future sales of substantial amounts of our common shares in the public market by those larger holders, or the perception that these sales could occur, may adversely impact the market price of our common shares and our shares could be difficult for a holder to liquidate.
The market price of our common shares is likely to be highly volatile, and you may lose some or all of your investment. The market price of our common shares is likely to be highly volatile and may be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- results of clinical trials of our product candidates or those of our competitors;
- any delay in filing an NDA or similar application for vibegron and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that NDA or similar application, as the case may be;
- failure to successfully develop and commercialize our current or any future product candidates;
- failure to maintain our relationships with Merck and ICI or to comply with the terms of our license agreements with these licensors;
- inability to obtain additional funding;
- regulatory or legal developments in the United States or other countries or jurisdictions applicable to our current and any future product candidates;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for our current or any future product candidates, or the inability to do so at acceptable prices;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in estimates of financial results or investment recommendations by securities analysts;
- significant lawsuits, including patent or shareholder litigation and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- short sales of our common shares;
- any delay in filing an NDA or similar application for vibegron and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that NDA or similar application, as the case may be;
sales of a substantial number of shares of our common shares in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares;

sales or purchases of our common shares by our Section 16 officers;

sales of our common shares by us or our shareholders in the future;

negative coverage in the media or analyst reports, whether accurate or not;

issuance of subpoenas or investigative demands, or the public fact of an investigation by a government agency, whether meritorious or not;

size of our public float;

trading liquidity of our common shares;

investors’ general perception of our company and our business;

general economic, industry and market conditions; and

the other factors described in this "Risk factors" section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and market conditions, may negatively affect the market price of our common shares, regardless of our actual operating performance. The market price of our common shares may decline below the initial public offering price, and you may lose some or all of your investment.

Volatility in our share price could subject us to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

We will be a “controlled company” within the meaning of the applicable Nasdaq listing rules and, as a result, will qualify for exemptions from certain corporate governance requirements. If we rely on these exemptions, you will not have the same protections afforded to shareholders of companies that are subject to such requirements.

Upon the closing of this offering, RSL will continue to control a majority of the voting power of our outstanding common shares. As a result, we will be a “controlled company” within the meaning of applicable Nasdaq listing rules. Under these rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a “controlled company.” In addition, for so long as the RSL designated directors control all matters presented to our board of directors for a vote, we will be a “controlled company.” For so long as we remain a “controlled company,” we may elect not to comply with certain corporate governance requirements, including the requirements:

• that a majority of the board of directors consists of independent directors;

• for an annual performance evaluation of the nominating and corporate governance and compensation committees;
• that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee’s purpose and responsibilities; and

• that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee’s purpose and responsibility.

We intend to use these exemptions upon the closing of this offering and we may continue to use all or some of these exemptions in the future. As a result, you may not have the same protections afforded to shareholders of companies that are subject to all of the Nasdaq corporate governance requirements.

**RSL will continue to own a significant percentage of our common shares and will be able to exert significant control over matters subject to shareholder approval.**

RSL is currently our sole shareholder, and after this offering is completed, we will continue to be controlled by RSL. Upon the closing of this offering, RSL will beneficially own approximately % of the voting power of our outstanding common shares, or approximately % if the underwriters exercise their option to purchase additional common shares in full. Therefore, even after this offering, RSL will have the ability to substantially influence us and exert significant control through this ownership position. For example, RSL and its shareholders may be able to control elections of directors, issuance of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. RSL’s interests may not always coincide with our corporate interests or the interests of other shareholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. Further, RSL is a privately held company whose ownership and governance structure is not transparent to our other shareholders. There may be changes to the management or ownership of RSL that could impact RSL’s interests in a way that may not coincide with our corporate interests or the interests of other shareholders. So long as RSL continues to own a significant amount of our equity, it will continue to be able to strongly influence and effectively control our decisions.

**RSL will have the right to appoint two directors to our board of directors, each of whom will have three votes.**

RSL will be entitled to appoint two directors to our board of directors, each of whom will have three votes on all matters presented to the board of directors. All other directors will have one vote on all matters presented to the board of directors. While the directors appointed by RSL will be obligated to act in accordance with their fiduciary duty, they may have equity or other interests in RSL and, accordingly, their interests may be aligned with RSL’s interests, which may not always coincide with our corporate interests or the interests of our other shareholders. Upon the closing of this offering, the two directors appointed by RSL will be able to determine the outcome of all matters presented to the board of directors.

**Our organizational and ownership structure may create significant conflicts of interests.**

Our organizational and ownership structure involves a number of relationships that may give rise to certain conflicts of interest between us and minority holders of our common shares, on the one hand, and RSL and its shareholders, on the other hand. Certain of our directors and employees have equity interests in RSL and, accordingly, their interests may be aligned with RSL’s interests, which may not always coincide with our corporate interests or the interests of our other shareholders. Further, our other shareholders may not have visibility into the RSL ownership of any of our directors or officers, which may change at any time through acquisition, disposition, dilution, or otherwise. Any change in our directors’ or officers’ RSL ownership could impact the interests of those holders.

In addition, we are party to certain related party agreements with RSL, RSI and RSG. These entities and their shareholders, including certain of our directors and employees, may have interests which differ from our
interests or those of the minority holders of our common shares. Any material transaction between us and RSL, RSI, RSG or any other subsidiary of RSL is subject to our related party transaction policy, which requires prior approval of such transaction by our audit committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to do business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows.

If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common shares will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common shares or change their opinion of our common shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Because we do not anticipate paying any cash dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common shares would be your sole source of gain on an investment in our common shares for the foreseeable future. Additionally, we are subject to Bermuda legal constraints that may affect our ability to pay dividends on our common shares and make other payments. See the section titled “Dividend policy” for additional information.

Our management will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and our shareholders will not have the opportunity as part of their investment decision to assess whether the net proceeds are being used appropriately. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our failure to apply the net proceeds of this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

Future sales of our common shares may depress our share price.

After this offering, based on the 75,000,000 common shares outstanding as of June 30, 2018, there will be common shares outstanding, assuming no exercise by the underwriters of their option to purchase additional common shares. Sales of a substantial number of our common shares in the public market after this offering, or the perception that these sales might occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities. Of our issued and outstanding common shares, all of the shares sold in this offering will be freely transferable without restrictions or further registration under the Securities Act of 1933, as amended, or the Securities Act. The remaining 75,000,000 common shares outstanding after this offering will be restricted as a result of securities laws,
lock-up agreements or other contractual restrictions that restrict transfers for 180 days after the date of this prospectus. See the section titled "Underwriting—Lock-up agreements" for a more detailed description of the lock-up period.

We intend to file a registration statement on Form S-8 under the Securities Act to register the total number of our common shares that may be issued under our equity incentive plans. See the section titled "Shares eligible for future sale—Form S-8 registration statements" for a more detailed description of the common shares that will be available for future sale upon the registration and issuance of such common shares, subject to any applicable vesting or lock-up period or other restrictions provided under the terms of the applicable plan or the option agreements entered into with the option holders. Sales of these common shares have an adverse effect on the trading price of our common shares. In addition, in the future we may issue common shares or other securities if we need to raise additional capital. The number of our new common shares issued in connection with raising additional capital could constitute a material portion of our then outstanding common shares.

If you purchase our common shares in this offering, you will incur immediate and substantial dilution in the book value of your common shares.

The initial public offering price of our common shares is substantially higher than the as adjusted net tangible book value per common share of our common shares. Therefore, if you purchase our common shares in this offering, you will pay a price per common share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. Based on the assumed initial public offering price of $ per common share, you will experience immediate dilution of $ per common share, representing the difference between our as adjusted net tangible book value per common share, after giving effect to this offering, and the initial public offering price. Further, the future exercise of any options to purchase our common shares will cause you to experience additional dilution. See the section titled "Dilution" for additional information.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, and particularly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors’ and officers’ liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

As a result of becoming a public company, we will be obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common shares.

We will be required, pursuant to Section 404 of the Sarbanes Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for the
fiscal year beginning April 1, 2019. This assessment will need to include disclosure of any material weaknesses identified by our
management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to
the effectiveness of our internal controls over financial reporting until our first annual report required to be filed with the SEC following the
date we are no longer an emerging growth company, as defined in the JOBS Act. At such time as we are required to obtain auditor
attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting
from our independent registered public accounting firm. We will be required to disclose significant changes made in our internal controls
procedures on a quarterly basis.

We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the
evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a
timely fashion. Our compliance with Section 404 will require that we incur substantial legal, accounting and other compliance expense and
expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and
finance staff and consultants with appropriate public company experience and technical accounting knowledge and compile the system and
process documentation necessary to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal controls over
financial reporting, we will be unable to assert that our internal controls over financial reporting are effective. We cannot assure you that there
will not be material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. Any failure to maintain
effective internal controls over financial reporting could severely inhibit our ability to accurately report our financial condition or results of
operations. If we are unable to conclude that our internal controls over financial reporting is effective, or if our independent registered public
accounting firm determines we have a material weakness or significant deficiency in our internal controls over financial reporting, we could
lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common shares could decline,
and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material
weakness in our internal controls over financial reporting, or to implement or maintain other effective control systems required of public
companies, could also negatively impact our ability to access to the capital markets.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial
information that we are required to disclose. As a public company, if our disclosure controls and procedures are ineffective, we may be
unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results
or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our common
shares to decline.

**We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging
growth companies will make our common shares less attractive to investors.**

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may
take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging
growth companies," including exemption from compliance with the auditor attestation requirements of Section 404, 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 earlier of (1) the date (a) March 31, 2024, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in
which we are deemed to be a large accelerated
filer, which means the market value of our common shares that are held by non-affiliates exceeds $700 million as of the prior September 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

We are a Bermuda company and it may be difficult for you to enforce judgments against us or our directors and executive officers.

We are a Bermuda exempted company. As a result, the rights of our shareholders are governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in another jurisdiction. It may be difficult for investors to enforce in the U.S. judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the United States, against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions. See "Enforcement of civil liabilities under U.S. federal securities laws" for additional information.

Bermuda law differs from the laws in effect in the United States and may afford less protection to our shareholders.

We are incorporated under the laws of Bermuda. As a result, our corporate affairs are governed by the Bermuda Companies Act 1981, as amended, or the Companies Act, which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company’s memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company’s shareholders than those who actually approved it.
When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company’s affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our bye-laws and as permitted by Bermuda law, each shareholder has waived any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the United States, particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the United States.

There are regulatory limitations on the ownership and transfer of our common shares. Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non-residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed stock exchange, which includes Nasdaq. Additionally, we have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer. The general permission or the specific permission would cease to apply if we were to cease to be listed on Nasdaq or another appointed stock exchange.

Our amended and restated bye-laws enable our board of directors to issue preference shares, which may discourage a change of control. Our amended and restated bye-laws contain provisions that enable our board of directors to determine the powers, preferences and rights of our preference shares and to issue the preference shares without shareholder approval. This could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our common shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of this provision may adversely affect the prevailing market price of our common shares if it is viewed as discouraging takeover attempts in the future.

We may become subject to unanticipated tax liabilities and higher effective tax rates. We are incorporated under the laws of Bermuda, where we are not subject to any income or withholding taxes. We are centrally managed and controlled in the United Kingdom, and, under current U.K. tax law, a company which is centrally managed and controlled in the United Kingdom is regarded as resident in the United Kingdom for taxation purposes. Accordingly, we expect to be subject to U.K. taxation on our income and gains, except where an exemption applies. We may be treated as a dual resident company for U.K. tax purposes. As a result, our right to claim certain reliefs from U.K. tax may be restricted, and changes in law or practice in the United Kingdom could result in the imposition of further restrictions on our right to claim U.K. tax reliefs. We may also become subject to income, withholding or other taxes in certain jurisdictions by reason of our activities and
operations, and it is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such additional tax liability could adversely affect our results of operations. For example, our wholly owned subsidiary, USG, is the principal operating company for conducting our business and the entity that holds our intellectual property rights in vibegron and hMaxi-K. The establishment of this Swiss entity as our principal operating company and the acquisition of our intellectual property rights by this entity may result in a higher overall effective tax rate.

The intended tax effects of our corporate structure and intercompany arrangements depend on the application of the tax laws of various jurisdictions and on how we operate our business.

We and RSL, our sole shareholder, are incorporated under the laws of Bermuda. We currently have subsidiaries in the United Kingdom, Switzerland and the United States. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various countries and tax jurisdictions, in part through intercompany service agreements between us, our parent company and our subsidiaries. In that case, our corporate structure and intercompany transactions, including the manner in which we develop and use our intellectual property, will be organized so that we can achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms’ length and that appropriate documentation be maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. As we intend to operate in numerous countries and taxing jurisdictions, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm’s length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. For example, on December 22, 2017, an “Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018,” commonly known as the Tax Cuts and Jobs Act, was enacted, which introduced a comprehensive set of tax reforms. We continue to assess the impact of such tax reform legislation on our business and may determine that changes to our structure, practice or tax positions are necessary in light of the Tax Cuts and Jobs Act. Certain impacts of this legislation have been taken into account, including the reduction of the U.S. corporate income tax rate from the previous 35% to 21%. The Tax Cuts and Jobs Act in conjunction with the tax laws of other jurisdictions in which we operate, however, may require consideration of changes to our structure and the manner in which we conduct our business. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms’ length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our
changes in effective tax rate may reduce our net income in future periods.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the United Kingdom and Switzerland), the United States, Bermuda and other jurisdictions as well as being affected by certain changes currently proposed by the Organisation for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation were to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties and reputational damage, which could adversely affect our business, results of our operations and our financial condition.

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of share-based compensation; (6) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure.

U.S. holders that own 10% or more of the vote or value of our common shares may suffer adverse tax consequences because we and/or any of our non-U.S. subsidiaries are expected to be characterized as a “controlled foreign corporation,” or a CFC, under Section 957(a) of the U.S. Internal Revenue Code of 1986, as amended, or the Code.

A non-U.S. corporation is considered a CFC if more than 50% of (1) the total combined voting power of all classes of stock of such corporation entitled to vote, or (2) the total value of the stock of such corporation, is owned, or is considered as owned by applying certain constructive ownership rules, by United States shareholders (U.S. persons who own stock representing 10% or more of the vote or, for taxable years of non-U.S. corporations beginning after December 31, 2017 and for taxable years of shareholders with or within which such taxable years of non-U.S. corporations end, 10% or more of the value) on any day during the taxable year of such non-U.S. corporation. Certain United States shareholders of a CFC generally are required to include currently in gross income such shareholders’ share of the CFC’s “Subpart F income,” a portion of the CFC’s earnings to the extent the CFC holds certain U.S. property, and a portion of the CFC’s “global intangible low-taxed income” (as defined under Section 951A of the Code). Such United States shareholders are subject to current U.S. federal income tax with respect to such items, even if the CFC has not made an actual distribution to such shareholders. “Subpart F income” includes, among other things, certain passive income (such as income from dividends, interests, royalties, rents and annuities or gain from the sale of property that produces such types of income) and certain sales and services income arising in connection with transactions between the CFC and a person related to the CFC. “Global intangible low-taxed income” may include most of the remainder of a CFC’s income over a deemed return on its tangible assets.

As a result of certain changes in the U.S. tax law introduced by the Tax Cuts and Jobs Act, we believe that we and our non-U.S. subsidiaries were classified as CFCs in the current taxable year prior to this offering. For U.S. holders who hold 10% or more of the vote or value of our common shares, this may result in adverse U.S.
federal income tax consequences, such as current U.S. taxation of Subpart F income and of any such shareholder’s share of our accumulated non-U.S. earnings and profits (regardless of whether we make any distributions), taxation of amounts treated as global intangible low-taxed income under Section 951A of the Code with respect to such shareholder, and being subject to certain reporting requirements with the U.S. Internal Revenue Service. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the vote or value of our common shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing of our common shares and the impact of the Tax Cuts and Jobs Act, especially the changes to the rules relating to CFCs. **U.S. holders of our common shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.**

Generally, if, for any taxable year, 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, and gains from the sale or exchange of investment property 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. Additionally, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our common shares may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income, rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our common shares. In addition, special information reporting may be required. See the section titled “Material Bermuda, U.K. and U.S. federal income tax considerations—U.S. federal income tax consequences for U.S. holders—Passive foreign investment company.”

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile. If we are a CFC and not publicly traded throughout the relevant taxable year, however, the test may be applied based on the adjusted basis of our assets. Our status may also depend, in part, on how quickly we utilize the cash proceeds from this offering in our business and whether we earn primarily passive income (such as interest income) in the current taxable year or future taxable years. We believe that we were classified as a CFC prior to this offering in the current taxable year beginning on April 1, 2018. Based on this belief, and the current and expected adjusted basis of our assets, we may be classified as a PFIC with respect to the current taxable year. Because the determination of whether we are a PFIC for any taxable year is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC in any taxable year. Our U.S. counsel expresses no opinion with respect to our PFIC status for our current or future taxable years. We will determine whether we were a PFIC or not for each taxable year and make such determination available to U.S. holders.

The tax consequences that would apply if we are classified as a PFIC would also be different from those described above if a U.S. holder were able to make a valid “qualified electing fund,” or QEF, election. At this time, we do not expect to provide U.S. shareholders with the information necessary for a U.S. holder to make a QEF election. Prospective investors should assume that a QEF election will not be available.
Special note regarding forward-looking statements

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled “Prospectus summary,” “Risk factors,” “Management’s discussion and analysis of financial condition and results of operations” and “Business,” but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will” and “would,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- the progress, timing, costs and results of our international Phase 3 EMPOWUR trial for vibegron in patients with OAB;
- the potential advantages and differentiated profile of vibegron compared to existing therapies for OAB;
- the timing, costs and results of our proposed Phase 3 clinical trial for vibegron for the treatment of OAB in men with BPH and our proposed Phase 2a clinical trial for vibegron in patients with IBS-associated pain;
- the timing, costs and results of our proposed Phase 2a clinical trial for hMaxi-K for the treatment of OAB in patients who have not responded to oral pharmacological therapies;
- our ability to successfully commercialize our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectation that the net proceeds from this offering will be sufficient to enable us to complete ;
- our ability to maintain intellectual property protection for our product candidates;
- our ability to identify, acquire or in-license and develop new product candidates;
- our ability to identify, recruit and retain key personnel;
- our use of proceeds from this offering;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

You should refer to the section titled “Risk factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives.
and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.
Industry and market data

Certain industry data and market data included in this prospectus were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of management’s estimates presented herein are based upon management’s review of independent third-party surveys and industry publications prepared by a number of sources and other publicly available information. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe that the information from these industry publications and surveys included in this prospectus is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.
Use of proceeds

We estimate that the net proceeds from our issuance and sale of common shares in this offering will be approximately $\_\_\_\_\_\_\_\_ million, or approximately $\_\_\_\_\_\_\_\_ million if the underwriters exercise their option to purchase additional common shares in full, based upon an assumed initial public offering price of $\_\_\_\_\_\_\_\_ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting 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 common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease the net proceeds to us from this offering by approximately $\_\_\_\_\_\_\_\_ million, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of common shares we are offering. Each increase or decrease of 1.0 million in the number of common shares we are offering at the assumed initial public offering price of $\_\_\_\_\_\_\_\_ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions would increase or decrease the net proceeds to us from this offering by approximately $\_\_\_\_\_\_\_\_ million, assuming the assumed initial public offering price stays the same.

We intend to use the net proceeds from this offering for the following purposes:

- approximately $\_\_\_\_\_\_\_\_ million to $\_\_\_\_\_\_\_\_ million to fund our international Phase 3 EMPOWUR trial for vibegron in patients with OAB;
- approximately $\_\_\_\_\_\_\_\_ million to $\_\_\_\_\_\_\_\_ million to advance both our planned Phase 3 clinical trial for vibegron for the treatment of OAB in men with BPH and our planned Phase 2a clinical trial for vibegron in patients with IBS-associated pain;
- approximately $\_\_\_\_\_\_\_\_ million to $\_\_\_\_\_\_\_\_ million to advance our planned Phase 2a clinical trial for hMaxi-K for the treatment of OAB in patients who have not responded to oral pharmacological therapies; and
- the remainder to fund working capital and general corporate purposes, which may include research and development of vibegron for other indications.

We believe that the net proceeds from this offering, together with our existing cash, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through \_\_\_\_\_\_\_\_\_. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. Even with the net proceeds from this offering, we will require additional capital to complete the development and potential commercialization of vibegron in each of the indications set forth above. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies and clinical trials, as well as any collaborations that we may enter into with third parties, and any unforeseen cash needs.
We believe opportunities may exist from time to time to expand our current business through the acquisition or in-license of complementary product candidates. While we have no current agreements or commitments for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. We may choose to invest these net proceeds in short-term, interest bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our operations.

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Dividend policy

We have never declared or paid any dividends on our common shares. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any decision to declare and pay dividends in the future will be made at the sole discretion of our board of directors and will depend on, among other things, our results of operations, cash requirements, financial condition, contractual restrictions and other factors that our board of directors may deem relevant. In addition, pursuant to Bermuda law, a company may not declare or pay dividends, or make distributions out of contributed surplus, if there are reasonable grounds for believing that (1) the company is, or would after the payment be, unable to pay its liabilities as they become due or (2) the realizable value of its assets would thereby be less than its liabilities. "Contributed surplus" is defined for purposes of section 54 of the Bermuda Act to include the proceeds arising from donated shares, credits resulting from the redemption or conversion of shares at less than the amount set up as nominal capital and donations of cash and other assets to the company. Under our amended and restated bye-laws, each common share is entitled to dividends if, as and when dividends are declared by our board of directors, subject to any preferred dividend right of the holders of any preference shares.
## Capitalization

The following table sets forth our cash and capitalization as of June 30, 2018 on an:

- actual basis; and
- as adjusted basis to give effect to the issuance and sale of common shares in this offering at an assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and offering expenses payable by us.

The following information is illustrative only of our capitalization following the closing of this offering and will change based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with the sections titled “Use of proceeds,” “Selected consolidated financial data” and “Management’s discussion and analysis of financial condition and results of operations,” and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

<table>
<thead>
<tr>
<th>Shareholder’s (deficit) equity:</th>
<th>Actual</th>
<th>As adjusted(1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common shares, $0.00001 par value per share; 1,000,000,000 shares authorized, 75,000,000 shares issued and outstanding, as adjusted</td>
<td>$750</td>
<td>$</td>
</tr>
<tr>
<td>Common shares subscribed</td>
<td>(750)</td>
<td></td>
</tr>
<tr>
<td>Shareholder receivable</td>
<td>(1,310,000)</td>
<td></td>
</tr>
<tr>
<td>Accumulated other comprehensive loss</td>
<td>(212,736)</td>
<td></td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>91,867,863</td>
<td></td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(95,480,252)</td>
<td></td>
</tr>
<tr>
<td>Total shareholder’s (deficit) equity</td>
<td>(5,135,125)</td>
<td></td>
</tr>
<tr>
<td>Total capitalization</td>
<td>$ (5,135,125)</td>
<td>$</td>
</tr>
</tbody>
</table>

(1) Each $1.00 increase or decrease in the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, would increase or decrease the as adjusted amount of each of cash, additional paid-in capital, total shareholder's equity and total capitalization by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Each increase or decrease of 1.0 million in the number of common shares we are offering at the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions, would increase or decrease each of cash, additional paid-in capital, total shareholder's equity and total capitalization on an as adjusted basis by approximately $ million.

The number of common shares outstanding in the table above excludes:

- 9,071,750 common shares issuable upon the exercise of stock options outstanding as of June 30, 2018, with a weighted-average exercise price of $1.26 per share; and
- 2,428,250 common shares reserved for future issuance under our 2017 Equity Incentive Plan, as amended, as of June 30, 2018, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.
**Dilution**

If you invest in our common shares in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per common share and the as adjusted net tangible book value per common share of our common shares immediately after this offering. Net tangible book value (deficit) per common share is determined by dividing our total tangible assets less total liabilities by the number of outstanding common shares.

As of June 30, 2018, we had a net tangible book deficit of $(6.0) million, or $(0.08) per common share.

After giving effect to the issuance and sale of common shares in this offering at an assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2018 would have been $ million, or $ per common share. This represents an immediate increase in the as adjusted net tangible book value of $ per common share to our existing shareholder, and an immediate dilution in the as adjusted net tangible book value of $ per common share to investors purchasing our common shares in this offering. The following table illustrates this per common share dilution:

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assumed initial public offering price per common share</td>
<td>$</td>
</tr>
<tr>
<td>Net tangible book deficit per common share as of June 30, 2018</td>
<td>$(0.08)</td>
</tr>
<tr>
<td>Increase in net tangible book value per common share attributable to new investors participating in this offering</td>
<td>$</td>
</tr>
<tr>
<td>As adjusted net tangible book value per common share after this offering</td>
<td>$</td>
</tr>
<tr>
<td>Dilution per common share to investors participating in this offering</td>
<td>$</td>
</tr>
</tbody>
</table>

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our as adjusted net tangible book value as of June 30, 2018 by $ per common share, and would increase (decrease) dilution to investors in this offering by $ per common share, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us. Similarly, each increase of 1.0 million in the number of common shares offered by us would increase our as adjusted net tangible book value per common share after this offering by $ per common share and decrease the dilution to new investors by $ per common share, assuming that the assumed initial public offering price remains the same, and after deducting the underwriting discounts and commissions. A decrease of 1.0 million in the number of common shares offered by us would decrease our as adjusted net tangible book value per common share after this offering by $ per common share and increase the dilution to new investors by $ per common share, assuming that the assumed initial public offering price remains the same, and after deducting the underwriting discounts and commissions. The 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.

If the underwriters exercise their option in full to purchase an additional common shares in this offering, the as adjusted net tangible book value per common share after the offering would be $ per common share, the increase in the as adjusted net tangible book value per common share to our existing shareholder would be $ per common share and the dilution to new investors purchasing common shares in this offering would be $ per common share.
The following table sets forth as of June 30, 2018, on the as adjusted basis described above, the differences between the number of common shares purchased from us, the total consideration paid and the weighted-average price per common share paid by our existing shareholder and by investors purchasing our common shares in this offering at an assumed initial public offering price of $\_\_\_\_ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

<table>
<thead>
<tr>
<th>Shares purchased</th>
<th>Total consideration</th>
<th>Average price per common share</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Existing shareholder</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>New investors</td>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

Each $1.00 increase or decrease in the assumed initial public offering price of $\_\_\_\_ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by $\_\_\_\_ million, and increase or decrease the percent of total consideration paid by new investors by less than a quarter of a percentage point, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The table and discussion above exclude:

- 9,071,750 common shares issuable upon the exercise of stock options outstanding as of June 30, 2018, with a weighted-average exercise price of $1.26 per share; and
- 2,428,250 common shares reserved for future issuance under our 2017 Equity Incentive Plan, as amended, as of June 30, 2018, as well as any automatic increases in the number of common shares reserved for future issuance under this plan.

To the extent any additional options are issued under our equity incentive plan, or we issue additional common shares in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If 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 shareholders.
Selected consolidated financial data

The following tables set forth our selected consolidated statement of operations data for the periods indicated. We derived the consolidated statement of operations data for the years ended March 31, 2017 and 2018 and our consolidated balance sheet data as of March 31, 2017 and 2018 from our audited consolidated financial statements appearing elsewhere in this prospectus. We derived the consolidated statement of operations data for the three months ended June 30, 2018 and the consolidated balance sheet data as of June 30, 2018 from our unaudited condensed financial statements appearing elsewhere in this prospectus. We have prepared the unaudited condensed consolidated financial statements on the same basis as the audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. The data should be read together with the section titled "Management’s discussion and analysis of financial condition and results of operations" and our consolidated financial statements and related notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future, and our operating results for the years ended March 31, 2017 and 2018 and for the three months ended June 30, 2018 are not indicative of the results that may be expected for a full fiscal year or any other future period. Our fiscal year ends on March 31.

### Consolidated statement of operations data:

<table>
<thead>
<tr>
<th>Year ended March 31, 2017</th>
<th>Year ended March 31, 2018</th>
<th>Three months ended June 30, 2017</th>
<th>Three months ended June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development</td>
<td>$26,047,370</td>
<td>$32,359,078</td>
<td>$3,131,553</td>
</tr>
<tr>
<td>General and administrative</td>
<td>1,016,166</td>
<td>4,639,900</td>
<td>334,125</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td><strong>27,063,536</strong></td>
<td><strong>36,998,978</strong></td>
<td><strong>3,465,678</strong></td>
</tr>
</tbody>
</table>

| Other income (expense)   | 93,454                    | (37,467)                        | (146,711)                       | 229,361                          |
| **Loss before provision for income taxes** | **(26,970,082)**          | **(37,036,445)**                | **(3,612,389)**                 | **(31,239,675)**                 |
| Provision for income taxes | —                        | 37,229                         | 2,103                           | 55,429                           |
| **Net loss**             | $(26,970,082)             | $(37,073,674)                   | $(3,614,492)                    | $(31,295,104)                    |
| Net loss per common share—basic and diluted(1) | $(2.70)                   | $(0.58)                         | $(0.12)                         | $(0.42)                          |
| Weighted-average common shares outstanding—basic and diluted(1) | 10,000,000                | 64,136,986                      | 31,428,571                      | 75,000,000                       |

(1) See Note 2[L] to our consolidated financial statements for an explanation of the method used to compute basic and diluted net loss per common share.

### Consolidated balance sheet data:

<table>
<thead>
<tr>
<th>As of March 31, 2017</th>
<th>As of March 31, 2018</th>
<th>As of June 30, 2017</th>
<th>As of June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>$4,767,471</td>
<td>$7,193,962</td>
<td>$4,252,962</td>
</tr>
<tr>
<td>Total assets</td>
<td>4,776,099</td>
<td>12,983,456</td>
<td>11,662,384</td>
</tr>
<tr>
<td>Total liabilities</td>
<td>866,402</td>
<td>5,909,471</td>
<td>16,797,509</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(27,111,474)</td>
<td>(64,185,148)</td>
<td>(95,480,252)</td>
</tr>
<tr>
<td>Total shareholder’s (deficit) equity</td>
<td>3,909,697</td>
<td>7,073,985</td>
<td>(5,135,125)</td>
</tr>
</tbody>
</table>
Management’s discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes thereto included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled “Risk factors” for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our fiscal year ends on March 31.

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Our lead product candidate, vibegron, is an oral, once-daily, small molecule that was observed to be highly selective for the human beta-3 adrenergic receptor in in vitro assays. We are currently evaluating vibegron in our 1,400 patient, international pivotal Phase 3 clinical trial for the treatment of OAB. We expect to report top-line results from this clinical trial in the first or second quarter of 2019 and, if the results are positive, we plan to submit an NDA to the FDA by early 2020. OAB is a highly prevalent condition, with more than 30 million Americans over the age of 40 suffering from bothersome symptoms. In large, randomized, placebo-controlled, international Phase 2b and Japanese Phase 3 clinical trials in a total of over 2,600 OAB patients, vibegron 50 mg and 100 mg met all primary and secondary efficacy endpoints compared to placebo at week 8 and week 12, respectively. Our ongoing Phase 3 clinical trial has a design similar to these clinical trials. We believe vibegron, if successful in meeting the efficacy endpoints in our pivotal Phase 3 EMPOWUR trial, and if approved by the FDA, may offer a differentiated profile compared to current OAB therapies, including the potential for broader efficacy claims if the FDA approves the inclusion of urgency data, rapid onset of action data, and a single convenient once-daily dose in the label. Vibegron has been well tolerated in all clinical trials to date, has not been associated with clinically relevant drug-drug interactions, such as the inhibition of CYP2D6, and has not demonstrated a QTc signal at any of the human doses tested. In addition to OAB, we are developing vibegron for two potential additional indications, the treatment of OAB in men with BPH and the treatment of IBS-associated pain. By the end of 2018, we expect to commence a Phase 3 clinical trial for OAB in men with BPH and a Phase 2a clinical trial for IBS-associated pain. Our second product candidate, hMaxi-K, is a novel gene therapy that we are developing for patients with OAB who have failed oral pharmacological therapy. There are no currently available FDA-approved gene therapy treatments for OAB. Subject to feedback from the FDA, we plan to initiate a proof-of-concept Phase 2a clinical trial in 2019 to evaluate the safety and efficacy of hMaxi-K. We intend to continue to expand our pipeline with the goal of creating a leading urology company by developing, commercializing and acquiring innovative therapies.

We were incorporated in January 2016, and our operations to date have been limited to organizing and staffing our company, acquiring the rights to vibegron and hMaxi-K, and initiating and advancing our pivotal Phase 3 EMPOWUR trial of vibegron in patients with OAB. We have not generated any revenue and have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of vibegron, hMaxi-K and any future product candidates. We recorded a net loss of $27.0 million and $37.1 million for the years ended March 31, 2017 and 2018, respectively, and $31.3 million for the three months ended June 30, 2018. As of March 31, 2018 and June 30, 2018, we had an accumulated deficit of $64.2 million and $95.5 million, respectively. These factors raise substantial doubt about our ability to continue as a going concern.
Our operations are supported by our affiliates, RSI and RSG, each a wholly owned subsidiary of our parent company, RSL. RSI provides us with certain administrative, financial and research and development services, and RSG provides us with services in relation to the identification of potential product candidates, assistance with clinical trials and other development, administrative and financial activities, in each case, pursuant to the Services Agreements. Under the terms of the Services Agreements, we are obligated to pay or reimburse RSI and RSG for the costs they, or third parties acting on their behalf, incur in providing services to us. In addition, we are obligated to pay to RSI and RSG a pre-determined markup on costs incurred by them in connection with any general and administrative and support services as well as research and development services. Following the closing of this offering, we expect that our reliance on RSI and RSG will decrease over time as we continue to hire the necessary personnel to manage the development and potential commercialization of our current and future product candidates. See the section titled “Certain relationships and related party transactions—Affiliate services agreements” for additional information.

License and collaboration agreements

We received an exclusive license to develop, manufacture and commercialize vibegron worldwide, excluding Japan and certain other Asian territories, pursuant to our license agreement with Merck, which we entered into in February 2017. Pursuant to this agreement, we made an upfront payment of $25.0 million to Merck during the year ended March 31, 2017. Additionally, we agreed to pay Merck up to an aggregate of $44.0 million upon the achievement of certain regulatory milestone events and up to an aggregate of $80.0 million upon the achievement of certain sales milestone events. Further, we agreed to pay Merck tiered royalties in the sub-teen double-digits on net sales of licensed products made by us, our affiliates or our sublicensees, subject to standard offsets and reductions as set forth in the agreement. See the section titled “Business—License agreement with Merck” for additional information regarding our license agreement with Merck.

In June 2017, we entered into an intellectual property purchase agreement with RSG, a wholly owned subsidiary of our parent company, RSL, as amended on May 22, 2018, pursuant to which we assigned all of our rights, titles, claims and interests in and to all intellectual property rights under our license agreement with Merck to RSG, solely as it relates to any of our rights or obligations in China. In connection with this assignment, we also entered into a separate collaboration agreement with RSG in June 2018, setting forth the parties’ respective rights and obligations to each other in connection with the development of vibegron in their respective territories. See the section titled “Certain relationships and related party transactions—China intellectual property purchase agreement” for additional information.

Vibegron is also being developed by Kyorin for the treatment of OAB in Japan and certain other Asian territories. We entered into a collaboration agreement with Kyorin in August 2017. Pursuant to this agreement, our maximum obligation to Kyorin is $11.5 million, of which $1.0 million was paid during the year ended March 31, 2018. The remaining obligations under this agreement will be due upon the achievement of certain regulatory milestones by Kyorin in Japan and us in the United States, subject to certain conditions. See the section titled “Business—Collaboration agreement with Kyorin” for additional information regarding our collaboration agreement with Kyorin.

We received an exclusive license to develop, manufacture and commercialize hMaxi-K worldwide, pursuant to our license agreement with ICI, which we entered into in August 2018. Pursuant to this agreement, we made an upfront payment of $250,000 to ICI during the year ending March 31, 2019. Additionally, we agreed to pay ICI up to an aggregate of $35.0 million upon the achievement of certain development and regulatory milestone events and up to an aggregate of $60.0 million upon the achievement of certain sales milestone events. Further, we agreed to pay ICI tiered royalties in the mid-to-high single digits on net sales of licensed products made by us, our affiliates or our sublicensees, subject to certain reductions. See the section titled “Business—License agreement with Ion Channel Innovations” for additional information regarding our license agreement with ICI.
Financial operations overview

Revenue

We currently do not have any products approved for sale and have not generated any revenue since inception. If we are able to successfully develop, receive regulatory approval for and commercialize any of our current or future product candidates alone or in collaboration with third parties, we may generate revenue from the sales of these product candidates.

Research and development expenses

Our research and development expenses have primarily been limited to the license of the rights to vibegron and hMaxi-K. Our research and development expenses for the year ended March 31, 2018 and three months ended June 30, 2018 were $32.4 million and $28.0 million, respectively, and consisted primarily of research and development expenses for our international pivotal Phase 3 EMPOWUR trial for the treatment of OAB, share-based compensation expense and costs allocated under the Services Agreements, including third-party costs. Our research and development expenses for the year ended March 31, 2017 were $26.0 million and consisted primarily of in-process research and development expenses under our license agreement with Merck of $25.0 million in February 2017, share-based compensation expense and costs allocated under the Services Agreements, including third-party costs. Following the closing of this offering, we expect to significantly increase our research and development efforts as we advance our ongoing Phase 3 EMPOWUR trial for the treatment of OAB, and initiate and advance our planned Phase 3 clinical trial of vibegron for the treatment of OAB in men with BPH, our planned Phase 2a clinical trial of vibegron for the treatment of IBS-associated pain and our planned Phase 2a clinical trial for hMaxi-K for the treatment of OAB in patients who have not responded to oral pharmacological therapies. Research and development expenses will include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expense for our research and development personnel;
- costs allocated to us under the Services Agreements and share-based compensation expense allocated to us from RSL;
- direct third-party costs (as well as third-party pass-through costs from RSL) such as expenses incurred under agreements with CROs, and contract manufacturing organizations, or CMOs, the cost of consultants who assist with the development of vibegron on a program-specific basis, investigator grants, sponsored research, manufacturing costs in connection with producing materials for use in conducting nonclinical studies and clinical trials, and other third-party expenses directly allocatable to the development of our product candidates;
- other expenses, which include the costs of consultants who assist with research and development activities not specific to a program; and
- depreciation expense for assets used in research and development activities.

Research and development activities will continue to be central to our business model. Product candidates in later stages of clinical development, such as vibegron, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to be significant over the next several years as we advance the clinical development of vibegron and prepare to seek regulatory approval. It is difficult to determine with certainty the duration and completion costs of any clinical trial we may conduct.
The duration, costs and timing of clinical trials of our current and future product candidates will depend on a variety of factors that include, but are not limited to: the number of trials required for approval; the per patient trial costs; the number of patients that participate in the trials; the number of sites included in the trials; the countries in which the trial is conducted; the length of time required to enroll eligible patients; the number of doses that patients receive; the drop-out or discontinuation rates of patients; the potential additional safety monitoring or other studies requested by regulatory agencies; the duration of patient follow-up; the timing and receipt of regulatory approvals; the costs of clinical trial material; and the efficacy and safety profile of the product candidate.

**General and administrative expense**

General and administrative expenses consist primarily of legal and accounting fees relating to our formation and corporate matters, consulting services, services received under the Services Agreements, and employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for general and administrative personnel.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, potential commercialization efforts and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the SEC, insurance and investor relations costs. If any of our current or future product candidates obtains U.S. regulatory approval, we expect that we would incur significantly increased expenses associated with building a sales and marketing team.

**Results of operations for the three months ended June 30, 2017 and 2018**

The following table sets forth our results of operations for the three months ended June 30, 2017 and 2018.

<table>
<thead>
<tr>
<th>Three months ended June 30,</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>$3,131,553</td>
<td>$27,964,780</td>
</tr>
<tr>
<td>General and administrative</td>
<td>334,125</td>
<td>3,504,256</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>3,465,678</td>
<td>31,469,036</td>
</tr>
<tr>
<td>Other income (expense)</td>
<td>(146,711)</td>
<td>229,361</td>
</tr>
<tr>
<td>Loss before provision for income taxes</td>
<td>(3,612,389)</td>
<td>(31,239,675)</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>2,103</td>
<td>55,429</td>
</tr>
<tr>
<td>Net loss</td>
<td>($3,614,492)</td>
<td>($31,295,104)</td>
</tr>
</tbody>
</table>

**Research and development expenses**

Research and development expenses increased by $24.8 million, to $28.0 million, for the three months ended June 30, 2018 compared to the three months ended June 30, 2017, primarily due to increases in expenses for the advancement of our Phase 3 EMPOWUR trial for the treatment of OAB, as well as employee-related expenses due to our increased headcount to support our clinical operations. Research and development expenses for the three months ended June 30, 2018 primarily consisted of program-specific research and development costs for vibegron of $24.4 million, which includes CRO costs of $23.0 million, chemistry, manufacturing and controls costs of $0.7 million, and other third-party research and development costs of
$0.7 million. The remainder consisted primarily of unallocated personnel-related costs of $0.7 million, share-based compensation expense for stock options granted to employees of $0.1 million, share-based compensation expense of $0.4 million allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters, and costs of $2.0 million billed to us under the Services Agreements, including personnel and third-party costs.

Research and development expenses were $3.1 million for the three months ended June 30, 2017 and consisted primarily of program-specific research and development costs for vibegron of $0.8 million, which includes CRO costs of $0.6 million and chemistry, manufacturing and controls costs of $0.2 million. The remainder consisted primarily of unallocated share-based compensation expense of $0.8 million allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters, and costs of $1.5 million billed to us under the Services Agreements, including personnel and third-party costs.

**General and administrative expenses**

General and administrative expenses increased by $3.2 million, to $3.5 million, for the three months ended June 30, 2018 compared to the three months ended June 30, 2017, primarily due to an increase in employee salaries and benefits resulting from increased headcount to support our operations, as well as an increase in legal and other professional fees. General and administrative expenses for the three months ended June 30, 2018 consisted primarily of personnel-related costs of $1.3 million, share-based compensation expense for stock options granted to employees, board members and consultants of $0.2 million, share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters of $0.1 million, legal and other professional and consulting fees of $0.9 million, and costs of $0.8 million billed to us under the Services Agreements, including personnel costs, overhead allocations and third-party costs. The remainder consisted primarily of general overhead expenses.

General and administrative expenses were $0.3 million for the three months ended June 30, 2017 and consisted primarily of share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters of approximately $40,000, and costs of $0.2 million billed to us under the Services Agreements, including personnel costs, overhead allocations and third-party costs. The remainder consisted primarily of legal and other professional fees.

**Results of operations for the years ended March 31, 2017 and 2018**

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

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>$26,047,370</td>
<td>$32,359,078</td>
</tr>
<tr>
<td>General and administrative</td>
<td>1,016,166</td>
<td>4,639,900</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>27,063,536</td>
<td>36,998,978</td>
</tr>
<tr>
<td><strong>Other income (expense)</strong></td>
<td>93,454</td>
<td>(37,467)</td>
</tr>
<tr>
<td>Loss before provision for income taxes</td>
<td>(26,970,082)</td>
<td>(37,036,445)</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>—</td>
<td>37,229</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>$ (26,970,082)</td>
<td>$(37,073,674)</td>
</tr>
</tbody>
</table>

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Research and development expenses

Research and development expenses increased by $6.4 million, to $32.4 million, for the year ended March 31, 2018 compared to the year ended March 31, 2017, primarily due to increases in expenses for the commencement of our Phase 3 EMPOWUR trial for the treatment of OAB. Research and development expenses for the year ended March 31, 2018 primarily consisted of research and development expenses of $23.7 million for our clinical trial, which includes CRO costs of $16.7 million, chemistry, manufacturing and controls costs of $4.5 million, and other third-party research and development costs associated with our clinical trial of $2.5 million, share-based compensation expense of $2.5 million allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters, and costs of $5.2 million billed to us under the Services Agreements, including personnel and third-party costs. Research and development expenses were $26.0 million for the year ended March 31, 2017, and consisted primarily of in-process research and development expenses of $25.0 million under our license agreement with Merck, share-based compensation expense of $0.4 million allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters, and costs of $0.6 million billed to us under the Services Agreements, including personnel and third-party costs.

General and administrative expenses

General and administrative expenses increased by $3.6 million, to $4.6 million, for the year ended March 31, 2018 compared to the year ended March 31, 2017, primarily due to an increase in employee salaries and benefits resulting from increased headcount to support our operations. General and administrative expenses for the year ended March 31, 2018 consisted primarily of personnel-related costs of $1.5 million, share-based compensation expense for stock options granted to employees and consultants of $0.4 million, share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters of $0.3 million, and costs of $1.1 million billed to us under the Services Agreements, including personnel costs, overhead allocations and third-party costs. The remainder consisted primarily of legal and other professional and consulting fees. General and administrative expenses were $1.0 million for the year ended March 31, 2017, and consisted primarily of share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters of $0.4 million, and costs of $0.4 million billed to us under the Services Agreements, including personnel costs, overhead allocations and third-party costs. The remainder consisted primarily of legal and other professional fees.

Liquidity and capital resources

Overview

For the year ended March 31, 2018 and the three months ended June 30, 2018, we had a net loss of $37.1 million and $31.3 million, respectively. As of June 30, 2018, we had an accumulated deficit of $95.5 million and a cash balance of $4.3 million, as compared to $64.2 million and $7.2 million, respectively, as of March 31, 2018, and we have never generated any revenue. All operations to date have been financed through capital contributions or short-term advances from RSL or its affiliates.

We expect to continue to incur significant and increasing operating losses at least for the next several years. We do not expect to generate product revenue until we successfully complete development and obtain regulatory approval for any of our current or future product candidates, which may never occur. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned
clinical trials, our expenditures on other research and development activities and our pre-commercialization efforts. We anticipate that our expenses will increase substantially as we:

- advance our Phase 3 EMPOWUR trial of vibegron for the treatment of OAB;
- initiate and advance our planned Phase 3 trial of vibegron for the treatment of OAB in men with BPH;
- initiate and advance our planned Phase 2a trial of vibegron for the treatment with IBS-associated pain;
- initiate and advance our planned Phase 2a clinical trial for hMaxi-K for the treatment of OAB in patients who have not responded to oral pharmacological therapies;
- seek to identify, acquire, develop and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our drug development efforts;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval; and
- begin to operate as a public company.

We intend to use the proceeds of this offering primarily to fund the clinical development of vibegron for our three current target indications, the treatment of OAB, OAB in men with BPH and IBS-associated pain, as well as the clinical development of hMaxi-K for the treatment of OAB in patients who have not responded to oral pharmacological therapies. We will need additional funding to complete the clinical development of, seek regulatory approval for and, if approved, commercially launch vibegron and hMaxi-K in these indications.

Until such time, if ever, as we can generate substantial product revenue from sales of any of our current or future product candidates, we expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaboration, license or development agreements. 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 a common shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations.
Table of Contents

Cash flows
The following table sets forth a summary of our cash flows for the years ended March 31, 2017 and 2018 and the three months ended June 30, 2017 and 2018:

<table>
<thead>
<tr>
<th></th>
<th>Year ended March 31, 2017</th>
<th>Year ended March 31, 2018</th>
<th>Three months ended June 30, 2017</th>
<th>Three months ended June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net cash used in operating activities</td>
<td>$(25,256,375)</td>
<td>$(34,086,438)</td>
<td>$(600,597)</td>
<td>$(20,760,483)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>—</td>
<td>$(521,986)</td>
<td>—</td>
<td>$(115,367)</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>30,023,846</td>
<td>37,034,915</td>
<td>34,882</td>
<td>17,934,850</td>
</tr>
</tbody>
</table>

Operating activities
For the year ended March 31, 2018, $34.1 million of cash was used in operating activities. This was primarily attributable to a net loss of $37.1 million and an increase of $5.2 million in prepaid expenses and other current assets. These amounts were partially offset by an increase of $4.4 million in accounts payable and accrued expenses primarily due to the commencement of our Phase 3 EMPOWUR trial, $0.4 million in share-based compensation expense from stock options granted to employees and consultants, $2.8 million in share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters, and an increase of $0.6 million in amounts due to RSL based on the allocation of personnel expenses associated with the formation of our company, development of our product pipeline and corporate matters.

For the year ended March 31, 2017, $25.3 million of cash was used in operating activities. This was primarily attributable to a net loss of $27.0 million which was offset primarily by $0.9 million in share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters and an increase of $0.8 million in amounts due to RSL based on the allocation of personnel expenses associated with the formation of our company, development of our product pipeline and corporate matters.

For the three months ended June 30, 2018, $20.8 million of cash was used in operating activities. This was primarily attributable to a net loss of $31.3 million and an increase of $0.7 million in prepaid expenses and other current assets. These amounts were partially offset by an increase of $9.4 million in accounts payable and accrued expenses primarily due to the advancement of our Phase 3 EMPOWUR trial, $0.3 million in share-based compensation expense from stock options granted to employees, board members and consultants, $0.5 million in share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters, and an increase of $1.2 million in amounts due to RSL based on the allocation of personnel expenses associated with the development of our product pipeline and corporate matters.

For the three months ended June 30, 2017, $0.6 million of cash was used in operating activities. This was primarily attributable to a net loss of $3.6 million and an increase of $0.2 million in prepaid expenses and other current assets. These amounts were partially offset primarily by an increase of $0.7 million in accounts payable and accrued expenses, $0.9 million in share-based compensation expense allocated to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters and an increase of $1.5 million in amounts due to RSL based on the allocation of personnel expenses associated with the formation of our company, development of our product pipeline and corporate matters.

Investing activities
For the year ended March 31, 2018, $0.5 million of cash was used in investing activities, all for the purchases of property and equipment.
For the year ended March 31, 2017, there were no cash flows from investing activities.

For the three months ended June 30, 2018, $0.1 million of cash was used in investing activities, all for the purchases of property and equipment.

For the three months ended June 30, 2017, there were no cash flows from investing activities.

**Financing activities**

For the year ended March 31, 2018, cash provided by financing activities of $37.0 million was attributable to capital contributions from RSL.

For the year ended March 31, 2017, cash provided by financing activities of $30.0 million was attributable to capital contributions from RSL.

For the three months ended June 30, 2018, cash provided by financing activities of $17.9 million was primarily attributable to capital contributions from RSL of $18.5 million which was offset by payments for our initial public offering costs of $0.6 million.

For the three months ended June 30, 2017, cash provided by financing activities of approximately $35,000 was attributable to capital contributions from RSL.

**Outlook**

Based on the expected net proceeds from this offering, our research and development plans and our timing expectations related to the development of our clinical programs for vibegron and hMaxi-K, we expect that the net proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements through at least . However, we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect.

**Contractual obligations and commitments**

As of March 31, 2018, we did not have any ongoing material financial commitments, such as lines of credit or guarantees that we expect to affect our liquidity over the next several years.

We enter into agreements in the normal course of business with CROs for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are cancelable at any time by us, subject to payment of our remaining obligations under binding purchase orders and, in certain cases, nominal early termination fees, generally upon 30 days’ prior written notice. These payments are not included in the table of contractual obligations below.

As of March 31, 2018, we had contractual obligations for operating lease obligations, as summarized in the table that follows:

<table>
<thead>
<tr>
<th>Payments Due by Period</th>
<th>Total</th>
<th>Less than 1 Year</th>
<th>1-3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease obligations(1)</td>
<td>$370,000</td>
<td>$193,000</td>
<td>$177,000</td>
</tr>
</tbody>
</table>

(1) In December 2017, we entered into a non-cancelable operating sub-lease for 8,038 square feet of office space through February 2020 in Irvine, California.

**License and collaboration agreements**

We have also entered into license and collaboration agreements with third parties in the normal course of business. We have not included these future payments in a table of contractual obligations because the
payment obligations under these license and collaboration agreements are contingent upon future events such as achievement of specified regulatory and commercial milestones, or royalties on net product sales. As of March 31, 2018, the aggregate maximum amount of milestone payments we could be required to make under our license agreement with Merck was $124 million and our collaboration agreement with Kyorin was $10.5 million. As of March 31, 2018, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. See the sections titled “Business—License agreement with Merck” and “—Collaboration agreement with Kyorin” for additional information regarding these agreements.

Our contractual obligations under our license agreements have not materially changed outside the ordinary course of our business since March 31, 2018, however, in August 2018, we entered into a new license agreement with ICI. Pursuant to this license agreement, the aggregate maximum amount of milestone payments we could be required to make is $95 million. See the section titled “Business—License agreement with Ion Channel Innovations” for additional information regarding this agreement.

Supply agreement
As of March 31, 2018, under our enzyme supply agreement, we could be required to make minimum purchase commitments of up to $3.75 million and a milestone payment of $0.5 million. We are unable to estimate the timing or likelihood of the payments under this agreement as the financial commitment is subject to the first regulatory approval of vibegron in any of the United States, Europe or Canada.

Off-balance sheet arrangements
During the years ended March 31, 2017 and 2018 and the three months ended June 30, 2018, we did not have any off-balance sheet arrangements, as defined under SEC rules.

Critical accounting policies and significant judgments and estimates
Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. Significant estimates include assumptions used in the determination of some of our costs incurred under our Services Agreements and which costs are charged to research and development and general and administrative expense. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this prospectus, we believe the following are the critical accounting policies used in the preparation of our consolidated financial statements that require significant estimates and judgments.

Share-based compensation
We recognize share-based compensation expense related to stock options granted to employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting
share-based compensation expense, for stock options that only have service vesting requirements or performance-based vesting requirements without market conditions using the Black-Scholes option-pricing model. The grant date fair value of the share-based awards with service vesting requirements is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed. For performance-based awards with market conditions, we determine the fair value of awards as of the grant date using a Monte Carlo simulation model.

We recognize share-based compensation expense related to stock options granted to non-employees issued in exchange for services based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model; however, the fair value of the stock options granted to non-employees is remeasured each reporting period until the service is complete, and the resulting increase or decrease in value, if any, is recognized as expense or a reduction in previously recognized expense, respectively, during the period the related services are rendered.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions, which determine the fair value of share-based awards. These assumptions include:

- **Expected term.** Our expected term represents the period that our share-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term). For share-based awards granted to non-employees, the expected term represents the contractual term of the award.

- **Common share price.** Our board of directors estimates the fair value of our common shares. Given the absence of a public trading market for our common shares, and in accordance with the American Institute of Certified Public Accountants’ Practice Guide, *Valuation of Privately Held-Company Equity Securities Issued as Compensation*, our board of directors exercises reasonable judgment and considers a number of objective and subjective factors to determine its best estimate of the fair value of our common shares, as further described below under “—Common share valuations.”

- **Expected volatility.** Prior to this offering we were a privately held company and did not have any trading history for our common shares and the expected volatility was estimated using weighted-average measures of implied volatility and the historical volatility of our peer group of companies for a period equal to the expected life of the stock options. Our peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty.

- **Risk-free interest rate.** The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the stock options.

- **Expected dividend.** We have never paid, and do not anticipate paying, cash dividends on our common shares. Therefore, the expected dividend yield was assumed to be zero.

In addition to the Black-Scholes assumptions, we adopted ASU 2016-09 on April 1, 2017 and as a result, we have made an entity-wide accounting policy election to account for pre-vesting award forfeitures when they occur.

A significant component of total share-based compensation expense relates to the RSL common share awards and RSL options issued by RSL to RSL, RSG and RSI employees. Share-based compensation expense is allocated...
to us by RSL based upon the relative percentage of time utilized by employees of RSL, RSG and RSI on our matters. The RSL common share awards and RSL options are fair valued on the date of grant and that fair value is recognized over the requisite service period. As RSL is a non-public entity, the RSL common share awards and RSL options are classified as Level 3 due to their unobservable nature. Significant judgment and estimates were used to estimate the fair value of these awards and options, as they are not publicly traded. RSL common share awards and RSL options are subject to specified vesting schedules and requirements (a mix of time-based and performance-based events). The fair value of each RSL common share award is based on various corporate event-based considerations, including targets for RSL’s post-IPO market capitalization and future financing events. The fair value of each RSL option on the date of grant is estimated using the Black-Scholes closed-form option-pricing model.

Common share valuations

Prior to this offering, the fair value of our common shares was estimated on each grant date by our board of directors. In order to determine the fair value of our common shares, our board of directors considered, among other things, timely valuations of our common shares prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately Held-Company Equity Securities Issued as Compensation. Given the absence of a public trading market for our common shares, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common shares, including (1) our business, financial condition and results of operations, including related industry trends affecting our operations; (2) our forecasted operating performance and projected future cash flows; (3) the illiquid nature of our common shares; (4) the rights and privileges of our common shares; (5) market multiples of our most comparable public peers and (6) market conditions affecting our industry.

After the closing of this offering, our board of directors will determine the fair value of each common share underlying share-based awards based on the closing price of our common shares as reported by the on the date of grant.

Based upon the assumed initial public offering price of $ per common share, the midpoint of the price range set forth on the cover of this prospectus, the aggregate intrinsic value of outstanding options to purchase our common shares as of June 30, 2018 was $ million, of which $ million related to vested options and $ million related to unvested options.

Research and development expense

Research and development costs are expensed as incurred. Clinical trial costs are accrued over the service periods specified in the contracts and adjusted as necessary based upon an ongoing review of the level of effort and costs actually incurred. Payments for a product license prior to regulatory approval of the product and payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of product sales over the remaining useful life of the asset. Research and development costs are charged to expense when incurred and primarily consist of the intellectual property and research and development materials acquired and expenses from third parties who conduct research and development activities on our behalf.

We have evaluated the in-license agreement of vibegron from Merck based on the applicable guidance in ASC No. 805, Business Combinations, and have determined that the in-process research and development asset, or IPR&D, licensed did not meet the definition of a business and thus the transaction was not considered a business combination. We then evaluated, pursuant to ASC 730, Research and Development, whether the IPR&D asset had an alternative future use and concluded it did not. As a result, we recorded the upfront license
payment of $25.0 million as research and development expense upon entry into the license agreement with Merck.

**Income taxes**

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of March 31, 2018 and June 30, 2018, we did not have any significant uncertain tax positions.

**Recent accounting pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, or ASU No. 2016-02, which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 will require lessees to present the assets and liabilities that arise from leases on their consolidated balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. We are currently evaluating the new standard and its impact on our consolidated financial position, results of operations and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, or ASU No. 2016-09. This ASU makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the consolidated financial statement presentation of excess tax benefits or deficiencies. ASU No. 2016-09 also clarifies the consolidated statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. We adopted this guidance on April 1, 2017 and the adoption of ASU No. 2016-09 did not have a significant impact on our consolidated financial position, results of operations and related disclosures.

In October 2016, the FASB issued ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*, or ASU No. 2016-16, which eliminates the exception in existing guidance which defers the recognition of the tax effects of intra-entity asset transfers other than inventory until the transferred asset is sold to a third party. Rather, the amended guidance requires an entity to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. This guidance is effective for interim and annual periods beginning after December 15, 2017, with early adoption permitted as of the beginning of an annual reporting period. Entities must apply the guidance on a modified retrospective basis though a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. The adoption of ASU 2016-16 on April 1, 2018 did not have a material impact on our consolidated financial position, results of operations and related disclosures.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, or ASU No. 2017-01, which clarifies the definition of a business with the objective of adding guidance
to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU No. 2017-01 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. We will apply the guidance to applicable transactions after the adoption date. The impact on our consolidated financial position, results of operations and related disclosures will depend on the facts and circumstances of any specific future transactions.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement-Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, or ASU No. 2018-02, which allows companies to reclassify stranded tax effects resulting from the Tax Cuts and Jobs Act, from accumulated other comprehensive (loss) income to retained earnings. ASU No. 2018-02 is effective for interim and annual reporting periods beginning after December 15, 2017 and early adoption is permitted. The adoption of ASU 2018-02 on April 1, 2018 did not have a material impact on our consolidated financial position, results of operations and related disclosures.

In March 2018, the FASB issued ASU No. 2018-05, Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118, or ASU No. 2018-05, which amends certain SEC material in ASC Topic 740 Income Taxes for the income tax accounting implications of the recently issued Tax Cuts and Jobs Act. ASU No. 2018-05 is effective immediately. We evaluated the impact of the Tax Cuts and Jobs Act, as well as the guidance of Staff Accounting Bulletin No. 118 and incorporated the changes into the determination of a reasonable estimate of deferred taxes and appropriate disclosures in the notes to our consolidated financial statements. We will continue to evaluate the impact this tax reform legislation may have on our consolidated financial position, results of operations and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting, or ASU No. 2018-07, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU No. 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. Entities must apply the guidance retrospectively with a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. We are currently evaluating the new standard and its impact on our consolidated financial position, results of operations and related disclosures.

JOBS Act

The JOBS Act was enacted in April 2017. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Quantitative and qualitative disclosures about market risk

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency rates and changes in the market value of equity instruments. As of March 31, 2018 and June 30, 2018, we had cash of $7.2 million and $4.3 million, respectively, consisting of non-interest-bearing deposits denominated in the U.S. dollar and Swiss franc. We do not believe we are currently exposed to any material market risk.
Business

Overview
We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Our lead product candidate, vibegron, is an oral, once-daily, small molecule that was observed to be highly selective for the human beta-3 adrenergic receptor in in vitro assays. We are currently evaluating vibegron in our 1,400 patient, international pivotal Phase 3 clinical trial for the treatment of overactive bladder, or OAB. We expect to report top-line results from this clinical trial in the first or second quarter of 2019, and if the results are positive, we plan to submit a new drug application to the U.S. Food and Drug Administration, or FDA, by early 2020. OAB is a highly prevalent condition, with more than 30 million Americans over the age of 40 suffering from bothersome symptoms. In large, randomized, placebo-controlled, international Phase 2b and Japanese Phase 3 clinical trials in a total of over 2,600 OAB patients, vibegron 50 mg and 100 mg met all primary and secondary efficacy endpoints compared to placebo at week 8 and week 12, respectively. We believe vibegron, if successful in meeting the efficacy endpoints in our pivotal Phase 3 EMPOWUR trial, and if approved by the FDA, may offer a differentiated profile compared to current OAB therapies, including the potential for broader efficacy claims if the FDA approves the inclusion of urgency data, rapid onset of action data, and a single convenient once-daily dose in the label. Vibegron has been well tolerated in all clinical trials to date, has not been associated with clinically relevant drug-drug interactions, such as the inhibition of CYP2D6, and has not demonstrated a QTc signal at any of the human doses tested. Our ongoing Phase 3 clinical trial has a design similar to these clinical trials. In addition to OAB, we are developing vibegron for two additional potential indications, the treatment of OAB in men with benign prostatic hyperplasia, or BPH, and the treatment of pain associated with irritable bowel syndrome, or IBS. By the end of 2018, we expect to commence a Phase 3 clinical trial for OAB in men with BPH and a Phase 2a clinical trial for IBS-associated pain. Our second product candidate, hMaxi-K, is a novel gene therapy that we are developing for patients with OAB who have failed oral pharmacological therapy. There are no currently available FDA-approved gene therapy treatments for OAB. Subject to feedback from the FDA, we intend to initiate a proof-of-concept Phase 2a clinical trial to evaluate the safety and efficacy of hMaxi-K in 2019. We intend to continue to expand our pipeline with the goal of creating a leading urology company by developing, commercializing and acquiring innovative therapies.

OAB is a clinical condition characterized by the sudden urge to urinate that is difficult to control, referred to as urgency, with or without accidental urinary leakage, and usually with increased frequency of urination. Accidental urinary leakage resulting from urgency is referred to as urge urinary incontinence, or UUI. Increases in age and body mass index, as well as diabetes and post-menopausal status, are known to increase the risk of developing OAB. Symptoms of OAB can have a debilitating impact on psychosocial functioning and quality of life, profoundly impacting normal social and occupational activities and leading to depression, anxiety and decreased sexual function and marital satisfaction. In 2017, over 19 million prescriptions were written for OAB medications in the United States. Current prescription pharmacological therapies for OAB consist of anticholinergic drugs and a beta-3 agonist.

Anticholinergic drugs have been the standard of pharmacologic care for OAB for decades; however, these drugs are associated with poor tolerability and increasing safety concerns, including increased dementia risk. Of the OAB patients prescribed anticholinergic drugs, 71% fail treatment within six months. In 2012, mirabegron (Myrbetriq), a beta-3 agonist, became the first drug other than an anticholinergic approved by the FDA for the treatment of OAB. Mirabegron remains the sole beta-3 agonist on the market for OAB, and since its approval, it has continued to take U.S. OAB prescription share from anticholinergics, primarily due to its safety and tolerability advantages. Despite its success, mirabegron requires dose titration that results in a slow onset of action and is associated with frequent drug-drug interactions and QTc prolongation.
We believe vibegron, if successful in meeting the efficacy endpoints in our pivotal Phase 3 EMPOWUR trial, and if approved by the FDA, has the potential to address the limitations of current OAB treatment options and become a differentiated beta-3 agonist. In large, randomized, placebo-controlled, international Phase 2b and Japanese Phase 3 clinical trials, vibegron 50 mg and 100 mg demonstrated statistically significant improvements compared to placebo on all primary and secondary efficacy endpoints at week 8 and week 12, respectively. These endpoints included reductions per day in number of urinations, or micturitions, urgency episodes, UUI episodes and total incontinence episodes. In addition, vibegron has demonstrated an onset of action in as early as two weeks in the international Phase 2b clinical trial and has been well tolerated in all trials conducted to date. Unlike the anticholinergic class of drugs, there is no evidence to date linking the use of beta-3 agonists with increased risk of dementia. Unlike mirabegron, vibegron is not an inhibitor of the CYP2D6 enzyme, an important enzyme involved in the metabolism of numerous drugs, thereby reducing the risk of potentially harmful drug-drug interactions. Further, in a thorough QTc study, vibegron showed no QTc prolongation at therapeutic or supratherapeutic doses. QTc prolongation refers to the lengthening of the QT interval in an electrocardiogram, during which interval, the heart recovers from one heartbeat and is preparing for the next heartbeat. The QT interval is a very vulnerable phase in the electric cycle of the heart, and prolongation of this interval may lead to serious and potentially life-threatening tachyarrhythmias, or very fast and irregular heartbeats that are not sufficient to support the function of the heart.

We received an exclusive license to develop, manufacture and commercialize vibegron worldwide, excluding Japan and certain other Asian territories, pursuant to our license agreement with Merck Sharp & Dohme Corp., or Merck, which we entered into in February 2017. We expect to maintain patent exclusivity for the licensed patents and applications, if approved, under this license agreement covering composition of matter and methods of use and manufacture of vibegron until approximately 2034, including through grant of patent term extension. Vibegron is also being developed by Kyorin Pharmaceutical Co., Ltd., or Kyorin, for the treatment of OAB in Japan and certain other Asian territories. Kyorin submitted a marketing application for vibegron to the Japan Pharmaceuticals and Medical Devices Agency, or PMDA, in September 2017.

We received an exclusive license to develop, manufacture and commercialize hMaxi-K worldwide, pursuant to our license agreement with Ion Channel Innovations, LLC, or ICI, which we entered into in August 2018. Pursuant to this agreement, we are the exclusive licensee of a pending international patent application relating to hMaxi-K gene therapy, covering the use of hMaxi-K gene therapy to treat signs or symptoms of OAB or detrusor overactivity. This patent application, if issued, would naturally expire in 2038, subject to any adjustment or extension of patent term that may be available in a particular country. In addition, we expect that hMaxi-K would receive 12 years of marketing exclusivity if approved by the FDA given its status as a biological product.

Our experienced management team is led by our Chief Executive Officer, Keith A. Katkin, who previously served as President and Chief Executive Officer of Avanir Pharmaceuticals, Inc., or Avanir, through its acquisition by Otsuka Pharmaceutical Co., Ltd. in 2015. Our Chief Medical Officer, Cornelia Haag-Molkenteller, M.D., Ph.D., previously served as the Therapeutic Area Head in Global Clinical Development for Women’s Health, Internal Medicine and Anti-Infectives and Urology at Allergan plc, or Allergan, where she led the clinical development of onabotulinumtoxinA (BOTOX) for OAB and neurogenic detrusor overactivity. Our Chief Commercial Officer, Michael McFadden, led sales and marketing efforts at Avanir and sales and payor efforts at Amylin Pharmaceuticals Inc., where he helped launched two first-in-class diabetes products. Together, the members of our management team have helped launch over 20 prescription products.
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Our strategy

Our goal is to be a leading urology company by developing, commercializing and acquiring innovative therapies. The key elements of our strategy to achieve this goal include:

• **Complete the development and obtain FDA approval of vibegron for the treatment of OAB.** In March 2018, we initiated a 1,400 patient, international pivotal Phase 3 clinical trial of vibegron for OAB, which we refer to as the EMPOWUR trial. We expect to report top-line results from this trial in the first or second quarter of 2019, and if these results are positive, we plan to submit a new drug application, or NDA, to the FDA by early 2020.

• **Expand the clinical development of vibegron for additional indications.** We plan to initiate a Phase 3 clinical trial of vibegron for OAB in men with BPH and a Phase 2a clinical trial of vibegron for IBS-associated pain by the end of 2018. Both of these potential indications present significant additional commercial opportunities to treat millions of patients in the United States. There are currently no FDA-approved drugs specifically for either of these indications.

• **Maximize the commercial potential of vibegron.** We intend to build a 300 to 400 person sales organization in the United States, targeting high-prescribing urologists, primary care physicians and other specialists that treat high numbers of patients with urologic conditions. We believe these physicians treat a majority of OAB patients and most often serve as the diagnosing and treating physicians for OAB. We believe that our commercial leadership team, with experience launching over 20 prescription products, positions us well to efficiently pursue the significant market opportunity for vibegron in the United States. We may opportunistically seek strategic collaborations to maximize the commercial opportunities for vibegron inside and outside the United States.

• **Advance the clinical development of hMaxi-K as a novel treatment for OAB patients who have not responded to oral pharmacological therapies.** Subject to feedback from the FDA, we intend to initiate a Phase 2a clinical trial of hMaxi-K in OAB patients who have not responded to other pharmacological therapies. With only two non-surgical therapies currently available for the treatment of OAB, BOTOX and neuromodulation, we believe there is an opportunity to both capture market share and expand the OAB third-line therapy market. Approximately 14 million Americans seek treatment from their physician for OAB and, of these patients, only an estimated 3.3 million patients take prescription therapy and only 300,000 patients utilize current third-line procedural therapies. We estimate that third-line treatments generate aggregate annual sales in excess of $700 million in the U.S. market. We believe a third-line treatment option that is non-surgical and not a toxin, unlike BOTOX, would be appealing to physicians and patients, potentially meeting the unmet needs of this patient population.

• **Acquire or in-license additional clinical- or commercial-stage product candidates for the treatment of urologic conditions in a capital-efficient manner.** Through focused business development efforts, we intend to identify and acquire or in-license additional innovative therapies for urologic conditions. Our initial focus is on conditions that are predominantly treated by urologists. Our parent company, Roivant Sciences Ltd., or RSL, and its subsidiaries have a track record of acquiring or in-licensing products in a range of therapeutic areas and will continue to support us in identifying and evaluating potential acquisition and in-licensing opportunities.
Our development program

The following chart sets forth our development programs and upcoming milestones:

<table>
<thead>
<tr>
<th>DRUG CANDIDATE</th>
<th>INDICATION</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>UPCOMING MILESTONE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vibegron</td>
<td>Overactive Bladder (OAB)</td>
<td></td>
<td></td>
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<td>Phase 3 Top-Line Data Q1/Q2 2019</td>
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<td></td>
<td>OAB In Men with BPH</td>
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<td>Phase 3 Initiation 2018¹</td>
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<td>IBS-Pain</td>
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<td>Phase 2a Initiation 2018²</td>
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<td>hMaxi-K DNA</td>
<td>OAB</td>
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<td></td>
<td>Phase 2a Initiation 2019⁴</td>
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<tr>
<td>Gene Therapy</td>
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</tr>
</tbody>
</table>

¹. Subject to feedback from the FDA.
². Pending submission of an IND to the FDA in this indication.

Vibegron for the treatment of overactive bladder

Overactive bladder overview

OAB is a clinical condition characterized by the sudden urge to urinate that is difficult to control, referred to as urgency, with or without accidental urinary leakage, and usually with increased frequency of urination. Accidental urinary leakage resulting from urgency is referred to as urge urinary incontinence, or UUI. Increases in age and body mass index, as well as diabetes and post-menopausal status, are known to increase the risk of developing OAB. Symptoms of OAB can have a debilitating impact on psychosocial functioning and quality of life, profoundly impacting normal social and occupational activities and leading to depression, anxiety and decreased sexual function and marital satisfaction. UUI, in particular, may have severe psychological and social consequences, resulting in restricted activities and unwillingness to be exposed to environments where access to a bathroom may be difficult. The OAB patient experience is depicted below.

![OAB Patient Experience Diagram](image-url)
OAB presents a significant burden on healthcare systems. A recent study found that healthcare costs among OAB patients in the United States were 1.4- to 2-times higher than individuals without OAB, and these costs may be substantially driven by managing complications such as falls, urinary tract infections, skin rash and depression or anxiety.

**Current treatment paradigm**

More than 30 million Americans over the age of 40 suffer from bothersome symptoms of OAB. Approximately 46% of this population, or 14 million people, talk to their physicians about their symptoms. Behavioral therapies such as bladder training, pelvic floor muscle training and fluid management are recommended as first-line treatment for OAB. Second-line treatment consists of prescription pharmacological therapy with an anticholinergic or a beta-3 agonist. In 2017, over 19 million prescriptions for oral OAB medications were written for an estimated 3.3 million patients in the United States. Third-line treatment includes procedural therapy using either intradetrusor onabotulinumtoxinA (BOTOX) or neuromodulation. This treatment paradigm is depicted below.

We estimate that each percentage point of the current U.S. OAB market is worth approximately $68 million per year in gross sales based on mirabegron’s wholesale acquisition cost of $353 per month (Red Book, May 2018) and the over 19 million oral OAB prescriptions in the United States in 2017. In 2017, according to IQVIA NSP, the three branded oral OAB medications, Myrbetriq, Vesicare and Toviaz, achieved over $2.3 billion gross sales in the United States.

Anticholinergic drugs have been the standard of pharmacologic care for OAB since the approval of flavoxate in 1970 and oxybutynin in 1975. Anticholinergics, however, are associated with poor tolerability and increasing safety concerns. According to an IQVIA custom longitudinal study of OAB diagnosed patients from March 2014 through September 2017, 86% of OAB patients treated with oral prescription therapy in the United States are initially prescribed anticholinergic drugs. Of those patients, 71% fail treatment within six months. Anticholinergic side effects include dry mouth, constipation and blurred vision. Further, there is a growing body of evidence associating anticholinergic use with cognitive impairment and dementia. Anticholinergics have also been associated with the increased use of healthcare resources.

In a 2015 study published in JAMA Internal Medicine, a journal of the American Medical Association, a prospective analysis of over 3,400 patients aged 65 and older showed a 10-year cumulative anticholinergic dose-response relationship with increased risk of both dementia and Alzheimer’s disease. In particular, this study showed that a subject with a cumulative exposure to over 1,095 total standardized daily doses of an anticholinergic medication (calculated as cumulative medication dose divided by the minimum effective daily dose recommended for older patients) would have an adjusted hazard ratio for the risk of incident dementia of 1.54 (95% confidence interval of 1.21 to 1.96). Adjusted hazard ratio represents relative risk of incident dementia compared to a subject with no
anticholinergic drug usage, adjusting for differences in 16 other characteristics that could confound the relationship between anticholinergic medicine use and dementia. Therefore, we estimate that exposure to over 1.5 years of 10 mg daily oxybutynin, the most commonly prescribed anticholinergic for OAB in the United States, would correspond to a 54% increase in the risk of dementia. The minimum effective daily dose for oxybutynin is 5 mg, but the most commonly prescribed daily dose is 10 mg. The observed relationship between cumulative anticholinergic use and incident dementia is shown in the following graph:

Due to the potential medication-related cognitive risks, the study emphasized that it is important to minimize anticholinergic use over time. Over 30 retrospective analyses, with a total of over 40,000 patients, have helped further establish a relationship between anticholinergic use and cognitive impairment. This risk of cognitive impairment in the elderly population is especially important given the well characterized age-dependent increased prevalence of OAB symptoms.

In a survey of 432 physicians that we commissioned, only 35% of physicians acknowledged that anticholinergic use can cause significant cognitive impact on patients and 30% of physicians acknowledged that anticholinergic use can significantly increase the risk for dementia. In contrast, approximately 30% of physicians indicated they did not believe anticholinergic use had a cognitive impact on patients and 28% of physicians indicated they did not believe anticholinergic use increased the risk for dementia. Based on these results, we believe there is low awareness among physicians around the significant cognitive risks associated with anticholinergic use.

When physicians and OAB patients are made aware of these increased risks of dementia and Alzheimer’s disease associated with anticholinergic use, aversion towards using these drugs increases. For example, the 2015 study published in JAMA Internal Medicine reported that over a mean follow-up period of 7.3 years, 797 participants, or 23%, developed dementia. In a third-party market research study we commissioned, which surveyed 120 OAB patients and 150 physicians, including urologists, primary care physicians and OB/GYNs,
when presented with this figure, 44% of surveyed physicians and 75% of OAB patients had a negative response towards using anticholinergics. BOTOX, as a third-line treatment for OAB, is expensive and invasive and has shown limited incremental efficacy. Administration involves 20 injections via cystoscopy into the detrusor muscle, approximately every 24 weeks. Unwanted side effects associated with the use of BOTOX for OAB include urinary tract infections and urinary retention. In addition, some patients need to self-catheterize post-treatment. Sacral neuromodulation and peripheral tibial nerve stimulation, which are highly invasive and used by a small fraction of the OAB patient population, are also available as third-line therapies.

**Beta-3 agonists**

Beta-3 agonists constitute the newest class of oral prescription therapy for OAB. The beta-3 adrenergic receptor is the most prevalent beta-adrenergic receptor subtype on the smooth muscle around the bladder. Bladder filling involves the relaxation of this muscle and the contraction of the urethral smooth muscle, while voiding involves contracting the bladder muscle and relaxation of the urethral muscle. Studies of isolated human bladder smooth muscle have shown that selective activation of the beta-3 adrenergic receptor results in smooth muscle relaxation. Therefore, beta-3 stimulation can increase bladder capacity and reduce the symptoms of OAB.
In 2012, mirabegron (Myrbetriq), a beta-3 agonist, became the first drug other than an anticholinergic approved by the FDA for the treatment of OAB. Mirabegron remains the sole beta-3 agonist on the market for OAB, and since its approval, it has continued to take U.S. OAB prescription share from anticholinergics, primarily due to its safety and tolerability advantages. In 2017, mirabegron’s share of oral OAB prescriptions in the United States grew 26%, from 12% in 2016 to 15% in 2017. In the first three months of 2018, according to IQVIA NPA, mirabegron’s share grew 20% from the comparable period in 2017, from 13.7% to 16.5%. Astellas reported net sales of mirabegron in the Americas of $657 million for the fiscal year ending March 31, 2018, representing growth of 29% over the prior fiscal year. The graph below shows the number of oral OAB prescriptions in the United States for the last three calendar years.

Despite its success, mirabegron requires dose titration that results in a slow onset of action and is associated with frequent drug-drug interactions and QTc prolongation. Mirabegron’s onset of action is eight weeks at the starting dose of 25 mg and within four weeks at a dose of 50 mg. Efficacy of both the starting dose and 50 mg doses of mirabegron was maintained through the 12-week treatment period. Further, mirabegron’s U.S. label has a note in the warnings and precautions section about drug-drug interaction risk related to its known inhibition of the CYP2D6 enzyme, an important enzyme involved in the metabolism of numerous drugs. According to a May 2018 IQVIA Rx/Dx claims analysis, approximately 37% of patients taking mirabegron are taking other drugs that are metabolized via the CYP2D6 pathway, presenting increased risk of exacerbated adverse events in patients taking mirabegron with these drugs. In addition, in a thorough QTc study, mirabegron demonstrated QTc prolongation in women at a supratherapeutic dose, or a dose greater than the maximum approved dose (50 mg), as noted in the pharmacodynamic section of its U.S. label.

**Our solution: vibegron**

Vibegron is an oral, once-daily, small molecule that was observed to be highly selective for the human beta-3 adrenergic receptor in *in vitro* assays. We are developing vibegron for the treatment of OAB.
We believe vibegron, if successful in meeting the efficacy endpoints in our pivotal Phase 3 EMPOWUR trial, and if approved by the FDA, has the potential to address the limitations of both anticholinergics and mirabegron and become a differentiated beta-3 agonist based on the following potential advantages:

- **Met primary and secondary efficacy endpoints and was well tolerated in large, randomized, placebo-controlled international Phase 2b and Japanese Phase 3 clinical trials.** Vibegron has been evaluated in multiple clinical trials with a total of over 2,600 OAB patients. In large, randomized, placebo-controlled, international Phase 2b and Japanese Phase 3 clinical trials, vibegron 50 mg and 100 mg met all primary and secondary efficacy endpoints compared to placebo at week 8 and week 12, respectively. These endpoints included reductions per day in number of micturitions, urgency episodes, UUI episodes and total incontinence episodes. In addition, vibegron was well tolerated in these trials.

- **Observed to be highly selective for the human beta-3 adrenergic receptor in in vitro assays.** 

- **No known dementia risk.** There is a growing body of evidence that “anticholinergic load” may lead to an increased risk of dementia. Existing data also suggest that use of anticholinergic agents may have an impact on cognition, especially in the elderly. This increased risk of dementia combined with the poor side effect profile of the anticholinergic class, such as dry mouth, constipation and blurred vision, has led to significant U.S. oral OAB prescription share gains of the beta-3 agonist class. There is no evidence to date linking the use of beta-3 agonists with increased risk of dementia.

- **Potential for broader efficacy claims, including urgency data, if successful in meeting the efficacy endpoints in our pivotal Phase 3 EMPOWUR trial.** Currently, no approved OAB therapies in the United States can promote efficacy data for the reduction of urgency episodes related to OAB symptoms. Based on our discussions with the FDA, we believe that the FDA will consider inclusion of urgency data, as well as additional data to support potentially broader efficacy claims, in the vibegron label if this efficacy is demonstrated in our Phase 3 EMPOWUR trial.

- **Rapid onset of action.** In clinical trials, vibegron has demonstrated an onset of action in as early as two weeks. If our Phase 3 EMPOWUR trial results further support this rapid onset of action, vibegron would be the only beta-3 agonist to demonstrate a starting dose with onset of action in two or four weeks.

- **Single, convenient dose.** We are studying a single, fixed dose of vibegron in our pivotal Phase 3 EMPOWUR trial. If approved, vibegron will be the only beta-3 agonist available that does not require dose titration. In addition, vibegron has the potential to be the only beta-3 agonist that does not require dose adjustments for patients with moderate hepatic impairment.

- **No CYP2D6 drug-drug interactions.** CYP2D6 is one of the most important and common enzymes involved in the metabolism of drugs with approximately 20% of all drugs being metabolized by CYP2D6. In addition, approximately 43% of patients taking any oral OAB medication, including 37% of mirabegron patients, are taking other drugs that are metabolized via the CYP2D6 pathway. Vibegron is not an inhibitor of CYP2D6 and therefore has a reduced risk for potentially harmful drug-drug interactions.

- **No QTc signal.** In a thorough QTc study designed to assess the potential for increased risk of ventricular arrhythmia and torsades de pointes, vibegron showed no QTc prolongation at therapeutic or supratherapeutic doses. If approved, vibegron would be the only beta-3 agonist without demonstrated QTc prolongation in the product label.

- **Crushable dose formulation.** We intend to conduct a relative bioavailability study to demonstrate that vibegron can be crushed and delivered to patients in food. If successful, vibegron would be the only beta-3 agonist that can be crushed and delivered in food, an important option for elderly and other select patients.
Based on a third-party market research study we commissioned, which surveyed 120 OAB patients and 150 physicians, including urologists, primary care physicians and OB/GYNs, we believe each of the above factors could represent a meaningful advantage over mirabegron. Specifically, both patients and prescribers identified the potential for no CYP2D6 drug-drug interactions and no QTc signal, as well as the potential for rapid onset of action and single-crushable dose formulation, as highly motivating differentiators. Furthermore, based on vibegron’s potential product profile, approximately 50% of surveyed physicians indicated that they would be attracted to, or willing to use, vibegron if approved with such a profile. Among OAB patients currently taking an anticholinergic, approximately 62% indicated that they would be attracted to, or willing to ask their physician to replace their current treatment with, vibegron based on its potential product profile. We believe there is a significant opportunity for a new OAB treatment as approximately 86% of OAB patients treated with oral prescription therapy in the United States are initially prescribed anticholinergic drugs.

**Current and projected reimbursement landscape for beta-3 agonists in the United States**

Access to oral OAB therapy is managed primarily by differential co-payments, or co-pays. Payors generally charge the lowest co-pays for generic drugs and higher co-pays for branded agents such as Vesicare or Myrbetriq. In 2017, 92% of commercial plans and 93% of Medicare plans covered Myrbetriq, the only currently marketed beta-3 agonist. According to IMS PayerTrak, in 2017, the U.S. payor mix for the oral OAB prescription market was approximately 52% Medicare D, 37% commercial or cash and 10% other payors. In addition, the long-term care channel accounted for approximately 17% of all oral OAB prescriptions in the United States. Based on a third-party database analysis we commissioned of over 4,600 commercial plans and 1,200 Medicare Part D plans, Myrbetriq has approximately 64% preferred access and 90% unrestricted access of Medicare Part D covered lives and approximately 45% preferred access and 71% unrestricted access of commercially covered lives.

In May 2018, we commissioned a third-party market research study to assess how vibegron would be covered, if approved. The research firm interviewed representatives of payors, who are involved with, but not solely responsible for, access and reimbursement decisions. Such interviewees represented payors covering over 80 million U.S. commercial and Medicare Part D lives.

Based on this study and our analysis of the current coverage of OAB therapies, we believe the OAB pharmacologic category is not highly managed by payors. The payor representatives interviewed expect that vibegron would be managed at a preferred or non-preferred branded tier, without prior authorization, allowing physicians and patients to make the choice of whether to pay a higher co-pay for a branded product or a lower co-pay for a generic. In addition, these payor representatives anticipate that vibegron’s coverage would not change following Myrbetriq’s loss of marketing exclusivity, which we expect to occur in 2023 or 2024. Based on this study, we also believe that access to vibegron, if approved, will not be restricted to patients who first fail any other oral therapies for OAB.

In June 2018, we commissioned a second market research study, conducted by a separate third-party market research firm, to further assess how vibegron would be covered, if approved. The research firm interviewed representatives of payors who are involved with, but not solely responsible for, access and reimbursement decisions. Such interviewees represented payors covering over 160 million U.S. commercial and Medicare Part D lives.

The results of this additional study reinforced the results of the May 2018 study with regard to vibegron’s potential coverage. In addition, the payors interviewed indicated that they believe the OAB pharmacologic category is not highly managed and is instead primarily controlled through differential co-pays for branded OAB drugs as compared to generic OAB drugs. They expect the OAB pharmacologic category will continue to be managed this way.
Our ongoing Phase 3 program for overactive bladder

In March 2018, we enrolled the first patients in our international pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. The EMPOWUR trial is a randomized, double-blind, placebo- and active comparator-controlled clinical trial in men and women with OAB wet or dry. The trial is expected to enroll approximately 1,400 patients and has a design similar to those of the Phase 2b and Japanese Phase 3 clinical trials.

Individuals who meet eligibility requirements will be randomized to one of three groups for a 12-week treatment period: vibegron 75 mg administered orally once daily, placebo administered orally once daily, or extended release tolterodine, or tolterodine ER (a commonly prescribed anticholinergic for OAB), 4 mg administered orally once daily. Eligible patients completing the initial 12-week blinded assessment will be offered the opportunity to enroll in a 40-week double-blind extension study to evaluate the safety and efficacy of longer-term treatment. To be eligible, patients must be at least 18 years old with a history of OAB (as diagnosed by a physician) for at least three months. During the screening period, volunteers must experience on average at least eight micturitions per day; either an average of at least three urgency episodes per day or at least one UUI episode per day; and total UUI episodes must exceed stress urinary incontinence episodes.

The co-primary efficacy endpoints at week 12 of our Phase 3 EMPOWUR trial are:
- change from baseline in the average number of micturitions per 24 hours in all patients; and
- change from baseline in the average number of UUI episodes per 24 hours in patients with OAB wet.

Secondary endpoints will include, among others, changes in the frequency of urgency episodes and total incontinence episodes (which includes all incontinence episodes, whether UUI or stress-related), as well as self-reported quality of life scores. Adverse events will be monitored during both the trial and the extension study. As of August 29, 2018, two patients, both in their mid-70s and with multiple comorbidities, have died in our three-arm Phase 3 EMPOWUR trial enrolling approximately 1,400 patients. In both cases, the investigators deemed the death not treatment-related. Separately, our independent assessment also deemed each death not treatment-related. Because this trial is blinded, we do not know which of the three treatment arms (vibegron, placebo or tolterodine ER) these two patients were in. The design of our Phase 3 EMPOWUR trial is shown below.

We expect to report top-line results from our Phase 3 EMPOWUR trial in the first or second quarter of 2019, and if these results are positive, we plan to submit an NDA to the FDA by early 2020. The IND for vibegron for the indication of OAB was transferred to us by Merck in February 2017.
Clinical data for vibegron in overactive bladder

Merck Phase 2b clinical trial

In 2013, Merck completed a large, randomized, double-blind, placebo-controlled international Phase 2b dose-ranging clinical trial conducted to evaluate the efficacy, safety and tolerability of once-daily vibegron in patients with OAB, administered alone and concomitantly with tolterodine ER. A total of 1,395 patients were randomized to 11 different treatment regimens. Eligibility criteria for this trial included a three-month clinical history of OAB. The design of this trial is shown below.

**Trial Design for Completed International Phase 2b Clinical Trial of Vibegron for the Treatment of OAB**

1. Change from baseline in mean micturitions per day at week 8, as measured in a seven-day diary.
2. Safety measures.
In this Phase 2b clinical trial, the 50 mg and 100 mg doses of vibegron demonstrated statistically significant improvements compared to placebo on all primary and secondary efficacy endpoints at week 8, which included reductions per day in number of micturitions, urgency episodes, UUI episodes and total incontinence episodes.

The results of the key efficacy endpoints that will be used in our Phase 3 EMPOWUR trial at week 8 of the completed Phase 2b clinical trial are depicted below.

Vibegron Phase 2b Data: Placebo-adjusted\(^1\) change from baseline to final visit (active – placebo)\(^2\)

<table>
<thead>
<tr>
<th></th>
<th>Micturitions (Frequency)</th>
<th>Urges Incontinence</th>
<th>Urgency Episodes</th>
<th>Dry Rate(^4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vibegron 50 mg</td>
<td>-0.66</td>
<td>-0.72</td>
<td>-0.76</td>
<td>14%</td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibegron 100 mg</td>
<td>-0.91</td>
<td>-0.71</td>
<td>-1.28</td>
<td>18%</td>
</tr>
<tr>
<td>Week 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) In this Phase 2b clinical trial, at week 8, the placebo group demonstrated a 1.16 reduction from baseline in micturitions per day, a 1.34 reduction from baseline in UUI episodes per day, a 1.59 reduction from baseline in urgency episodes per day, and a 2.6% dry rate.
\(^2\) Phase 2b Part 1 results. Past results do not guarantee future outcomes.
\(^3\) Defined as 100% reduction in urge incontinence.
\(^4\) Based on pre-specified constrained longitudinal data analysis, or the CLDA model. The CLDA model accounts for measuring study endpoints over time, and is adjusted for treatment, time in weeks, region and interaction of time in weeks by treatment. The CLDA model assumes a common mean across treatment groups at baseline and a different mean for each treatment at each of the post-baseline time points.
\(^5\) p-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of 0.05 or less represents statistical significance, meaning there is a less than 1-in-20 likelihood that the observed results occurred by chance. The FDA utilizes statistical significance, as measured by p-value, as an evidentiary standard of efficacy and would typically require a p-value of 0.05 or less to demonstrate statistical significance in a pivotal clinical trial.
The Phase 2b clinical trial data showing reductions in micturitions over time for the Base Study Part 1 and extension study are shown in the graphs below.

$p$-values: *<0.05, **<0.01, ***<0.001

1. Uses Mixed Model for Repeated Measures, or MMRM, model that will be used in our Phase 3 EMPOWER trial. Pre-specified CLDA model produced nearly identical results. The MMRM model studies endpoints over time and is adjusted for treatment, study visit, GAB type (wet vs dry), sex, region, baseline value and interaction of treatment by visit. The MMRM model, unlike the CLDA model, does not assume a common mean across treatment groups at baseline and treats the baseline value as part of the model. The FDA has indicated that the MMRM model is appropriate for our Phase 3 EMPOWER trial.
Vibegron Phase 2b Data: Change in Average Daily Micturitions Over Time
Base Study Part I + Extension Study
Only includes patients who continued onto extension study

1. Uses MMRM model that will be used in our Phase 3 EMPOWER trial. Pre-specified LDA model produced nearly identical results.
Vibegron was observed to be well tolerated in this Phase 2b trial. No clinically significant changes in blood pressure were observed compared to placebo or active control. In Parts 1 and 2 of the Phase 2b trial, there were no deaths and nine serious adverse events, or SAEs, reported in eight patients, consisting of: (1) one patient had anaphylactic reaction and one patient had hypertension in the placebo group; (2) one patient had atrial fibrillation and one patient had both gastroesophageal reflux and dizziness in the tolterodine ER 4 mg active control group; (3) one patient had foot fracture and one patient had overdose in the vibegron and tolterodine ER 4 mg group; (4) one patient had chronic obstructive lung disease in the vibegron 50 mg group; and (5) one patient had carcinoma in the vibegron 3 mg group. None of the reported SAEs were considered treatment related. The number and percentage of patients with the most common adverse events in select treatment groups in Parts 1 and 2 of the Phase 2b trial are shown in the table below.

### Vibegron Phase 2b Data: Incidence of Adverse Events

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Vibegron 50 mg</th>
<th>Vibegron 100 mg</th>
<th>Placebo</th>
<th>Tolterodine ER 4 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 2b (Part 1 + Part 2)</td>
<td>N = 148(^1)</td>
<td>N = 261</td>
<td>N = 205</td>
<td>N = 257</td>
</tr>
<tr>
<td>Accidental overdose</td>
<td>4 (2.7%)</td>
<td>11 (4.2%)</td>
<td>2 (1.0%)</td>
<td>6 (2.3%)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>3 (2.0%)</td>
<td>0</td>
<td>2 (1.0%)</td>
<td>3 (1.2%)</td>
</tr>
<tr>
<td>Constipation</td>
<td>6 (4.1%)</td>
<td>2 (0.8%)</td>
<td>5 (2.4%)</td>
<td>5 (1.9%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>3 (2.0%)</td>
<td>7 (2.7%)</td>
<td>5 (2.4%)</td>
<td>5 (1.9%)</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>7 (4.7%)</td>
<td>4 (1.5%)</td>
<td>6 (2.9%)</td>
<td>22 (8.6%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>5 (3.4%)</td>
<td>2 (0.8%)</td>
<td>1 (0.5%)</td>
<td>6 (2.3%)</td>
</tr>
<tr>
<td>Headache</td>
<td>6 (4.1%)</td>
<td>12 (4.6%)</td>
<td>9 (4.4%)</td>
<td>9 (3.5%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>3 (2.0%)</td>
<td>3 (1.1%)</td>
<td>3 (1.5%)</td>
<td>6 (2.3%)</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>4 (2.7%)</td>
<td>1 (0.4%)</td>
<td>1 (0.5%)</td>
<td>0</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>8 (5.4%)</td>
<td>8 (3.1%)</td>
<td>7 (3.4%)</td>
<td>12 (4.7%)</td>
</tr>
</tbody>
</table>

---

\(^1\) Vibegron 50 mg not tested in Phase 2b Part 2.
In the extension study, there were no deaths observed and 46 SAEs were reported in 41 patients. One patient in the tolterodine ER 4 mg active control group had a paralytic ileus, or the obstruction of the intestine due to paralysis of the intestinal muscle, which was considered to be treatment related by the investigator. No other SAEs were considered treatment related. The SAEs in select treatment groups reported in the extension study are shown in the table below.

### Vibegron Phase 2b Extension Study Data: Incidence of Serious Adverse Events

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Vibegron 50 mg</th>
<th>Vibegron 100 mg</th>
<th>Tolterodine ER 4 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subjects in population</strong></td>
<td>N = 223</td>
<td>N = 248</td>
<td>N = 240</td>
</tr>
<tr>
<td>with one or more serious adverse events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>with no serious adverse events</td>
<td>209 (93.7%)</td>
<td>240 (96.8%)</td>
<td>222 (92.5%)</td>
</tr>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>1 (0.4%)</td>
<td>0</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>0</td>
<td>2 (0.8%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Congenital, familial and genetic disorders</td>
<td>0</td>
<td>1 (0.4%)</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>1 (0.4%)</td>
<td>2 (0.8%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>1 (0.4%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>0</td>
<td>0</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>1 (0.4%)</td>
<td>0</td>
<td>4 (1.7%)</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>3 (1.3%)</td>
<td>1 (0.4%)</td>
<td>5 (2.1%)</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>0</td>
<td>0</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>5 (2.2%)</td>
<td>0</td>
<td>2 (0.8%)</td>
</tr>
<tr>
<td>Neoplasms benign, malignant and unspecified</td>
<td>0</td>
<td>1 (0.4%)</td>
<td>2 (0.8%)</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>3 (1.3%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>0</td>
<td>0</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Reproductive system and breast disorders</td>
<td>0</td>
<td>1 (0.4%)</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>0</td>
<td>0</td>
<td>1 (0.4%)</td>
</tr>
</tbody>
</table>
Kyorin Phase 3 program in Japan

In 2016, Kyorin completed a large, randomized, double-blind, placebo-controlled Phase 3 clinical trial of vibegron in patients with OAB in Japan. In this trial, a total of 1,232 patients were randomized to vibegron 50 mg or 100 mg once daily, imidafenacin (a commonly prescribed anticholinergic in Japan for OAB) 0.2 mg twice daily or placebo, each administered for 12 weeks. To be eligible, patients had to be at least 20 years old with symptoms of OAB for at least six months. In addition, during the two-week placebo run-in period, volunteers must have experienced on average at least eight micturitions per day; either an average of at least one urgency episode per day or at least one UUI episode per day; and total number of UUI episodes equal to at least half of the total incontinence episodes. The graphic below represents the Phase 3 clinical trial design.

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In this Phase 3 clinical trial, both doses of vibegron demonstrated statistically significant improvements compared to placebo on all of the primary and secondary efficacy endpoints, including reductions per day in number of micturitions, urgency episodes, UUI episodes and total incontinence episodes, as well as an increase in volume voided per micturition. Statistical analysis of differences between imidafenacin and placebo or vibegron was not performed. Results of the Phase 3 clinical trial are summarized in the table below.

### Japan Phase 3 Data: Change from baseline to final visit at week 12 (active – placebo)

<table>
<thead>
<tr>
<th></th>
<th>50 mg</th>
<th></th>
<th>100 mg</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Effect</td>
<td>p</td>
<td>N</td>
</tr>
<tr>
<td>Micturitions</td>
<td>370</td>
<td>-0.86</td>
<td>&lt; 0.001</td>
<td>368</td>
</tr>
<tr>
<td>Urge Incontinence</td>
<td>329</td>
<td>-0.27</td>
<td>0.001</td>
<td>327</td>
</tr>
<tr>
<td>Total Incontinence</td>
<td>329</td>
<td>-0.30</td>
<td>0.001</td>
<td>327</td>
</tr>
<tr>
<td>Urgency</td>
<td>370</td>
<td>-0.51</td>
<td>&lt; 0.001</td>
<td>368</td>
</tr>
<tr>
<td>Volume Voided (mL)</td>
<td>370</td>
<td>25.76</td>
<td>&lt; 0.001</td>
<td>368</td>
</tr>
</tbody>
</table>

Vibegron was observed to be well tolerated in this trial. No clinically significant changes in vital signs were observed compared to the placebo or active control groups. In this trial, there were no deaths and seven SAEs reported in six patients, consisting of: (1) back pain in one patient in the 50 mg group; (2) pyelonephritis in one patient in the 100 mg group; (3) colon cancer, acute myeloid leukemia, dizziness and hypertension in three patients in the placebo group; and (4) breast cancer in one patient in the imidafenacin 0.2 mg group. None of the reported SAEs were considered treatment related. The number and percentage of patients with most common adverse events is shown in the table below.

### Japan Phase 3 Data: Incidence of Adverse Events

*Most common adverse events (Vibegron >2% and >Placebo):

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Vibegron 50 mg</th>
<th>Vibegron 100 mg</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 370</td>
<td>N = 369</td>
<td>N = 369</td>
<td></td>
</tr>
<tr>
<td>Cystitis</td>
<td>9 (2.4%)</td>
<td>8 (2.2%)</td>
<td>3 (0.8%)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>32 (8.6%)</td>
<td>35 (9.5%)</td>
<td>27 (7.3%)</td>
</tr>
</tbody>
</table>

In 2016, Kyorin also completed a 52-week multicenter, open-label, non-controlled clinical trial in Japan to evaluate the long-term safety and efficacy of vibegron 50 mg and 100 mg in OAB patients. A total of 169 patients were initiated on a daily dose of 50 mg vibegron. After treatment for eight weeks, the daily vibegron dose could be increased from 50 mg to 100 mg if the investigator judged the efficacy as insufficient without any safety concern and patients agreed with the dose increase. Otherwise, patients continued to receive vibegron 50 mg for an additional 44 weeks. The primary endpoint of this trial was safety.
In this trial, 118 patients were maintained on the 50 mg dose of vibegron beyond week 8, while 51 were increased to the 100 mg dose. Both doses of vibegron, 50 mg and 100 mg, were well tolerated in the trial. No clinically significant changes in vital signs were observed. There was one death due to a patient fall in the 50 mg dose-maintained group. The investigator deemed the death not related to treatment. No newly identified, clinically significant adverse events were seen in this trial. Other than death, there were five SAEs reported in five patients in the 50 mg dose-maintained group, consisting of angina pectoris, Prinzmetal angina, cerebral infarction, vertebral disc protrusion and vertigo positional, each in one patient. None of these SAEs were considered treatment related, other than cerebral infarction, for which a causal relationship could not be ruled out. No SAEs were reported in the 100 mg group. In addition, it was observed that vibegron 50 mg and 100 mg improved OAB symptoms, including micturitions, UUI episodes and urgency episodes over 52 weeks.

In September 2017, Kyorin submitted a marketing application for vibegron to the Japan PMDA.

**Other beta-3 agonist clinical data**

In 2012, mirabegron (Myrbetriq) became the first beta-3 agonist approved by the FDA for the treatment of OAB. Astellas Pharma Inc., or Astellas, conducted three 12-week, double blind, randomized, placebo-controlled, parallel group, multicenter pivotal clinical trials of mirabegron in over an aggregate of 4,600 patients to support its FDA approval. Eligibility criteria for these trials included a clinical history of symptoms of OAB for at least three months. Only one of these trials (trial number ‘074) evaluated the approved 25 mg starting dose of mirabegron; all three trials evaluated the approved 50 mg dose, but important measures such as reduction in UUI episodes, urgency episodes and dry rate are only reported with their p-values in the FDA medical and statistical reviews for the 1,306-patient ‘074 trial. Astellas pooled results across all three trials for the co-primary endpoints of reductions per day in total incontinence episodes and micturitions, as well as for certain important secondary endpoints. All mirabegron doses in each of the three pivotal trials were clinically and statistically superior to placebo for the co-primary endpoints.

In this Phase 3 program, the 25 mg and 50 mg doses of mirabegron demonstrated statistically significant reductions compared to placebo in number of micturitions and UUI episodes per day. The 50 mg dose of mirabegron demonstrated a statistically significant reduction per day in number of urgency episodes, and the 25 mg dose showed a numerical reduction on the same endpoint. The 25 mg and 50 mg doses of mirabegron showed numerical improvements in the dry rate, defined here as percentage of patients with a 100% reduction in total incontinence.
Efficacy results from mirabegron’s Phase 3 program (as reported in its FDA medical and statistical reviews for doses approved in the United States) are shown below.

Vibegron for the treatment of overactive bladder in men with benign prostatic hyperplasia

BPH is characterized by prostate enlargement, which can block the urethra and prevent normal urine flow, and is progressive with age. There are approximately 40 million men between the ages of 50 and 80 in the United States with BPH, approximately 4.5 million of whom are treated for their BPH symptoms. In addition, approximately 50% of BPH patients also suffer from OAB. Currently, there are no FDA-approved therapies specifically for OAB in men with BPH.

We believe that developing vibegron specifically for the treatment of OAB in men with BPH would be highly complementary to our overall OAB program. According to IQVIA NDTI, as of March 2018, BPH patients, similar to OAB patients, are generally treated by urologists and primary care physicians. Further, due to historical concerns with acute urinary retention, a potential side effect of anticholinergics, there has been hesitancy among doctors to prescribe anticholinergics for the treatment of OAB in men with BPH. As a result, a majority of men with BPH and OAB are not treated for their OAB symptoms, and this remains an area of high unmet medical need.

We intend to initiate a Phase 3 clinical trial of vibegron for the treatment of OAB in men with BPH by the end of 2018, subject to feedback from the FDA.
Vibegron for the treatment of pain associated with irritable bowel syndrome

IBS is characterized by recurrent abdominal pain associated with two or more of the following: defecation, a change in frequency of stool and a change in form or appearance of stool. Additionally, IBS presents a significant health care burden and can severely impair a patient’s quality of life. There is a large and growing market for IBS with constipation (IBS-C) and IBS with diarrhea (IBS-D) branded prescription sales, as shown in the graph below.

The currently approved therapies for IBS-C include Linzess, marketed by Allergan and Ironwood Pharmaceuticals, Inc.; Amitiza, marketed by Mallinckrodt plc and Takeda Pharmaceutical Co. Ltd.; and Trulance, marketed by Synergy Pharmaceuticals Inc.; and the currently approved therapies for IBS-D include Xifaxan, marketed by Valeant Pharmaceuticals International, Inc., and Viberzi, marketed by Allergan. These drugs do not adequately address the pain associated with IBS, and there are no currently marketed drugs indicated specifically for IBS-associated pain. There are approximately 30 million to 40 million Americans with IBS symptoms, 30% of whom consult with their physician. Approximately 80% of these patients identify pain as a symptom contributing to the severity of their IBS. Based on this data, we estimate that there is an addressable market in the United States of approximately 7.2 to 9.6 million patients who suffer from IBS-associated pain.

The beta-3 adrenergic receptor is expressed in the neurons and the smooth muscle of the human colon. In vitro studies have shown that activation of the beta-3 adrenergic receptor in the colon causes the release of somatostatin from adipocytes, or fat cells, which causes pain relief. In a preclinical study, administration of a rat-selective beta-3 agonist caused a significant, dose-dependent decrease in abdominal arching (a sign of pain) in rats administered mustard oil to cause visceral pain. This pain reduction was reversed by pre-treatment with a somatostatin receptor antagonist, confirming the role of somatostatin in the mechanism of action (treatment with the somatostatin receptor antagonist alone did not alter pain behavior).
In Part 1 of a 26-week multicenter, randomized, placebo-controlled, two-period crossover Phase 2 clinical trial conducted by GlaxoSmithKline plc in 99 IBS patients, treatment with solabegron, another clinical-stage beta-3 agonist, led to an increase of adequate relief of pain and discomfort associated with IBS compared to placebo at six weeks (15%, p=0.061 using last observation carried forward methodology: 22%, p=0.009 using observed cases). Significantly more female patients on active treatment reported a >50% decrease on an 11-point pain score compared to placebo, odds ratio 4.77 (p<0.05); and an increase of over one pain-free-day per week (33.5%) relative to placebo (16.8%) (p<0.05). Twenty-three percent more female patients treated with the beta-3 agonist (54%) achieved adequate relief relative to placebo (31%) (p=0.019). Twenty-five percent more patients with alternating bowel symptoms treated with the beta-3 agonist (60%) achieved adequate relief of pain relative to placebo (35%) (p=0.013). The sponsor only performed efficacy analyses on the initial six-week treatment period.

We intend to initiate a Phase 2a clinical trial of vibegron for the treatment of IBS-associated pain by the end of 2018, pending the submission of an investigational new drug application, or IND, to the FDA in this indication.

Phase 1 clinical trials and preclinical studies of vibegron

Our current development plan for vibegron includes multiple Phase 1 clinical trials to study the safety and pharmacokinetics of vibegron, including two ongoing drug-drug interaction trials (one with rifampin, an antibiotic, and a second with warfarin, an anticoagulant, and metoprolol, taken for high blood pressure), a planned crushed-tablet bioavailability study and a planned ambulatory blood pressure study.

Prior to our license of vibegron, Merck conducted 16 Phase 1 clinical trials in which a total of 465 individuals received at least one dose of vibegron. The Phase 1 program included trials evaluating the safety and pharmacokinetics of vibegron in healthy young-adult, middle-aged and elderly volunteers. The Phase 1 program included single doses up to 600 mg (eight times our proposed therapeutic dose), multiple doses up to 400 mg daily for 14 days and 150 mg daily for 28 days.

Vibegron was well tolerated throughout the Phase 1 program, including in subjects with mild, moderate and severe renal impairment and moderate hepatic impairment. There were no SAEs reported. In addition, in a thorough QTc study, vibegron showed no QTc prolongation at therapeutic or supratherapeutic doses.

Merck also conducted drug-drug interaction studies with various drugs, including tolterodine ER (anticholinergic for OAB), metoprolol and amlodipine (antihypertensive agents), diltiazem and digoxin (used for treating various heart conditions), ketoconazole (anti-fungal medication), and ethinyl estradiol and levonorgestrel (oral contraceptives). Co-administration of vibegron, which is metabolized by the CYP3A4 enzyme, with any of these drugs did not appear to result in a clinically meaningful drug-drug interaction. While CYP3A4 is likely the predominant CYP responsible for in vitro metabolism, metabolism appears to only play a minor role in the elimination of vibegron. In addition, vibegron did not appear to have a clinically meaningful impact on the pharmacokinetics of oral contraceptives or digoxin. Based on *in vitro* studies, vibegron is not an inhibitor of any major enzymes produced from the cytochrome P450 genes, including CYP2D6 and CYP3A4. Vibegron did not impact the pharmacokinetics of tolterodine ER (a CYP2D6 substrate) in a clinical drug-drug interaction trial, confirming that vibegron is not a CYP2D6 inhibitor. CYP2D6 and CYP3A4 are important enzymes involved in the metabolism of numerous drugs, the inhibition of which can present drug-drug interaction risk. Drug-drug interactions can lead to clinically significant increased plasma levels of interacting drugs, which may become a safety risk for patients.

*In vitro* assays comparing the potency and selectivity of vibegron with mirabegron found that vibegron was the more potent beta-3 agonist and highly selective relative to beta-1 and beta-2 agonism receptor. The half maximal effective concentration, or EC\textsubscript{50}, of vibegron is 2.1 nanomolar, at the beta-3 adrenergic receptor. EC\textsubscript{50} is
**hMaxi-K for the treatment of overactive bladder**

hMaxi-K is a novel gene therapy product candidate that we are developing for patients with OAB who have failed oral pharmacological therapy. hMaxi-K is under development as a potential injectable treatment option for smooth muscle-based disorders such as OAB. hMaxi-K is a plasmid vector containing human DNA encoding the pore-forming component of the Maxi-K ion channel. Expression of this protein in muscle cells increases potassium ion flow across the cell membrane, reducing excitability of smooth muscle cells. We believe this mechanism could normalize the heightened detrusor smooth muscle tone in OAB, thereby reducing the symptoms of OAB. We plan to pursue hMaxi-K as a repeat administration that can be administered under local anesthesia to the bladder wall and as an outpatient procedure in a urologist’s office under cystoscopy.

There are no currently available FDA-approved gene therapy treatments for OAB. With only two non-surgical therapies currently available for treatment of OAB, BOTOX and neuromodulation, we believe there is an opportunity to both capture market share and expand the OAB third-line therapy market. Approximately 14 million Americans seek treatment from their physician for OAB and, of these patients, only an estimated 3.3 million patients take prescription therapy and only 300,000 patients utilize current third-line procedural therapies. We estimate that third-line treatments generate aggregate annual sales in excess of $700 million in the U.S. market. We believe a third-line treatment option that is non-surgical and not a toxin, unlike BOTOX, would be appealing to physicians and patients, potentially meeting the unmet needs of this patient population.

Subject to feedback from the FDA, we intend to initiate a proof-of-concept Phase 2a clinical trial in 2019 to evaluate the safety and efficacy of hMaxi-K for the treatment of OAB in patients who have not responded to oral pharmacological therapies.

**Clinical data for hMaxi-K**

Development of hMaxi-K was initiated by ICI and has been studied in four clinical trials to date, two Phase 1b clinical trials in OAB and one Phase 1 clinical trial and one Phase 2a clinical trial in erectile dysfunction. In these trials, hMaxi-K was studied in a total of 22 women for OAB and 38 men for erectile dysfunction in doses up to 24,000 µg of hMaxi-K. There were no gene transfer-related adverse events or other serious safety issues observed in these trials.

In 2017, ICI completed a multicenter, double-blind, imbalanced placebo-controlled Phase 1b clinical trial evaluating the potential activity and safety of hMaxi-K gene transfer by direct injection in women with OAB and detrusor overactivity. The Phase 1b clinical trial, which began in 2014, had two sequential active treatment groups. hMaxi-K was delivered into the bladder wall by direct injection in a total of 13 female OAB patients. hMaxi-K was observed to be generally well tolerated. Efficacy results of the trial, which included a limited number of patients (n=13), showed dose-dependent improvements in urinary urgency and frequency, achieving statistical significance (p<0.05) in the high dose cohort. Reductions of the measured endpoints of urinary urgency and frequency and improvements in the measured endpoint of quality of life lasted through the 24-week length of the trial.
In 2017, ICI completed a double-blind, placebo-controlled, parallel design, randomized Phase 2a clinical trial evaluating the potential activity and safety of hMaxi-K gene transfer in men with erectile dysfunction. hMaxi K was observed to be generally well tolerated in this trial.

License agreement with Merck

In February 2017, we entered into a license agreement with Merck, as amended in April 2017, or the Merck Agreement, pursuant to which Merck granted us an exclusive, royalty-bearing, sublicenseable license under certain patents, know-how and other intellectual property controlled by Merck, to develop, manufacture and commercialize the compound that we refer to as vibegron and any and all products containing this compound for use in any human disease or condition. The exclusive license under the Merck Agreement extends to all countries and territories worldwide, except for Japan, Brunei, Cambodia, Hong Kong, Indonesia, Korea, Laos, Malaysia, Myanmar, Philippines, Singapore, Taiwan, Thailand and Vietnam, which we refer to collectively as the Excluded Asian Territories. Merck also granted us a non-exclusive license to develop and manufacture the licensed products in the Excluded Asian Territories solely for further development and/or commercialization outside of such Excluded Asian Territories.

Pursuant to the Merck Agreement, we made an upfront payment of $25.0 million to Merck. Additionally, we agreed to pay Merck up to an aggregate of $44.0 million upon the achievement of certain regulatory milestone events and up to an aggregate of $80.0 million upon the achievement of certain sales milestone events. Further, we agreed to pay Merck tiered royalties in the sub-teen double-digits on net sales of licensed products made by us, our affiliates or our sublicensees, subject to standard offsets and reductions as set forth in the Merck Agreement. Our royalty obligations apply on a product-by-product and country-by-country basis and end upon the latest of the date on which the last valid claim of the licensed patents expire, the date which the data or market exclusivity expires and 15 years after the first commercial sale of the licensed product, in each case, with respect to a given product in a given country.

We are obligated to use commercially reasonable efforts to develop and commercialize a licensed product in certain urologic indications in the United States and the European Union by certain dates, subject to requisite governmental authorizations. Additionally, after obtaining regulatory approval of a licensed product in a given country, we are obligated to use commercially reasonable efforts to commercialize and maximize the value of such licensed product in such country.

Under the Merck Agreement, we control prosecution, defense and enforcement of the licensed patents, and Merck has backup rights to prosecution, defense and enforcement with respect to any licensed patents for which we elect not to exercise such rights. The Merck Agreement will expire on a product-by-product and country-by-country basis on the expiration of the royalty term with respect to a given licensed product in a given country, unless earlier terminated. We may terminate the Merck Agreement in its entirety, or on a country-by-country basis, for any reason, with or without cause, upon 90 days’ written notice. Merck may terminate the Merck Agreement if we or our affiliates challenge the validity of any of the licensed patents or for a change of control event that involves a competing product in the United States or at least three countries within the European Union that is not divested within a specified time frame thereafter. Either party may terminate the Merck Agreement with 90 days’ written notice for uncured material breach (or 30 days in the case of our non-payment), or immediately upon written notice in the event the other party files a voluntary petition, is subject to a substantiated involuntary petition or is otherwise declared insolvent.
In June 2017, we entered into an intellectual property purchase agreement with Roivant Sciences GmbH, or RSG, a wholly owned subsidiary of our parent company, RSL, as amended on May 22, 2018, pursuant to which we assigned all of our rights, titles, claims and interests in and to all intellectual property rights under the Merck Agreement to RSG, solely as it relates to any of our rights or obligations in China. See the section titled “Certain relationships and related party transactions—China intellectual property purchase agreement” for additional information.

Collaboration agreement with Kyorin

In August 2017, we entered into a collaboration agreement with Kyorin, or the Kyorin Collaboration Agreement, to exchange information relating to non-clinical studies and clinical trials involving vibegron conducted by each party. Pursuant to the Kyorin Collaboration Agreement, Kyorin granted us access and a right of reference to their regulatory materials (and all clinical data contained therein) to develop and commercialize vibegron worldwide (other than the Excluded Asian Territories), and we granted Kyorin access and a right of reference to our regulatory materials (and all clinical data contained therein) to develop and commercialize vibegron in the Excluded Asian Territories, including, in each case, the right to use such materials for any meeting with, or submission to, each party’s relevant government authority for the purpose of obtaining any regulatory approval for vibegron. Further, we granted Kyorin a right of first review and negotiation to obtain a license under the Japanese rights to any urology assets that we acquire during the 10-year period starting from the effective date of the Kyorin Collaboration Agreement.

Pursuant to the Kyorin Collaboration Agreement, our maximum obligation to Kyorin is $11.5 million, of which $1.0 million was paid during the year ended March 31, 2018. The remaining obligations under this agreement will be due upon the achievement of certain regulatory milestones by Kyorin in Japan and us in the United States, subject to certain conditions.

The term of the Kyorin Collaboration Agreement continues as long as both parties are developing or commercializing vibegron, unless otherwise terminated or extended. Either party may terminate the Kyorin Collaboration Agreement on 60 days’ written notice for uncured and undisputed material breach, or for the change of control of the other party.

Enzyme supply agreement with Codexis

In September 2017, we entered into a supply agreement with Codexis, Inc., or Codexis, pursuant to which Codexis agreed to supply its proprietary enzyme, currently used in the production of vibegron, to us on a non-exclusive basis. Pursuant to the agreement, we agreed to purchase from Codexis all of our requirements for such enzyme (with a minimum purchase commitment totaling $3.75 million) for use in the clinical and commercial production of vibegron worldwide (other than the Excluded Asian Territories) for the first six years after the first approved product in any of the United States, Europe or Canada. Under this agreement, Codexis granted us a non-exclusive, non-transferrable, non-sublicenseable worldwide license to use and import its proprietary enzyme to make, have made, use, import, sell and have sold vibegron worldwide (other than the Excluded Asian Territories). In consideration for these license rights, we also agreed to make a one-time $0.5 million payment upon our achievement of a regulatory milestone in any of the United States, Europe or Canada.

The term of our agreement with Codexis continues for six years after the first regulatory approval of vibegron in either the United States, Europe or Canada. We may terminate this agreement for any reason, with or without cause, following a written notice to Codexis prior to the first approved product in any of the United States, Europe or Canada. After such time, we may terminate this agreement for any reason, with or without cause, following a written notice to Codexis, but will be obligated to have met our minimum purchase obligations for
that year. Either party can terminate this agreement with 60 days’ notice for uncured material breach, or with 30 days’ written notice in the event the other party files a voluntary petition, suffers or permits the appointment of a receiver for its business or assets, or is otherwise declared insolvent.

License agreement with Ion Channel Innovations

In August 2018, we entered into a license agreement with ICI, or the ICI Agreement, pursuant to which ICI granted us an exclusive, royalty-bearing, sublicenseable license under certain patents and know-how controlled by ICI, to develop, manufacture and commercialize the gene therapy that we refer to as hMaxi-K and any and all products containing this gene therapy for use in any human or animal disease or condition. The exclusive license under the ICI Agreement extends to all countries and territories worldwide.

Pursuant to the ICI Agreement, we made an upfront payment of $250,000 to ICI. Additionally, we agreed to pay ICI up to an aggregate of $35.0 million upon the achievement of certain development and regulatory milestone events and up to an aggregate of $60.0 million upon the achievement of certain sales milestone events. Further, we agreed to pay ICI tiered royalties in the mid-to-high single digits on net sales of licensed products made by us, our affiliates or our sublicensees, subject to certain reductions as set forth in the ICI Agreement. Our royalty obligations apply on a product-by-product and country-by-country basis and end upon the date on which the last valid claim of the licensed patents expires with respect to a given product in a given country.

We are obligated to use commercially reasonable efforts to develop and seek regulatory approval of at least one licensed product. Under the ICI Agreement, we control prosecution, defense and enforcement of the licensed patents, and ICI has backup rights to prosecution, defense and enforcement with respect to any licensed patents for which we elect not to exercise such rights.

The ICI Agreement will expire on a product-by-product basis on the expiration of the royalty term with respect to a given licensed product, unless earlier terminated. We may terminate the ICI Agreement in its entirety, or on a product-by-product basis, for any reason, with or without cause, upon 90 days’ written notice or, if after regulatory approval of a licensed product, upon 180 days’ written notice. Either party may terminate the ICI Agreement with 90 days’ written notice for uncured material breach, or immediately in the event the other party files a voluntary petition, is subject to an involuntary petition not dismissed within 90 days, or assigns a substantial portion of its assets for the benefit of creditors.

Sales and marketing

We do not currently have our own marketing, sales or distribution capabilities. In order to commercialize vibegron, if approved for commercial sale, we must develop a sales and marketing infrastructure. We intend to build a 300 to 400 person sales organization in the United States, targeting high prescribing urologists, primary care physicians and other specialists that treat high numbers of patients with urology conditions. We believe these physicians treat a majority of OAB patients and most often serve as the diagnosing and treating physicians for OAB. We may opportunistically seek strategic collaborations to maximize the commercial opportunities for vibegron inside and outside the United States.

Manufacturing

We have no experience in drug formulation or manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While vibegron and hMaxi-K were being developed by Merck and ICI, respectively, it was also being manufactured by Merck and ICI.
We expect that the vibegron drug substance transferred to us under the Merck Agreement will be sufficient for us to complete our Phase 3 EMPOWUR trial and our other currently planned clinical trials for the treatment of OAB in men with BPH and IBS-associated pain. We have also contracted with a third party to fill, finish, supply, store and distribute the vibegron drug product for such purpose. If vibegron is approved by the FDA for commercial use, we will rely on third-party manufacturers to supply us with sufficient quantities of vibegron to be used for the commercialization of vibegron. Any material received from Merck under the Merck Agreement may only be used in preclinical and clinical work; however, Merck has agreed to reasonably assist us with a technical transfer of the manufacturing process for vibegron from Merck to us or our designee during a specified time-period. If we are unable to initiate or continue our relationships with one or more other third-party manufacturers, we could experience delays in our commercialization efforts as we locate and qualify new manufacturers.

Vibegron is a small molecule that can be manufactured using commercially available technologies. We acquired data from Merck related to the chemical synthesis and manufacturing of vibegron, and we have contracted with third-party manufacturers for commercial supplies of vibegron ingredients on a cost-efficient basis based on our understanding of the simple structure and synthesis of the compound. We currently rely on a single supplier, Codexis, for its proprietary enzyme, which we use in the production of vibegron, and we have agreed to purchase from Codexis all of our requirements for such enzyme for use in our clinical and commercial production of vibegron for the first six years after the first approval of vibegron in any of the United States, Europe or Canada. We are currently exploring alternative options for the synthesis of vibegron to enable us to identify and utilize a second source supplier. While we continue to explore these alternatives, we plan to build and maintain two years of inventory of vibegron using the Codexis enzyme prior to any regulatory approval.

hMaxi-K is a naked, or unprotected, DNA plasmid vector containing human DNA encoding the gene for the pore-forming component of the human smooth muscle Maxi-K ion channel. We expect the manufacturing process for hMaxi-K to be typical for that of biologics. Prior to our acquisition of hMaxi-K, it was developed and manufactured in academic and manufacturing facilities suitable to support manufacturing of early clinical development. While, pursuant to the ICI Agreement, and for a specified time period, ICI is obligated to transfer adequate manufacturing technical package, including necessary know-how, personnel and tangible materials for the clinical development and manufacture of hMaxi-K, and to reasonably assist us in the future with requested technical assistance and consulting, we do not currently have any supply of hMaxi-K for any proposed and future nonclinical studies and clinical trials. We intend to contract with third-party vendors for the manufacturing of h-Maxi-K for preclinical studies and clinical trials, as well as for commercialization if and when hMaxi-K receives marketing approval. If we are unable to initiate or continue our relationships with one or more third-party manufacturers for the development and manufacture of hMaxi-K, we could experience delays in our development efforts, and subsequent commercialization if approved.

Manufacturing of any product candidate is subject to extensive regulations that impose various procedural and documentation requirements, which govern recordkeeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. We expect that all of our contract manufacturing organizations will manufacture our product candidates under current Good Manufacturing Practice, or cGMP, conditions. cGMP is a regulatory standard for the production of pharmaceuticals to be used in humans.

**Competition**

We expect mirabegron (Myrbetriq, marketed by Astellas) to be our primary competitor for the treatment of OAB. Mirabegron, a beta-3 agonist, is marketed for the treatment of OAB with symptoms of urge urinary incontinence, urgency and urinary frequency.
demonstrated efficacy in OAB. Velicept Therapeutics, Inc., which has acquired the rights to solabegron, has developed a once-daily formulation and is advancing both its twice-daily and once-daily formulations into Phase 2b clinical trials.

Additionally, there are several other product candidates under development for the treatment of OAB. Taiho Pharmaceutical Co., Ltd. is developing TAC-302, a novel neurite outgrowth enhancer, currently in Phase 2 clinical trials in Japan. Dong-A ST Co., Ltd. is developing DA-8010, a novel anticholinergic, currently in a Phase 1 clinical trial. Taris Biomedical LLC is developing TAR-302, an intravesical drug-delivery system for trospium, an anticholinergic drug, currently in Phase 1 clinical trials. Outpost Medicine, LLC’s IND for OP-687 for OAB was accepted by the FDA in late 2017. In addition, a number of companies are developing injectable neurotoxins (biosimilar onabotulinumtoxinA, abobotulinumtoxinA, and nivobotulinumtoxinA) for OAB, and Allergan has advanced a BOTOX-based sustained release gel (RTGel) for the treatment of OAB into Phase 2 clinical development.

We also face significant competition from traditional anticholinergic drugs, which have been the standard of pharmacologic care for OAB since the approval of flavoxate in 1970 and oxybutynin in 1975. Anticholinergics continue to account for the largest share of prescriptions written for the treatment of OAB in the United States. There are a number of widely prescribed anticholinergics approved for sale in the United States, including solifenacin, tolterodine and oxybutynin. In addition, procedural therapies, such as BOTOX (marketed by Allergan) and neuromodulation are available as third-line treatments for OAB.

Drug development is highly competitive and subject to rapid and significant technological advancements. Our ability to compete will significantly depend upon our ability to complete necessary clinical trials and regulatory approval processes, and effectively market any drug that we may successfully develop. Our current and potential future competitors include pharmaceutical and biotechnology companies, academic institutions and government agencies. The primary competitive factors that will affect the commercial success of any product candidate for which we may receive marketing approval include efficacy, safety and tolerability profile, dosing convenience, price, coverage, reimbursement and public opinion. Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Additionally, we expect our gene therapy product candidate, hMaxi-K, to face significant competition from our competitors focused on more traditional therapies for OAB due to perceived risks and public perception associated with gene therapies.

Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical, biotechnology and gene therapy industries could result in even more resources being concentrated among a small number of our competitors.

Accordingly, our competitors may be more successful than us in obtaining regulatory approval for therapies and in achieving widespread market acceptance of their drugs. It is also possible that the development of a cure or more effective treatment method for any of our indications by a competitor could render our product candidates non-competitive or obsolete, or reduce the demand for our product candidates before we can recover our development and commercialization expenses.

**Intellectual property**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for vibegron and any of our future product candidates, novel discoveries, product development technologies and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other
methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position.

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the products or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our products or product candidates.

Following our execution of the Merck Agreement, as of February 3, 2017, by virtue of the license of patent rights under the Merck Agreement, we are the exclusive licensee of multiple granted U.S. patents and pending patent applications, as well as patents and patent applications in numerous foreign jurisdictions (including the United Kingdom, France, Germany, and Canada, but excluding China and the Excluded Asian Territories) relating to beta-3 agonists, including vibegron. As they relate to vibegron, these patents and patent applications cover the vibegron molecule and salts and stereoisomers thereof as a composition of matter, the use of vibegron to treat overactive bladder, urinary incontinence, UUI and urinary urgency, as well as methods of manufacturing. The patent family directed to the vibegron composition of matter and methods of use naturally expires in 2029 in the United States and in foreign jurisdictions, subject to any adjustment or extension of patent term that may be available in a particular jurisdiction. The U.S. Patent and Trademark Office, or the USPTO, has determined that one such patent within the composition of matter and methods of use patent family is entitled to 608 days of patent term adjustment. The patents and patent applications (if issued) directed to methods of manufacturing beta-3 agonists (including vibegron) and related synthetic intermediates would naturally expire between 2032 and 2034, subject to any adjustment or extension of patent term that may be available in a particular country. For example, the term of certain of the composition of matter patents for vibegron in the United States may be extended up to about five years under the patent term extension provisions of the Hatch-Waxman Act.

Following our execution of the ICI Agreement, as of August 24, 2018, by virtue of the license of patent rights under the ICI Agreement, we are the exclusive licensee of a pending international patent application relating to hMaxi-K gene therapy. This patent application covers the use of hMaxi-K gene therapy to treat signs or symptoms of overactive bladder or detrusor overactivity. Any patents issuing from this application would naturally expire in 2038, subject to any adjustment or extension of patent term that may be available in a particular country.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a period due to delay by the USPTO in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our affiliate Roivant Sciences GmbH has applied for trademark registration in the United States for UROVANT. Under the Merck Agreement, we have the right to market vibegron worldwide (other than the Excluded Asian Territories) under the trademark(s) of our choice, subject to regulatory approval.
Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies for our products or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention.

Government regulation

**FDA drug approval process**

In the United States, pharmaceutical and biological products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, quality control, manufacture, storage, recordkeeping, safety, effectiveness, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or biologics license applications, or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

We cannot market a drug or biological product candidate in the United States until the product candidate has received FDA approval. The steps required before a product may be marketed in the United States generally include the following:

- completion of extensive nonclinical laboratory tests, animal studies, and formulation studies in accordance with the FDA’s Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice, or GCP, requirements to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA or BLA, in the case of biological product candidates, including gene therapy product candidates, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient and finished drug or biological product are produced and tested to assess compliance with cGMP requirements; and
FDA review and approval of the NDA or BLA prior to any commercial marketing or sale of the drug in the United States.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Nonclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal regulations and requirements, including GLP regulations. The results of nonclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. If the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk, the FDA will place the IND on clinical hold and the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, including GCP requirements, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose a clinical hold or other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval at each site at which the clinical trial will be conducted. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

U.S. pharmaceutical and biological products development process

Clinical trials to support NDAs or BLAs for marketing approval of pharmaceutical product candidates are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine metabolism, pharmacokinetics, the effectiveness of the drug or biologic product candidate for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials, also called pivotal or registration trials, are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic product candidate and to provide adequate information for the labeling of the drug or biologic. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic product candidate. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with a potentially serious outcome and where confirmation of the result in a second trial would be practically or ethically impossible.
After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all nonclinical, clinical, and other testing, and a compilation of data relating to the product candidate’s pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA or BLA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA and BLA are also subject to annual program user fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of an application to determine whether the application will be accepted for filing based on the agency’s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of application. Most such applications for standard review drug products are reviewed within 10 to 12 months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs to treat serious conditions that the FDA determines offer significant improvement in safety or effectiveness. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug or biologic product candidate is manufactured. The FDA will not approve the product unless compliance with cGMP requirements is satisfactory and the NDA or BLA contains data that provide substantial evidence that the product is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA’s satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. As a condition of approval, the FDA may require a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of the product outweigh the potential risks.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product’s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a risk evaluation and mitigation strategy, or REMS. A REMS can include a medication guide, a communication plan for healthcare professionals, and elements to assure safe use, such as special training and certification requirements for individuals who prescribe or dispense the drug, requirements that patients enroll in a registry, and other measures that the FDA deems necessary to assure the safe use of the drug. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product’s safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory
standards is not maintained or problems are identified following initial marketing. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new application or application supplement before the change can be implemented. An application supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing application supplements as it does in reviewing applications. Such supplements are typically reviewed within 10 months of receipt.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain applications or application supplements must contain data that are adequate to assess the safety and effectiveness of the product candidates 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.

Once an application is approved, a product is subject to pervasive and ongoing post-approval regulatory requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs and biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, product sampling and distribution, reporting of adverse events, and promotional activities involving the internet and social media. Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, or surveillance to monitor the effects of an approved product, or restrictions on the distribution or use of the product. In addition, quality-control, manufacturing, packaging, and labeling procedures must continue to conform to cGMP requirements after approval. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP requirements. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMP requirements. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacture of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information; and
The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Additional requirements for U.S. biological products development process

Our gene therapy product candidate will be regulated by FDA as a biologic, which, in addition to the pharmaceutical development pathway described above, requires compliance with certain product-specific regulations.

Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines, is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA; however, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Under these guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial.

Prior to August 2018, the NIH guidelines also required human gene transfer protocols to be submitted for review by the NIH Office of Biotechnology Activities’ Recombinant DNA Advisory Committee, or RAC, a federal advisory committee, where (1) an oversight body such as an IBC or an IRB determined that the protocol would significantly benefit from RAC review, and (2) the protocol (a) used a new vector, genetic material, or delivery methodology that represents a first-in-human experience and thus presents an unknown risk, and/or (b) relied on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value, and/or (c) involved a proposed vector, gene construct, or method of delivery associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously. On August 17, 2018, the NIH issued a notice in the Federal Register and issued a public statement proposing changes to the oversight framework for gene therapy trials, including changes to the applicable NIH guidelines to modify the roles and responsibilities of the RAC with respect to human clinical trials of gene therapy products, and requesting public comment. During the public comment period, which closes October 16, 2018, the NIH has announced that it will no longer accept new human gene transfer protocols or convene the RAC to review individual clinical protocols. These trials will remain subject to the FDA’s oversight and other clinical trial regulations, and the roles and responsibilities of the IBC at the local level will continue as described in the NIH Guidelines.

The FDA recommends that sponsors observe subjects for potential gene therapy-related delayed adverse events for a 15-year period, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of trial subjects.
The NIH and the FDA have a publicly accessible database, the Genetic Modification Clinical Research Information System, which includes information on gene transfer studies and serves as an electronic tool to facilitate the reporting and analysis of adverse events on these studies.

After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. Systems need to be put in place to record and evaluate adverse events reported by health care providers and patients and to assess product complaints.

**Market and data exclusivity for biological products**

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the PPACA, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidance is expected to be finalized by FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a licensed biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the FDA must find that the biosimilar product can be expected to produce the same clinical results as the reference product and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of licensure of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed by FDA. The BPCIA also requires a 180-day notice of commercial marketing of a biosimilar to the reference product manufacturer. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor’s own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

**Foreign regulation**

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales, and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process
varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Other healthcare laws

Although we currently do not have any products on the market, our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may be subject to additional healthcare laws, regulations and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and physician sunshine laws. Some of our pre-commercial activities are subject to some of these laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer or a party acting on its behalf, to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item, or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although 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. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations 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 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 its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Additionally, the intent standard under the Anti-Kickback Statute was amended by the PPACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, PPACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid.

The federal civil and criminal false claims laws, including the federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, certain of our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny.
under this law. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the
government, plus mandatory civil penalties of between $11,181 and $22,363 for each separate false claim, the potential for exclusion from
participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, False Claims Act violations may
also implicate various federal criminal statutes.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit
among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program,
including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a
criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing, or covering up a material fact or making any
materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services.
Like the federal Anti-Kickback Statute, PPACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a
person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, 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.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing
regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common
healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require
the adoption of administrative, physical, and technical safeguards to protect such information. Among other things, HITECH makes HIPAA’s
security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create,
receive, or obtain protected health information in connection with providing a service for or on behalf of a covered entity. At present, it is
unclear if we would be considered a business associate subject to HIPAA based on our business activities and service offerings upon the
commercialization of a product. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and
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 attorney’s fees and costs associated with pursuing federal civil actions. In addition, certain state
laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many
of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to
comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

The federal Physician Payments Sunshine Act, created under PPACA and its implementing regulations, requires certain manufacturers of
drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance
Program to annually report information related to certain 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 certain
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. Covered manufacturers are required to submit reports on aggregate payment data to the Secretary of the U.S. Department of
Health and Human Services on an annual basis.

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Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor. 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, drug pricing or marketing expenditures. These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts. Additionally, to the extent that we have business operations in foreign countries or sell any of our products in foreign countries and jurisdictions, including Canada or the European Union, we may be subject to additional regulation.

Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs designed to establish internal control and facilitate compliance can mitigate the risk of violating these laws, and the subsequent investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, and oversight if we become subject to a corporate integrity agreement or similar agreement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

**Health reform**

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to healthcare systems that could affect our future results of operations. There have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs.

In particular, PPACA has had, and is expected to continue to have, a significant impact on the healthcare industry. This law was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, PPACA revises the definition of “average manufacturer price,” or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and imposes a significant annual fee on companies that manufacture or import certain branded prescription drug products. In January 2016, the Centers for Medicare and Medicaid Services 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 PPACA. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare providers and entities, and a significant number of provisions are not yet, or have only recently become, effective.

We cannot predict the full impact of PPACA on pharmaceutical companies, as many of the reforms require the promulgation of detailed regulations implementing the statutory provisions, some of which have not yet fully occurred.

Further, there have been judicial and Congressional challenges to certain aspects of PPACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of PPACA.
Since January 2017, the President of the United States has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of PPACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on January 22, 2018, the President of the United States signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Congress may consider other legislation to repeal or replace elements of PPACA. Although we cannot predict the ultimate content, timing or effect of any changes to PPACA or other federal and state reform efforts, we continue to evaluate the effect that PPACA, as amended or replaced, will have on our business. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our product candidate.

Other legislative changes have been proposed and adopted since PPACA was enacted. In August 2011, the President of the United States signed into law the Budget Control Act of 2011, which, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs.

Moreover, the Drug Supply Chain Security Act imposes obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing, which is being phased in over several years beginning in 2015. Among the requirements of this legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. The transfer of information to subsequent product owners by manufacturers will eventually be required to be done electronically. Manufacturers will also be required to verify that purchasers of the manufacturers’ products are appropriately licensed. Further, under this legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

**Coverage and reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any of our products, if and when approved. Sales in the United States will depend in part on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for our therapeutic product candidates can be subject to challenge, reduction or denial by payors.
The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor’s decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process if coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

Additionally, the containment of healthcare costs (including drug prices) has become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition. In addition, state and federal healthcare reform measures have been and will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

**Employees**

As of June 30, 2018, we had no employees, and our wholly owned subsidiary, Urovant Sciences, Inc., or USI, had 26 employees, including 12 who are engaged in research and development activities. The employees of USI provide services to us and our subsidiaries pursuant to an intercompany services agreement by and among us, USI and our wholly owned subsidiary, Urovant Sciences GmbH, or USG.
Facilities

Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda and our principal office is located at Suite 1, 3rd Floor, 11-12 St. James’s Square, London SW1Y 4LB, United Kingdom. We also have business operations at 5151 California Avenue, Suite 250, Irvine, California 92617.

Our wholly owned subsidiary, USI, has a sublease for approximately 8,038 square feet of office space in Irvine, California for clinical research and development operations and administrative functions through February 2020. Our affiliate, RSG, leases office space in Basel, Switzerland for business development, intellectual property management and other administrative functions. Our wholly owned subsidiary, USG, may sublease space from RSG in Basel, from where we would plan to conduct business development, intellectual property management, commercial preparation and clinical research and development activities. Our affiliate, Roivant Sciences, Inc., or RSI, leases office space in New York, New York and Durham, North Carolina for clinical and non-clinical research and development operations and finance operations. We do not anticipate that USI will separately sublease space in New York or North Carolina, and the clinical research and development and other activities in those locations will be carried out by RSI at our direction and in accordance with our services agreement with RSI. See “Certain relationships and related party transactions—Affiliate services agreements” for additional information regarding the services agreements pursuant to which our affiliates provide services to us. We intend to add new facilities or expand our existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.
Management

Directors and executive officers

The following table sets forth information concerning our executive officers and directors, including their ages as of August 27, 2018.

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Position</th>
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<tbody>
<tr>
<td><strong>Executive officers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keith A. Katkin*</td>
<td>47</td>
<td>Principal Executive Officer and Director;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chief Executive Officer of USI</td>
</tr>
<tr>
<td>Christine G. Ocampo*</td>
<td>46</td>
<td>Principal Financial and Accounting Officer;</td>
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<tr>
<td></td>
<td></td>
<td>Senior Vice President and Chief Accounting</td>
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<td></td>
<td></td>
<td>Officer of USI</td>
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<tr>
<td>Nori Ebersole*</td>
<td>55</td>
<td>Senior Vice President and Chief Human</td>
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<tr>
<td></td>
<td></td>
<td>Resources Officer of USI</td>
</tr>
<tr>
<td>Cornelia Haag-Molkenteller, M.D.,</td>
<td>60</td>
<td>Chief Medical Officer of USI</td>
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<tr>
<td>Ph.D.*</td>
<td></td>
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<tr>
<td>Michael McFadden*</td>
<td>50</td>
<td>Chief Commercial Officer of USI</td>
</tr>
<tr>
<td>Bryan E. Smith*</td>
<td>39</td>
<td>General Counsel of USI</td>
</tr>
<tr>
<td><strong>Non-Employee Directors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myrtle S. Potter(1)(2)(3)</td>
<td>59</td>
<td>Chairperson of our Board of Directors</td>
</tr>
<tr>
<td>Sef P. Kurstjens, M.D., Ph.D.(1)(4)</td>
<td>55</td>
<td>Director</td>
</tr>
<tr>
<td>Pierre Legault(1)(2)(3)(4)</td>
<td>58</td>
<td>Director</td>
</tr>
<tr>
<td>Frank M. Torti, M.D.(2)(3)(4)</td>
<td>39</td>
<td>Director</td>
</tr>
</tbody>
</table>

* Employee of our wholly owned subsidiary, USI. Such employee provides services to us pursuant to an inter-company services agreement between us and USI.

(1) Member of the compensation committee.
(2) Member of the nominating and corporate governance committee.
(3) Member of the compliance oversight committee.
(4) Member of the audit committee.

**Executive officers**

Keith A. Katkin has served as our Principal Executive Officer since May 2018, a member of our board of directors since July 2018, and as the President and Chief Executive Officer of USI since September 2017. From March 2007 through January 2016, he was President and Chief Executive Officer of Avanir Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, where he led the company through its acquisition by Otsuka Pharmaceutical Co., Ltd. in 2015. He also served as a member of the board of directors of Avanir since 2007.

Mr. Katkin joined Avanir in July 2005 as the Senior Vice President of Sales and Marketing and a member of Avanir's executive management team. From 2004 to 2005, Mr. Katkin served as the Vice President, Commercial Development for Peninsula Pharmaceuticals, Inc., a biopharmaceutical company, until it was acquired by Ortho-McNeil Pharmaceutical, Inc., a subsidiary of Johnson and Johnson. Additionally, Mr. Katkin's employment experience includes leadership roles at InterMune, Inc., Amgen Inc. and Abbott Laboratories. Mr. Katkin currently serves as director of Syndax Pharmaceuticals Inc., Novus Therapeutics, Inc. (Chairman) and Rigel Pharmaceuticals, Inc., all of which are publicly traded biopharmaceutical companies. Mr. Katkin earned a B.S. in Business and Accounting from Indiana University and an M.B.A. from the Anderson School at University of California, Los Angeles. Our board of directors believes that Mr. Katkin's executive experience and his membership on the board of directors of several biotechnology companies qualify him to serve as a member of our board of directors.

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Christine G. Ocampo has served as our Principal Financial and Accounting Officer since May 2018, and as the Senior Vice President and Chief Accounting Officer of USI since October 2017. From September 2015 to May 2017, Ms. Ocampo was the Senior Vice President and Chief Financial Officer of Otic Pharma, Ltd., until it was acquired by Novus Therapeutics, after which she served as the Chief Financial and Compliance Officer until July 2017, and as a consultant from July 2017 to October 2017. Ms. Ocampo has over 20 years of accounting and finance experience, including over 11 years as the head of Finance for publicly traded companies in the healthcare industry. From 2007 to September 2015, Ms. Ocampo served in various roles at Avanir, including Vice President of Finance, Chief Accounting Officer and Vice President of Finance, Chief Compliance Officer and Secretary. From 2001 to 2006, Ms. Ocampo served as the Senior Vice President, Chief Financial Officer, Chief Accounting Officer, Treasurer, Secretary and Vice President, Corporate Controller of Cardiogenesis Corporation (now CryoLife, Inc.), a publicly traded medical device company. From 1996 to 1997, Ms. Ocampo held a management role in Finance at Mills-Peninsula Health Systems in Burlingame, California, and from 1994 to 1996, served as an auditor for Ernst & Young LLP. Ms. Ocampo earned a B.A. in Accounting from Seattle University and is a licensed Certified Public Accountant in the state of Washington.

Nori Ebersole has served as the Senior Vice President and Chief Human Resources Officer of USI since December 2017. From September 2015 to December 2017, Ms. Ebersole was the Chief Human Resources Officer and Chief Talent Officer at Paul Hastings LLP. From April 1997 to June 2015, Ms. Ebersole served in various roles at Allergan Inc. (now Allergan plc), including most recently as Vice President, Human Resources from January 2014 to June 2015, partnering with executives globally on key strategic initiatives in the Urology, Neurology, Dermatology, Ophthalmology and Aesthetics business units. At Allergan plc, Ms. Ebersole led numerous commercial and R&D expansions, compensation planning, leadership development and retention strategies. Ms. Ebersole earned a B.S. in Business Administration from the University of Southern California Marshall School of Business.

Cornelia Haag-Molkenteller, M.D., Ph.D. has served as the Chief Medical Officer of USI since April 2018. From April 2015 to March 2018, Dr. Haag-Molkenteller was the Vice President in Clinical Development at Allergan plc, and from November 2007 to March 2015, the Vice President in Global Drug Development. While at Allergan, she led clinical development of onabotulinumtoxinA (BOTOX) for OAB and neurogenic detrusor overactivity. From 1988 to 2006, she was the Vice President of Clinical Program Leadership at Schwarz Biosciences GmbH. Dr. Haag-Molkenteller earned an M.D. and Ph.D. from Johann Wolfgang Goethe-Universität Frankfurt am Main.

Michael McFadden has served as the Chief Commercial Officer of USI since January 2018. From April 2015 to January 2017, Mr. McFadden was the Senior Vice President for Commercial at Avanir Pharmaceuticals, Inc., where he led Avanir’s sales and marketing efforts, and from May 2010 to March 2015, the Vice President of U.S. Sales and Managed Markets. From July 2007 to April 2010, Mr. McFadden was the Senior Director, Managed Markets at Amylin Pharmaceuticals Inc., and from and from 2004 to 2007, a Regional Sales Director. While at Amylin, he launched two first-in-class diabetes products. From 2001 to 2003, Mr. McFadden was a State Purchasing Director at Pharmacia Corporation (prior to its acquisition by Pfizer Inc.). Mr. McFadden has nearly 30 years of pharmaceutical commercialization experience. Since July 2017, Mr. McFadden has also been an advisor to Akhu Therapeutics, Inc. Mr. McFadden earned a B.A. in Business Administration from the University of Louisiana at Monroe.

Bryan E. Smith has served as the General Counsel of USI since April 2018. From August 2011 to April 2018, Mr. Smith was an Associate Vice President and Senior Counsel at Allergan. At Allergan, he was Chief Counsel to the Allergan Medical Division and was the lead lawyer responsible for the Urology, Neurology and Dermatology divisions. In his capacity as Senior Counsel, he was the legal advisor to Allergan’s executive management, marketing and business teams and provided counsel regarding promotional materials, regulatory requirements for investigational and approved products, regulatory submissions, product labeling, clinical trials and drug safety management. From 2008 to 2011, Mr. Smith was an attorney in the litigation department at the law firm of Gibson, Dunn & Crutcher LLP, and from 2006 to 2008, an attorney at the law firm of Morrison & Foerster.
LLP. From 2005 to 2006, Mr. Smith was a judicial law clerk to the Honorable Cormac J. Carney of the United States District Court for the Central District of California. He earned a B.A. in Political Science from Brigham Young University and a J.D. from the University of Southern California Law School.

Non-employee directors

Myrtle S. Potter has served as the Chairperson of our board of directors since August 2018. Ms. Potter has served as a Vant Operating Chair of Roivant Sciences, Inc. since July 2018. Ms. Potter founded Myrtle Potter & Company, LLC, a private healthcare and life sciences consulting firm, in September 2005, and served as the Chief Executive Officer until June 2018. From August 2009 until December 2014, Ms. Potter served as Founder and Chief Executive Officer of Myrtle Potter Media, Inc., a consumer healthcare company. From 2000 to 2004, Ms. Potter served as Chief Operating Officer at Genentech, Inc., a biopharmaceutical company, and from 2004 to 2005, she served as the President, Commercial Operations and Executive Vice President of Genentech. Prior to that, Ms. Potter held various positions, including President, Cardiovascular/Metabolics at Bristol-Myers Squibb and a vice president at Merck Corporation. Ms. Potter currently serves on the boards of directors of Rite Aid Corporation, a leading drugstore chain, Liberty Mutual Holding Company Inc., a diversified global insurance company, Axsome Therapeutics, Inc., a biopharmaceutical company, INSmed Incorporated, a biopharmaceutical company, and a number of privately held companies. Ms. Potter previously served on the boards of directors of Everyday Health, Inc., a leading provider of digital health and wellness solutions, from October 2010 until its acquisition in December 2016, and Amazon.com, Inc., a leading e-commerce company, from 2004 to 2009. She also served on the boards of directors of Medco Health Solutions Inc. and Express Scripts Holding Co., subsequent to its acquisition of Medco Health Solutions, as well as other privately held companies. Ms. Potter earned a B.A. from the University of Chicago. Our board of directors believes that Ms. Potter’s extensive operational experience leading biopharmaceutical companies and her expertise in commercializing prescription drugs qualifies her to serve as a member of our board of directors.

Sef P. Kurstjens, M.D., Ph.D. has served as a member of our board of directors since July 2018. From April 2013 to April 2018, Dr. Kurstjens served as Chief Medical Officer at Astellas Pharma Inc. At Astellas, Dr. Kurstjens was responsible for development, regulatory affairs, medical affairs, pharmacovigilance and quality assurance and was a member of the Corporate Executive Committee. From 2010 to 2013, Dr. Kurstjens was the President and Chief Executive Officer at Agensys, Inc., an early stage oncology Astellas affiliate. From 2007 to 2010, Dr. Kurstjens served as the Senior Vice President, Chief Medical Officer and Head, Global Drug Development at Allergan plc. Dr. Kurstjens entered the pharmaceutical industry with Sandoz Pharmaceuticals (now a Novartis International AG company) in Basel, Switzerland in 1991, and from 1993 to 2005 held positions of increasing responsibility with Pfizer Inc. in both Europe and the United States, including Vice President Worldwide Therapeutic Area Head of Gastrointestinal and Genitourinary. Dr. Kurstjens received his qualifications in medicine and physiology from University of the Witwatersrand in Johannesburg, South Africa. Our board of directors believes that Dr. Kurstjens’s experience in various research and development roles for biopharmaceutical companies qualifies him to serve as a member of our board of directors.

Pierre Legault has served as a member of our board of directors since July 2018. Mr. Legault has served on the board of directors of Poxel SA since January 2016 and has been Chairman of such board since March 2016. Since February 2018, Mr. Legault has also served on the board of directors and as Chairman of the board of Artios Pharma Limited. Mr. Legault has also served as a director of Clementia Pharmaceuticals Inc. since January 2018 and Syndax Pharmaceuticals Inc. since January 2017. Mr. Legault has also previously served as a member of the boards of directors at Forest Laboratories, Inc., Tobira Therapeutics, Inc., NPS Pharmaceuticals, Inc., Regado Biosciences, Inc., ARMO Biosciences, Iroko Pharmaceuticals LLC, Cyclacel Pharmaceuticals Inc., Eckerd Pharmacy and NephroGenex, Inc., where he also served as the Chairman and Chief Executive Officer from 2012 to 2016. From 2010 to 2012, Mr. Legault served as the Chief Executive Officer of Prosidion Ltd.,
Mr. Legault also previously served as the Chief Executive Officer of Eckerd Pharmacy and Senior Executive Vice President and Chief Accounting Officer of the Rite Aid Corporation. Between 1989 and 2005, Mr. Legault held various global roles such as President, Chief Executive Officer and Chief Financial Officer at legacy companies of the Sanofi-Aventis group. Mr. Legault earned a B.B.A. in Business & International Finance from HEC Montreal, an M.B.A. in Marketing from McGill University and holds C.A. and C.P.A. diplomas. He also studied at Harvard Business School in their Graduate Executive MBA program. Our board of directors believes that Mr. Legault’s experience leading and managing a number of biopharmaceutical companies as chief executive officer qualifies him to serve as a member of our board of directors.

Frank M. Torti, M.D.

has served as a member of our board of directors since August 2018. Dr. Torti has served as a Vant Investment Chair of RSI since August 2018. Prior to joining RSI, from August 2007 to August 2018, Dr. Torti served as a Partner of New Enterprise Associates, or NEA, specializing in investments in healthcare. Prior to joining NEA, Dr. Torti worked for the Duke University Center for Clinical & Genetic Economics from 2002 to 2005 in various capacities, where he was involved in clinical trials research and economic evaluations of multinational clinical trials. Dr. Torti has also previously served on the boards of directors of several development and commercial stage private healthcare companies, including Annexon Biosciences, Inc., Eargo Inc., Galera Therapeutics, Inc., NeoTract, Inc., Novast Pharmaceuticals Ltd., OrphoMed, Inc., Tarveda Therapeutics, Inc. and XOC Pharmaceuticals, Inc. Dr. Torti earned an M.D. from the University of North Carolina School of Medicine, an M.B.A. from Harvard Business School and a B.A. from the University of North Carolina. Our board of directors believes that Dr. Torti’s extensive experience in healthcare investing, as well as his clinical trial background, qualifies him to serve on our board of directors.

Family relationships

There are no family relationships between our board of directors and our executive officers.

Board of directors

Our business and affairs are managed under the direction of our board of directors, which currently consists of five members. In accordance with our amended and restated bye-laws, our board of directors will consist of a single class of directors. Each member of our board of directors (other than a director appointed by RSL, or an RSL Director), will serve a term as determined by our shareholders and each RSL Director will serve a term as determined by RSL. In either case, if no such determination is made, each such director will serve a one-year term expiring at our next annual meeting of shareholders, subject to his or her office being vacated sooner pursuant to our amended and restated bye-laws. Our amended and restated bye-laws will provide that the authorized number of directors (being no less than five directors and no more than seven directors) may be changed only by resolution approved by a majority of our board of directors.

Director independence and controlled company exemptions

After the closing of this offering, we will be a “controlled company” within the meaning of the listing rules of The Nasdaq Global Markets, or Nasdaq. We will remain a “controlled company” so long as either more than 50% of the voting power for the election of directors is held by RSL or the RSL designated directors control all matters presented to our board of directors for a vote. As such, we intend to avail ourselves of the controlled company exemptions under the Nasdaq listing rules. As a controlled company, we will not be required to have a majority of “independent directors” on our board of directors, as defined under the Nasdaq listing rules, or to have a compensation committee or a board committee performing the board nominating function composed entirely of independent directors. Accordingly, you may not have the same protections afforded to shareholders.
of companies that are subject to all of the corporate governance requirements of Nasdaq. We may continue to rely on these exemptions so long as we are allowed to as a “controlled company.”

The “controlled company” exemption does not modify the independence requirements for the audit committee, and we intend to comply with the requirements of Rule 10A-3 of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Nasdaq listing rules, which rules require that our audit committee be composed of at least three members. Under Rule 10A-3 of the Exchange Act, we are permitted to phase in our compliance with the independent audit committee requirements set forth in Rule 10A-3 of the Exchange Act as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing.

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors has determined that Dr. Kurstjens and Mr. Legault representing two of the five members of our board of directors, are independent, as that term is defined under the applicable rules and regulations of the U.S. Securities and Exchange Commission, or SEC, and the Nasdaq listing rules. Our board of directors has determined that Mr. Katkin, Ms. Potter and Dr. Torti are not independent under applicable SEC and Nasdaq listing rules. We plan to comply with the corporate governance requirements of the SEC and the Nasdaq listing rules.

Committees of the board of directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the management of our business.

Audit committee

Our audit committee consists of Mr. Legault and Drs. Kurstjens and Torti. Mr. Legault is the chairperson of the audit committee.

Our board of directors has determined that each of Dr. Kurstjens and Mr. Legault is an independent director under the Nasdaq listing rules and is independent under Rule 10A-3 of the Exchange Act. Our board of directors has further determined that each of the members of the audit committee satisfy the financial literacy and sophistication requirements of the SEC and the Nasdaq listing rules. In addition, our board of directors has determined that Mr. Legault qualifies as an audit committee financial expert, as defined in Item 407(d)(5) of Regulation S-K promulgated under the U.S. Securities Act of 1933, as amended, or the Securities Act.

The principal duties and responsibilities, among others, of our audit committee include:

• recommending and retaining an independent registered public accounting firm to serve as independent auditor to audit our financial statements, overseeing the independent auditor's work and determining the independent auditor's compensation;

• approving in advance all audit services and non-audit services to be provided to us by our independent auditor;

• establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
overseeing our risk assessment and risk management processes;

reviewing and ratifying all related party transactions, based on the standards set forth in our related party transactions policy;

reviewing and discussing with management and our independent auditor the results of the annual audit and the independent auditor’s review of our quarterly financial statements; and

conferring with management and our independent auditor about the scope, adequacy and effectiveness of our internal accounting controls, the objectivity of our financial reporting and our accounting policies and practices.

Both our independent registered public accounting firm and management periodically will meet privately with our audit committee.

**Compensation committee**

Our compensation committee consists of Dr. Kurstjens, Mr. Legault and Ms. Potter. Each of Dr. Kurstjens and Mr. Legault is a non-employee member of our board of directors as defined in Rule 16b-3 under the Exchange Act. Dr. Kurstjens is the chairperson of the compensation committee.

The principal duties and responsibilities, among others, of our compensation committee include:

- establishing and approving, and making recommendations to the board of directors regarding, performance goals and objectives relevant to the compensation of our chief executive officer, evaluating the performance of our chief executive officer in light of those goals and objectives and setting, or recommending to the full board of directors for approval, the chief executive officer’s compensation, including incentive-based and equity-based compensation, based on that evaluation;

- setting the compensation of our other executive officers, based in part on recommendations of the chief executive officer;

- exercising administrative authority under our equity incentive plan and employee benefit plans;

- establishing policies and making recommendations to our board of directors regarding director compensation;

- overseeing risks and exposures associated with executive and director compensation plans and arrangements;

- reviewing and discussing with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings; and

- preparing a compensation committee report on executive and director compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

**Nominating and corporate governance committee**

Our nominating and corporate governance committee consists of Ms. Potter, Mr. Legault and Dr. Torti. Ms. Potter is the chairperson of the nominating and corporate governance committee.

The principal duties and responsibilities, among others, of our nominating and corporate governance committee include:

- assessing the need for new directors and identifying individuals qualified to become directors;
• recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
• assessing individual director performance, participation and qualifications;
• developing, recommending, overseeing the implementation of and monitoring compliance with, our corporate governance guidelines, and periodically reviewing and recommending any necessary or appropriate changes to our corporate governance guidelines;
• monitoring the effectiveness of the board and the quality of the relationship between management and the board; and
• overseeing an annual evaluation of the board’s performance.

Compliance oversight committee
Our compliance oversight committee consists of Ms. Potter, Mr. Legault and Dr. Torti. Ms. Potter is the chairperson of the compliance oversight committee.

The principal duties and responsibilities, among others, of our compliance oversight committee include:
• identifying our compliance officer and reviewing and assessing the compliance officer’s performance in administering our compliance program;
• making periodic reports to the board regarding compliance matters, including reporting any substantial deviations from, or potential violations of, our compliance policies and procedures;
• establishing internal reporting procedures for our employees to confidentially report to our compliance officer any identified issues or questions regarding our compliance program; and
• developing, recommending, reviewing and updating our compliance policies and procedures to ensure continued compliance with the current legal and regulatory landscape in which we operate.

Code of business conduct and ethics for employees, executive officers and directors
We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct will be available on our website at www.urovant.com. The nominating and corporate governance committee of our board of directors is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

Compensation committee interlocks and insider participation
None of our directors who serve as a member of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.

Director compensation
Our board of directors has adopted a director compensation policy pursuant to which our non-employee directors will be eligible to receive cash compensation for the time and effort necessary to serve as a members
of our board of directors. We expect that our board of directors will amend this director compensation policy to provide for the grant of equity compensation to our non-employee directors in addition to cash compensation. Pursuant to this policy, we expect that any director who is also an employee of ours or our subsidiary will not receive any additional compensation for his or her service as a director.

Pursuant to our non-employee director compensation policy, each non-employee director will be eligible to receive an annual cash retainer of $40,000 for serving on our board of directors. The chairperson of our board of directors will receive an additional annual cash retainer of $30,000.

The chairperson and members of the audit, compensation and nominating and corporate governance committees of our board of directors will be entitled to the following annual cash retainers:

<table>
<thead>
<tr>
<th>Board committee</th>
<th>Chairperson fee</th>
<th>Member fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audit committee</td>
<td>$ 20,000</td>
<td>$ 10,000</td>
</tr>
<tr>
<td>Compensation committee</td>
<td>$ 15,000</td>
<td>$ 7,500</td>
</tr>
<tr>
<td>Nominating and corporate governance committee</td>
<td>$ 8,000</td>
<td>$ 4,000</td>
</tr>
</tbody>
</table>

During the year ended March 31, 2018, our sole director was RSL, our sole shareholder.
Executive compensation

Our named executive officers for the year ended March 31, 2018, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- Keith A. Katkin, our Principal Executive Officer and President and Chief Executive Officer of USI;
- Michael McFadden, Chief Commercial Officer of USI; and
- Christine G. Ocampo, our Principal Financial and Accounting Officer and Senior Vice President and Chief Accounting Officer of USI.

Summary compensation table for year ended March 31, 2018

The following table sets forth information regarding compensation earned during the year ended March 31, 2018 by our named executive officers.

<table>
<thead>
<tr>
<th>Name and principal position(1)</th>
<th>Salary</th>
<th>Bonus</th>
<th>Stock awards(2)</th>
<th>Option awards(3)</th>
<th>Non-equity incentive plan compensation(4)</th>
<th>All other compensation(5)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keith A. Katkin(6)</td>
<td>$158,077</td>
<td>$ —</td>
<td>$ —</td>
<td>$2,540,175(7)</td>
<td>$330,000</td>
<td>$665</td>
<td>$3,028,917</td>
</tr>
<tr>
<td>Principal Executive Officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Michael McFadden(8)</td>
<td>59,231</td>
<td>—</td>
<td>$ —</td>
<td>$481,387</td>
<td>$24,742</td>
<td>750</td>
<td>566,110</td>
</tr>
<tr>
<td>Chief Commercial Officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Christine G. Ocampo(9)</td>
<td>121,314</td>
<td>30,000(10)</td>
<td>$ —</td>
<td>$310,741</td>
<td>$54,196</td>
<td>313</td>
<td>516,564</td>
</tr>
<tr>
<td>Principal Financial and Accounting Officer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(1) Each of our named executive officers is an employee of our wholly owned subsidiary, USI. Such employee provides services to us pursuant to an inter-company services agreement between us and USI.

(2) In accordance with SEC rules, this column does not include any amount for the grant date fair value of the RSL restricted stock units, or RSUs, granted to Mr. Katkin calculated in accordance with ASC Topic 718 for stock-based compensation transactions. The RSL RSUs will vest only to the extent certain RSL performance criteria are achieved and certain RSL liquidity conditions are satisfied within a specified number of years of the grant date, provided that Mr. Katkin has provided continued service to RSL or a subsidiary of RSL, such as Urovant, through such date. As of the grant date and March 31, 2018, the liquidity events were considered not probable of occurring. As a result, the grant date fair value of the RSL RSUs, for purposes of this table, is $0. Assuming that both of the vesting conditions to the RSL RSUs were met, the value of the RSL RSUs as of the grant date would have been $930,482. Mr. McFadden and Ms. Ocampo did not receive any stock awards during the year ended March 31, 2018. For a discussion of the valuation of RSL common shares, see “Management’s discussion and analysis of financial condition and results of operations—Share-based compensation.”

(3) This column reflects the full grant date fair value for options granted during the year as measured pursuant to ASC Topic 718 as share-based compensation in our consolidated financial statements. The assumptions we used in valuing options are described in Note 8 to our consolidated financial statements included elsewhere in this prospectus.

(4) Amounts reflect cash incentive bonuses paid by us in April 2018 for the performance of services in the year ended March 31, 2018, which were based upon our board of directors’ assessment of individual performance, as well as the achievement of corporate performance goals, which included goals related to business and corporate development objectives.

(5) Amounts reflect 401(k) matching contributions paid by us to each named executive officer.

(6) Mr. Katkin joined USI in September 2017.

(7) In accordance with SEC rules, this amount does not include the value of an option award for 750,000 common shares granted to Mr. Katkin on September 21, 2017, as more fully described in the table titled “Outstanding equity awards at March 31, 2018” below. This option award is subject to certain performance criteria and time-based vesting components. As of the grant date and March 31, 2018, the performance criteria were considered not “probable” of occurring. As a result, the grant date fair value of this option award, for purposes of this table, is $0. Assuming that both of the vesting conditions to the option award were met, the value of this option award as of the grant date would be $495,396.

(8) Mr. McFadden joined USI in January 2018.

(9) Ms. Ocampo joined USI in October 2017.

(10) Represents a discretionary performance bonus.
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Outstanding equity awards at March 31, 2018

The following table provides information about outstanding equity awards held by each of our named executive officers at March 31, 2018. All stock options were granted under our 2017 Equity Incentive Plan, as amended.

<table>
<thead>
<tr>
<th>Name</th>
<th>Grant date</th>
<th>Exercisable</th>
<th>Unexercisable</th>
<th>Number of securities underlying unexercised options (#)</th>
<th>Equity incentive plan awards: number of securities underlying unexercised unearned options(#)</th>
<th>Option exercise price</th>
<th>Option expiration date</th>
<th>Stock awards: Equity incentive plan awards: Market or payout value of unearned units that have not vested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keith A. Katkin</td>
<td>9/21/2017</td>
<td>—</td>
<td>3,750,000(2)</td>
<td>—</td>
<td>750,000(3)</td>
<td>1.03</td>
<td>9/21/2027</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>9/21/2017</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1.03</td>
<td>3/18/2028</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>3/19/2018</td>
<td>—</td>
<td>92,250(6)</td>
<td>—</td>
<td>—</td>
<td>1.07</td>
<td>2/19/2028</td>
<td>66,845(4) 930,482(5)</td>
</tr>
<tr>
<td>Michael McFadden</td>
<td>9/21/2017</td>
<td>—</td>
<td>700,000(7)</td>
<td>—</td>
<td>—</td>
<td>1.07</td>
<td>11/19/2027</td>
<td>—</td>
</tr>
<tr>
<td>Christine G. Ocampo</td>
<td>11/20/2017</td>
<td>—</td>
<td>500,000(8)</td>
<td>—</td>
<td>—</td>
<td>0.97</td>
<td>11/19/2027</td>
<td>—</td>
</tr>
</tbody>
</table>

(1) All option awards listed in this table were granted pursuant to our 2017 Equity Incentive Plan, as amended, the terms of which are described below under "— 2017 Equity Incentive Plan."

(2) This stock option vests over a period of four years, with 25% of the common shares underlying the option vesting on the first anniversary of the option grant date, and the remaining vesting in 12 equal quarterly installments thereafter, subject to Mr. Katkin’s continuous service through the relevant vesting dates.

(3) This stock option vests upon the satisfaction of both the time-based vesting condition set forth in the first sentence of footnote (2) and an anti-dilution performance vesting condition. The latter condition requires that until such point that we have cumulatively raised an aggregate of $200 million in capital (including capital contributions from RSL or otherwise), if we are to issue new common shares, this option will vest (subject to time-based vesting) with respect to the portion of the option equal to a number of shares equal to 5% of the total common shares issued and outstanding in excess of 75,000,000 (excluding any common shares that become issued and outstanding through the exercise or vesting of outstanding equity awards after September 21, 2017). Any portion of the option that has not satisfied this anti-dilution performance vesting condition at the time when the capital-raising goal has been met will be forfeited.

(4) Represents the number of RSL common shares underlying the RSL RSUs. The RSL RSUs will vest only to the extent certain RSL performance criteria are achieved and certain RSL liquidity conditions are satisfied within a specified number of years of the grant date, provided that Mr. Katkin has provided continued service to RSL or a subsidiary of RSL, such as Urovant, through such date.

(5) Significant judgment and estimates were used to estimate the fair value of the RSL RSUs held by Mr. Katkin, as they are not publicly traded. The fair value was estimated based on various corporate event-based considerations, including certain thresholds for RSL’s future financing and liquidity events as defined in the RSL agreements and Monte Carlo simulation.

(6) This stock option vests over a period of four years, with 25% of the common shares underlying the option vesting on March 14, 2019, and the remaining vesting in 12 equal quarterly installments thereafter, subject to Mr. Katkin’s continuous service through the relevant vesting dates.

(7) This stock option vests over a period of four years, with 25% of the common shares underlying the option vesting on January 22, 2019, and the remaining vesting in 36 equal monthly installments thereafter, subject to Mr. McFadden’s continuous service through the relevant vesting dates.

(8) This stock option vests over a period of four years, with 25% of the common shares underlying the option vesting on October 5, 2018, and the remaining vesting in 36 equal monthly installments thereafter, subject to Mr. Ocampo’s continuous service through the relevant vesting dates.

Employment arrangements and potential payments and benefits upon termination or change in control

Keith A. Katkin

In September 2017, our wholly owned subsidiary, USI, entered into an employment agreement with Mr. Katkin, pursuant to which he serves as its President and Chief Executive Officer. The agreement provides for an annual base salary of $300,000, which may be increased from time to time in the discretion of our board of directors. Mr. Katkin will be eligible to earn an annual discretionary cash bonus with a target of 150% of base salary based on our board of directors’ assessment of his individual performance, as well as overall company performance.
With respect to the year ended March 31, 2018, Mr. Katkin was eligible to receive a guaranteed cash bonus equal to $300,000 (Mr. Katkin’s actual bonus for such year equaled $330,000), subject to his employment through March 31, 2018. Mr. Katkin is eligible to participate in benefit plans and arrangements made available to similarly situated executives.

In September 2017, pursuant to his employment agreement, we granted Mr. Katkin an option to purchase 3,750,000 common shares, with an exercise price of $1.03 per share with 25% of the shares vesting in September 2018, and the remainder vesting quarterly over three years from September 2018. We concurrently also granted Mr. Katkin an option to purchase 750,000 common shares, with an exercise price of $1.03 per share, or the anti-dilution option, with the terms of his vesting as set forth above in the table titled “Outstanding Equity Awards at March 31, 2018.” In the event that we issue more than an aggregate of 15,000,000 common shares (excluding any common shares that become issued and outstanding through the exercise or vesting of outstanding equity awards after the date hereof), or the share cap, before we have raised an aggregate of $200 million from any source (including capital contributions from RSL or otherwise), then Mr. Katkin will receive one or more additional option grants equal to 5% of the excess amount over the share cap. Such options will vest over a period of four years, with 25% of the common shares underlying the options vesting on the first anniversary of the option grant date and the remaining common shares vesting in 12 equal quarterly installments thereafter. In addition, on each six-month anniversary of Mr. Katkin’s employment start date, he is eligible to receive an option award equal to 5% of the net positive number of equity awards that were granted by us to individuals (other than Mr. Katkin) in the prior six-month period less any such equity awards that were forfeited during that period, provided that the cumulative net number of equity grants issued since Mr. Katkin’s start date (excluding the awards issued to Mr. Katkin) compared to the number of such equity awards forfeited is positive at the time of measurement, and until such time as we have raised $200 million (including capital contributions from RSL or otherwise). Such options will vest over a period of four years, with 25% of the common shares underlying the options vesting on the first anniversary of the option grant date and the remaining common shares vesting in 12 equal quarterly installments thereafter. The first such award granted pursuant to the terms of this provision is set forth above in the table titled “Outstanding Equity Awards at March 31, 2018.” Upon a change of control (as defined in the employment agreement), any then-unvested portion of Mr. Katkin’s unvested options, other than any portion of an anti-dilution option that has not met the dilution performance condition, will vest in full. In October 2017, pursuant to his employment agreement, Mr. Katkin was granted an equity award of 66,845 restricted stock units in RSL. The restricted stock units will vest to the extent certain performance criteria are achieved and certain liquidity conditions are satisfied within eight years of the grant date.

Mr. Katkin’s employment is at-will and may be terminated at any time, with or without cause, provided that Mr. Katkin must provide us with at least three months’ notice of intention to resign other than for “good reason” (as defined in the employment agreement). If Mr. Katkin’s employment is terminated without “cause” (as defined in the employment agreement) or by Mr. Katkin for good reason, then, subject to the delivery and effectiveness of a waiver and release of claims, he will be entitled to receive: (a) a lump sum payment equal to the sum of his base salary and target bonus (or, if such termination occurs within 24 months following the consummation of a change of control, two times the sum of his base salary and target bonus); (b) reimbursement of COBRA premiums for the first 36 months of COBRA coverage or a direct taxable cash payment of equivalent value, if the COBRA reimbursement is not permitted pursuant to applicable law; and (c) vesting of 100% of his then-unvested equity awards, other than any portion of his anti-dilution option that has not met the dilution performance condition. If Mr. Katkin’s employment is terminated due to death or “disability” (as defined in the employment agreement), Mr. Katkin (or his estate) will be paid an amount equal to his target bonus. Following the closing of this offering, if any amounts would constitute a parachute payment within the meaning of Section 280G of the Internal Revenue Code, or the Code, and be subject to the excise tax
imposed by Section 4999 of the Code, the amounts will either be paid in full (and subject to the excise tax), or cut back so that no excise tax applies, whichever would put Mr. Katkin in a better after-tax position.

Michael McFadden
In January 2018, our wholly owned subsidiary, USI, entered into an offer letter with Mr. McFadden, pursuant to which he serves as its Chief Commercial Officer. The agreement provides for an annual base salary of $300,000, which may be increased from time to time in the discretion of our board of directors. Mr. McFadden is eligible to earn an annual discretionary cash bonus with a target of 40% of base salary based on our board of directors’ assessment of his individual performance, as well as overall company performance. Mr. McFadden is eligible to participate in benefit plans and arrangements made available to all full-time employees. In February 2018, we granted Mr. McFadden an option to purchase 700,000 common shares, with an exercise price of $1.07 per share with 25% of the shares vesting in January 2019 and the remainder vesting monthly over 36 months from January 2019. Mr. McFadden’s employment is at-will and may be terminated at any time, with or without cause.

Christine G. Ocampo
In September 2017, our wholly owned subsidiary, USI, entered into an offer letter with Ms. Ocampo, pursuant to which she serves as its Senior Vice President and Chief Accounting Officer. The offer letter provides for an annual base salary of $250,000, which may be increased from time to time in the discretion of our board of directors. Ms. Ocampo is eligible to earn an annual discretionary cash bonus with a target of 40% of base salary based on our board of directors’ assessment of her individual performance as well as overall company performance. Ms. Ocampo is eligible to participate in benefit plans and arrangements made available to all full-time employees. In November 2017, we granted Ms. Ocampo an option to purchase 500,000 common shares, with an exercise price of $0.97 per share with 25% of the shares vesting in October 2018 and the remainder vesting monthly over 36 months from October 2018. Ms. Ocampo’s employment is at-will and may be terminated at any time, with or without cause.

2017 Equity Incentive Plan
Our board of directors adopted our 2017 Equity Incentive Plan, or the 2017 Plan, in June 2017 and our shareholder approved the 2017 Plan in . We have amended the 2017 Plan in connection with this offering, effective upon the execution of the underwriting agreement related to this offering. All references herein to our 2017 Plan will be deemed to refer to the 2017 Plan, as amended, unless context otherwise requires. The 2017 Plan provides for the grant of incentive options within the meaning of Section 422 of the Code to our employees and our parent and subsidiary corporations’ employees, and for the grant of nonstatutory options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. The 2017 Plan also provides for the grant of performance cash awards to our employees, consultants and directors.

Authorized shares
The maximum number of common shares that may be issued under the 2017 Plan is shares. The number of common shares reserved for issuance under the 2017 Plan will automatically increase on April 1 of each year, for a period of ten years, from April 1, 2019 continuing through April 1, 2028, by % of the total number of our common shares outstanding on March 31 of the preceding fiscal year, or a lesser number of shares as may be determined by our board of directors. The maximum number of common shares that may be issued pursuant to the exercise of incentive options under the 2017 Plan is .

Shares issued under the 2017 Plan may be authorized but unissued or reacquired common shares. Shares subject to stock awards granted under the 2017 Plan that expire or terminate without being exercised in full, or
that are paid out in cash rather than in shares, will not reduce the number of common shares available for issuance under the 2017 Plan. Additionally, common shares issued pursuant to stock awards under the 2017 Plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under the 2017 Plan.

Administration

Our board of directors, or a duly authorized committee thereof, will have the authority to administer the 2017 Plan. Our board of directors will delegate its authority to administer the 2017 Plan to our compensation committee under the terms of the compensation committee’s charter. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees other than officers to receive specified stock awards and (2) determine the number of our common shares to be subject to such stock awards. Subject to the terms of the 2017 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of common shares subject to each stock award, the fair market value of a common share, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under the 2017 Plan.

The administrator has the power to modify outstanding awards under our 2017 Plan. Subject to the terms of the 2017 Plan, the administrator has the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Performance awards

The 2017 Plan permits the grant of performance-based stock and cash awards. To enable us to grant performance-based awards that will qualify, our compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of specified pre-established performance goals during a designated performance period.

Changes to capital structure

In the event there is a specified type of change in our capital structure, such as a split, reverse split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under our 2017 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options and (4) the class and number of shares and exercise price, strike price or purchase price, if applicable, of all outstanding stock awards.

Corporate transactions

The 2017 Plan provides that in the event of a specified corporate transaction, including without limitation a consolidation, merger, or similar transaction involving our company, the sale of all or substantially all of the assets of our company, the direct or indirect acquisition by an person or persons acting as a group of ownership of shares representing a majority of the then outstanding share capital of our company, the administrator will determine how to treat each outstanding stock award. The administrator may:

- arrange for the assumption, continuation or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
• arrange for the lapse, in whole or in part, of any reacquisition or repurchase right held by us;
• cancel the stock award prior to the transaction in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the stock award; or
• make a payment, in such form as determined by the administrator, equal to the excess, if any, of the value of the property that would have been received if such award was exercised immediately prior to the effective time of the corporate transaction over any exercise price payable.

The administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner. The administrator may take different actions with respect to the vested and unvested portions of a stock award.

Change in control

The administrator may provide, in an individual award agreement or in any other written agreement between us and the participant, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change in control. In the absence of such a provision, no such acceleration of the stock award will occur.

Plan amendment or termination

Our board has the authority to amend, suspend, or terminate the 2017 Plan, provided that such action does not materially impair the existing rights of any participant without such participant’s written consent. Unless terminated sooner by our board, the 2017 Plan will automatically terminate on the day before the tenth (10th) anniversary of the earlier of (1) the date the 2017 Plan was adopted by our board, or (2) the date the 2017 Plan was approved by our shareholder. No incentive options may be granted after the tenth anniversary of the date our board of directors adopted the 2017 Plan.

Rule 10b5-1 sales plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell our common shares on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information, subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.
Certain relationships and related party transactions

The following is a description of transactions since our inception on January 27, 2016 to which we have been a participant and in which (1) the amount involved exceeded or will exceed $120,000, and (2) any of our directors, executive officers or holders of more than 5% of our share capital, or any members of their immediate family, had or will have a direct or indirect material interest.

Affiliate services agreements

We have entered into services agreements with each of Roivant Sciences, Inc. and Roivant Sciences GmbH, wholly owned subsidiaries of our controlling shareholder RSL, each as further described below. Pursuant to these services agreements, during the years ended March 31, 2017 and 2018 and the three months ended June 30, 2018, we incurred expenses of $1.0 million, $6.3 million and $2.8 million, respectively, inclusive of the mark-up under these agreements.

Roivant Sciences, Inc. Services Agreement

Effective as of July 9, 2018, we and our wholly owned subsidiaries, USI and USG, entered into an amended and restated services agreement with RSI, a wholly owned subsidiary of RSL, or the RSI Services Agreement, pursuant to which RSI provides us with services in relation to the identification of potential product candidates, project management of clinical trials and other development, administrative and financial activities. Following the closing of this offering, we expect that our reliance on RSI will decrease over time as we, USI, USG and any other future subsidiary of ours continue to hire the necessary personnel to manage the development and potential commercialization of vibegron or any future product candidates.

Under the terms of the RSI Services Agreement, we are obligated to pay or reimburse RSI for the costs it, or third parties acting on its behalf, incur(s) in providing services to us. In addition, we are obligated to pay to RSI a pre-determined mark-up on costs incurred by it in connection with any general and administrative and support services as well as research and development services.

Administrative and support services include, but are not limited to, payroll, general administrative, corporate and public relations, investor relations, financial marketing, activities in connection with raising capital, accounting and auditing, tax, health, safety, environmental and regulatory affairs, staffing and recruiting, benefits, information and technology services, purchasing and legal services. Research and development services include, but are not limited to, drug discovery and development from target identification through regulatory approval.

Under the RSI Services Agreement, RSI has agreed to indemnify us, USI and USG, and each our respective officers, employees and directors against all losses arising out of, due to or in connection with the provision of services (or the failure to provide services) under the RSI Services Agreement, subject to certain limitations set forth in the RSI Services Agreement. In addition, we, USI and USG have agreed to indemnify RSI and its affiliates and their respective officers, employees and directors against all losses arising out of, due to or in connection with the receipt of services under the RSI Services Agreement, subject to certain limitations set forth in the RSI Services Agreement. Such indemnification obligations will not exceed the payments made by us, by USI and by USG under the RSI Services Agreement for the specific service that allegedly caused or was related to the losses during the period in which such alleged losses were incurred. The term of the RSI Services Agreement will continue until terminated upon 90 days’ written notice by RSI or by either USI or USG with respect to the services either such party receives thereunder.

Roivant Sciences GmbH Services Agreement

Effective as of July 9, 2018, USG entered into an amended and restated services agreement with RSG, a wholly owned subsidiary of RSL, or the RSG Services Agreement, pursuant to which RSG provides USG various services,
including, but not limited to, the identification of potential additional product candidates, project management of clinical trials and other
development, administrative and financial activities. Following the closing of this offering, we expect that reliance on RSG by USG will
decrease over time as USG hires the necessary personnel to manage the development and potential commercialization of vibegron.

Under the terms of the RSG Services Agreement, USG is obligated to pay or reimburse RSG for the costs it, or third parties acting on its
behalf, incur(s) in providing services to us. In addition, USG is obligated to pay to RSG a pre-determined mark-up on costs incurred by it in
connection with any general and administrative and support services as well as research and development services.

Administrative and support services include, but are not limited to, payroll, general administrative, corporate and public relations, investor
relations, financial marketing, activities in connection with raising capital, accounting and auditing, tax, health, safety, environmental and
regulatory affairs, staffing and recruiting, benefits, information and technology services, purchasing and legal services. Research and
development services include, but are not limited to drug discovery and development from target identification through regulatory approval.

Under the RSG Services Agreement, RSG has agreed to indemnify USG, and each of its officers, employees and directors against all
losses arising out of, due to or in connection with the provision of services (or the failure to provide services) under the RSG Services
Agreement, subject to certain limitations set forth in the RSG Services Agreement. USG has also agreed to indemnify RSG and its affiliates
and their respective officers, employees and directors against all losses arising out of, due to or in connection with the receipt of services
under the RSG Services Agreement, subject to certain limitations set forth in the RSG Services Agreement. Such indemnification obligations
will not exceed the payments made by USG under the RSG Services Agreement for the specific service that allegedly caused or was related
to the losses during the period in which such alleged losses were incurred. The term of the RSG Services Agreement will continue until
terminated by RSG or USG upon 90 days' written notice.

RSL information sharing and cooperation agreement

In July 2018, we entered into an information sharing and cooperation agreement, or the Cooperation Agreement, with RSL. The Cooperation
Agreement, among other things: (1) obligates us to deliver to RSL periodic financial statements and other information upon reasonable
request and to comply with other specified financial reporting requirements; (2) requires us to supply certain material information to RSL to
assist it in preparing any future SEC filings; and (3) requires us to implement and observe certain policies and procedures related to
applicable laws and regulations. We agreed to indemnify RSL and its affiliates and their respective officers, employees or directors against
all losses arising out of, due to or in connection with RSL's status as a shareholder under the Cooperation Agreement and the operations of
or services provided by RSL or its affiliates or their respective officers, employees or directors to us or any of our subsidiaries, subject to
certain limitations set forth in the Cooperation Agreement. No amounts have been paid or received under this agreement; however, we
believe this agreement is material to our business and operations.

Subject to specified exceptions, the Cooperation Agreement will terminate upon the earlier of (1) the mutual written consent of the parties or
(2) the later of when RSL is no longer (a) required by U.S. GAAP to consolidate our results of operations and financial position, account for
its investment in us under the equity method of accounting or, by any rule of the SEC, include our separate financial statements in any
filings it may make with the SEC and (b) has the right to elect directors constituting a majority of our board of directors.

Data sharing agreement

On May 22, 2018, our wholly owned subsidiary, USG, entered into a data sharing agreement, or the Data Sharing Agreement, with Datavant,
Inc., or Datavant, a subsidiary of our parent company, RSL. Pursuant to this Data
Sharing Agreement, USG granted to Datavant a royalty-free, worldwide (excluding jurisdictions prohibited by the United States government), non-exclusive, irrevocable license to all data, subject to certain exceptions set forth in the Data Sharing Agreement, collected as part of clinical trials (but not prior to completion of such clinical trials and the publication or presentation of the data generated in connection with such clinical trials) or other patient-level data that is owned or licensed by USG or its wholly owned subsidiaries and all other data mutually agreed by USG and Datavant, solely for Datavant to (1) use such data to develop its data or other analytics products, or the Datavant Products, or (2) provide such data to third parties, subject to the limitations and conditions set forth in the Data Sharing Agreement, including limitations on providing such data to any third party that competes with USG. Pursuant to the Data Sharing Agreement, Datavant granted to USG a royalty-free, worldwide (excluding jurisdictions prohibited by the United States government), non-exclusive, irrevocable license to use all data, subject to certain exceptions set forth in the Data Sharing Agreement, owned or licensed by Datavant and applicable Datavant Products for such specified purposes as set forth in the Data Sharing Agreement. No amounts have been paid or received under this agreement, however, we believe this agreement is material to our business and operations.

Each of USG and Datavant has agreed to indemnify the other and their respective officers, employees and directors from and against any and all losses arising out of, due to or in connection with licensed data provided by USG or Datavant, as applicable, to the other party under the Data Sharing Agreement. The Data Sharing Agreement has an initial term of two years and will automatically renew annually thereafter, subject to 30 days’ written notice of termination by either party. In addition, either party may terminate (1) upon a change of control of either party upon 60 days’ written notice or (2) upon 90 days’ written notice for an uncured material breach by the other party.

China IP purchase agreement

In June 2017, we entered into an intellectual property purchase agreement with RSG, a wholly owned subsidiary of our parent company, RSL, as amended on May 22, 2018, pursuant to which we assigned all of our rights, titles, claims and interests in and to all intellectual property rights under the Merck Agreement to RSG, solely as it relates to any of our rights or obligations in China for an aggregate purchase price of approximately $1.8 million. The assignment is subject to the terms of the Merck Agreement, and RSG is obligated to make royalty and milestone payments owed under the Merck Agreement to us, to the extent such payment obligations arise from the development, regulatory approval or sales of vibegron product in China. In connection with this assignment, we also entered into a separate collaboration agreement with RSG in June 2018, setting forth the parties’ respective rights and obligations to each other in connection with the development of vibegron in their respective territories.

RSL registration rights agreement

In July 2018, we entered into a registration rights agreement with RSL. After the closing of this offering, pursuant to the terms of this agreement, RSL will be entitled to rights with respect to the registration of their common shares under the Securities Act, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. For a description of these registration rights, see the section titled “Description of share capital—Registration rights.”

Employment arrangements

Each of our executive officers is employed by our wholly owned subsidiary, USI, and provides services to us pursuant to an inter-company services agreement between us and USI. USI has an employment agreement with each of our executive officers that sets forth the initial terms and conditions of employment. For additional

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information regarding these employment arrangements, see the section titled “Executive compensation—Employment arrangements and potential payments and benefits upon termination or a change in control.”

Other transactions
We have granted and intend to continue to grant equity awards to our executive officers and non-employee directors. For a description of these equity awards, see the sections titled “Executive compensation” and “Management—Director Compensation”

Indemnification agreements
In connection with this offering, we will enter into indemnification agreements with each of our directors and executive officers. These indemnification agreements will provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Bermuda law. See the section titled “Description of share capital—Indemnification of directors and officers” for additional information regarding indemnification under Bermuda law and our amended and restated bye-laws.

Related person transaction policy
Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. Our board of directors has adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy will become effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including RSL, and any of their respective immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct that we expect to adopt prior to the closing of this offering, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

• the risks, costs and benefits to us;
the impact on a director’s independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;

• the availability of other sources for comparable services or products; and

• the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.
## Principal shareholders

The following table sets forth the beneficial ownership of our common shares as of June 30, 2018 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common shares;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

The percentage ownership information before the offering is based upon 75,000,000 common shares outstanding as of June 30, 2018. The percentage ownership information after the offering assumes the sale and issuance of common shares in this offering and no exercise by the underwriters of their option to purchase additional common shares.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include common shares issuable pursuant to the exercise of options that are either immediately exercisable or exercisable on or before August 29, 2018, which is 60 days after June 30, 2018. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for persons or entities listed in the table is c/o Urovant Sciences Ltd., Suite 1, 3rd Floor, 11-12 St. James’s Square, London SW1Y 4LB, United Kingdom.

<table>
<thead>
<tr>
<th>Name of beneficial owner</th>
<th>Number of shares beneficially owned</th>
<th>Percentage of shares beneficially owned Before Offering</th>
<th>Percentage of shares beneficially owned After Offering</th>
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<tbody>
<tr>
<td><strong>5% shareholders</strong></td>
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<td></td>
<td></td>
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<tr>
<td>Roivant Sciences Ltd.(1)</td>
<td>75,000,000</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td><strong>Named executive officers and directors</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Keith A. Katkin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Michael McFadden</td>
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<td></td>
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<tr>
<td>Christine G. Ocampo</td>
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<td></td>
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<tr>
<td>Myrtle S. Potter</td>
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<tr>
<td>Sef P. Kurstjens, M.D., Ph.D.</td>
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<tr>
<td>Pierre Legault</td>
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<tr>
<td>Frank M. Torti, M.D.</td>
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<tr>
<td><strong>All current directors and executive officers as a group (10 persons)</strong></td>
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</tbody>
</table>

(1) Consists of 75,000,000 common shares directly owned by Roivant Sciences Ltd. ("RSL"). Under RSL’s internal governance arrangements, dispositive decisions of RSL require approval by a majority of the directors of RSL, including (a) at least two independent directors (as defined in RSL’s internal governance documents) or (b) if there is only one independent director, that sole independent director. Vivek Ramaswamy, Ilan Oren, Keith Manchester, Akshay Naheta, Patrick Machado and Andrew Lo comprise the board of directors of RSL. Patrick Machado and Andrew Lo are each currently serving as independent directors of RSL and therefore may each be deemed to share dispositive power over, and to be an
indirect beneficial owner of, our common shares directly beneficially owned by RSL. In addition, RSL’s internal governance documents provide that four principal shareholders of RSL, Dexxon, Viking, QVT and SVF (each as defined below), voting unanimously, have the right to override certain decisions of the board of directors of RSL, including with respect to dispositions of our common shares. Accordingly, Dexxon Holdings Limited, Dexcel Pharma Technologies Ltd. and their sole shareholder, Dan Oren (collectively, “Dexxon”), Viking Global Investors LP, Viking Global Performance LLC, Viking Global Equities LP, Viking Global Equities II LP, VGE III Portfolio Ltd., Viking Long Fund GP LLC, Viking Long Fund Master Ltd., Viking Global Opportunities GP LLC, Viking Global Opportunities Portfolio GP LLC, Viking Global Opportunities Illiquid Investments Sub-Master LP, O. Andreas Halvorsen, Rose S. Shabet and David C. Ott (collectively, “Viking”), QVT Financial LP, QVT Financial GP LLC, QVT Associates GP LLC and QVT Fund V LP (collectively, “QVT”) and SVF Investments (UK) Limited, SVF Holdings (UK) LLP, SoftBank Vision Fund LP. and SVF GP (Jersey) Limited (collectively, “SVF”, and together with Dexxon, Viking and QVT, the “Major Shareholders”) may each be deemed to have shared dispositive power, and therefore, beneficial ownership, over our common shares owned directly by RSL. Each of the Major Shareholders and each of their affiliates thereof named above disclaims beneficial ownership in the common shares owned by RSL except to the extent of their pecuniary interest therein. The principal business address of Dr. Lo, Mr. Machado and RSL is Suite 1, 3rd Floor, 11-12 St. James’s Square, London, SW1Y 4LB, United Kingdom. The principal business address of Dexxon and Mr. Oren is 1 Dexcel Street, Or Akiva 30600000, Israel. The principal business address for QVT (other than QVT Fund V LP) is 1177 Avenue of the Americas, 9th Floor, New York, New York 10036. The registered office for QVT Fund V LP is located at 190 Elgin Avenue, George Town, Grand Cayman KY1-9005, Cayman Islands. The principal business address for Viking is 55 Railroad Avenue, Greenwich, Connecticut 06830. The principal business address for SVF is 69 Grosvenor Street, London, United Kingdom W1K 3JP, other than SVF GP (Jersey) Limited, whose principal business address is Aztec Group House, 11-15 Seaton Place, St. Helier, Jersey JE4 0QH.
Description of share capital

The following description of our share capital and provisions of our memorandum of association and amended and restated bye-laws are summaries. You should also refer to the memorandum of association and the amended and restated bye-laws, which are filed as exhibits to the registration statement of which this prospectus is part.

General

We are an exempted company incorporated under the laws of Bermuda. We are registered with the Registrar of Companies in Bermuda under registration number 51141. We were incorporated on January 27, 2016 under the name Roivant PPS Holdings Ltd. We changed our name to Thalavant Sciences Ltd. in November 2016 and Urovant Sciences Ltd. in January 2017. Our principal office is located at Suite 1, 3rd Floor, 11-12 St. James’s Square, London SW1Y 4LB, United Kingdom, and our registered office is located in Bermuda at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. We also have business operations at 5151 California Avenue, Suite 250, Irvine, California 92617.

The objects of our business are unrestricted, and Urovant Sciences Ltd. has the capacity of a natural person. We can therefore undertake activities without restriction on our capacity.

Since our incorporation, other than a subdivision of our authorized and issued share capital, there have been no material changes to our share capital, mergers, amalgamations or consolidations of us or any of our subsidiaries, no material changes in the mode of conducting our business, no material changes in the types of products produced or services rendered. There have been no bankruptcy, receivership or similar proceedings with respect to us or our subsidiaries.

There have been no public takeover offers by third parties for our shares nor any public takeover offers by us for the shares of another company that have occurred during the last or current financial years.

Initial settlement of our common shares will take place on the closing date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities registered through DTC’s book-entry transfer system. Each person beneficially owning common shares registered through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the common shares.

Share capital

Immediately following the closing of this offering, our authorized share capital will consist of 1,000,000,000 common shares, $0.00001 par value per common share. As of June 30, 2018, we had 75,000,000 common shares issued and outstanding. All of our issued and outstanding common shares prior to the closing of this offering are fully paid. Pursuant to our amended and restated bye-laws, subject to the requirements of Nasdaq, and to any resolution of the shareholders to the contrary, our board of directors is authorized to issue any of our authorized but unissued shares. There are no limitations on the right of non-Bermudians or non-residents of Bermuda to hold or vote our shares provided our common shares remain listed on an appointed stock exchange, which includes Nasdaq.

Common shares

Holders of common shares have no pre-emptive, redemption, conversion or sinking fund rights. Holders of common shares are entitled to one vote per share on all matters submitted to a vote of holders of common shares, subject to the limitations described below. Unless a different majority is required by law or by our amended and restated bye-laws, resolutions to be approved by holders of common shares require approval by a simple majority of the votes cast at a meeting at which a quorum is present.
Other than as set forth in our amended and restated bye-laws, shareholder voting rights may only be altered with the consent of our shareholders as set forth under “—Variation of rights” below.

In the event of our liquidation, dissolution or winding up, the holders of common shares are entitled to share equally and ratably in our assets, if any, remaining after the payment of all of our debts and liabilities, subject to any liquidation preference on any issued and outstanding preference shares.

Preference shares

Pursuant to Bermuda law and our amended and restated bye-laws, our board of directors may, by resolution, establish one or more series of preference shares having such number of shares, designations, dividend rates, relative voting rights, conversion or exchange rights, redemption rights, liquidation rights and other relative participation, optional or other special rights, qualifications, limitations or restrictions as may be fixed by the board of directors without any further shareholder approval. Such rights, preferences, powers and limitations, as may be established, could have the effect of discouraging an attempt to obtain control of our company.

Dividend rights

Under Bermuda law, a company may not declare or pay dividends, or make distributions out of contributed surplus, if there are reasonable grounds for believing that (1) the company is, or would after the payment be, unable to pay its liabilities as they become due; or (2) the realizable value of its assets would thereby be less than its liabilities. “Contributed surplus” is defined for purposes of section 54 of the Bermuda Act to include the proceeds arising from donated shares, credits resulting from the redemption or conversion of shares at less than the amount set up as nominal capital and donations of cash and other assets to the company. Under our amended and restated bye-laws, each common share is entitled to dividends if, as and when dividends are declared by our board of directors, subject to any preferred dividend right of the holders of any preference shares. We do not anticipate paying cash dividends in the foreseeable future.

Variation of rights

If at any time we have more than one class of shares, the rights attaching to any class, unless otherwise provided for by the terms of issue of the relevant class, may be varied either: (1) with the consent in writing of the holders of 75% of the issued shares of that class; or (2) with the sanction of a resolution passed by a simple majority of the votes cast at a general meeting of the relevant class of shareholders at which a quorum is present. Our amended and restated bye-laws specify that the creation or issue of shares ranking equally with existing preference shares will not, unless expressly provided by the terms of issue of existing preference shares, vary the rights attached to existing preference shares. In addition, the creation or issue of preference shares ranking prior to common shares will not be deemed to vary the rights attached to common shares or, subject to the terms of any other class or series of preference shares, to vary the rights attached to any other class or series of preference shares.

Transfer of shares

Our board of directors may, in its absolute discretion and without assigning any reason, refuse to register the transfer of a share on the basis that it is not fully paid. Our board of directors may also refuse to recognize an instrument of transfer of a share unless it is accompanied by the relevant share certificate and such other evidence of the transferor’s right to make the transfer as our board of directors shall reasonably require and must refuse to register the transfer unless all applicable consents, authorizations and permissions of any governmental agency or body in Bermuda have been obtained. Subject to these restrictions, a holder of
common shares may transfer the title to all or any of his common shares by completing a form of transfer in the form set out in our amended and restated bye-laws (or as near thereto as circumstances admit) or in such other common form as our board of directors may accept or in accordance with the rules of the exchange on which the common shares are listed. If required, the instrument of transfer must be signed by the transferor and transferee, although in the case of a fully paid share our board of directors may accept the instrument signed only by the transferor.

Meetings of shareholders

Under Bermuda law, a company is required to convene at least one general meeting of shareholders each calendar year, which we refer to as the annual general meeting. However, the shareholders may by resolution waive this requirement, either for a specific year or period of time, or indefinitely. When the requirement has been so waived, any shareholder may, on notice to the company, terminate the waiver, in which case an annual general meeting must be called. We have chosen not to waive the convening of an annual general meeting.

Bermuda law provides that a special general meeting of shareholders may be called by the board of directors of a company and must be called upon the request of shareholders holding not less than 10% of the paid-up capital of the company carrying the right to vote at general meetings. Bermuda law also requires that shareholders be given at least five days’ advance notice of a general meeting, but the accidental omission to give notice to any person does not invalidate the proceedings at a meeting. Our amended and restated bye-laws provide that our principal executive officer or the chairperson or any two directors or any director and the secretary or board of directors may convene an annual general meeting and our principal executive officer or the chairperson or any two directors or any director and the secretary or our board of directors may convene a special general meeting. Under our amended and restated bye-laws, at least 14 days’ notice of an annual general meeting or ten days’ notice of a special general meeting must be given to each shareholder entitled to vote at such meeting. This notice requirement is subject to the ability to hold such meetings on shorter notice if such notice is agreed: (1) in the case of an annual general meeting by all of the shareholders entitled to attend and vote at such meeting; or (2) in the case of a special general meeting by a majority in number of the shareholders entitled to attend and vote at the meeting holding not less than 95% in nominal value of the shares entitled to vote at such meeting. A quorum will be present at any general meeting of shareholders if holders of a majority of the aggregate voting power of our issued and outstanding shares entitled to vote at the meeting are present, in person or by proxy.

The chairperson of our board of directors will chair all general meetings at which such individual is present.

Access to books and records and dissemination of information

Members of the general public have a right to inspect the public documents of a company available at the office of the Registrar of Companies in Bermuda. These documents include a company’s amended and restated memorandum of association, including its objects and powers, and certain alterations to the amended and restated memorandum of association. The shareholders have the additional right to inspect the bye-laws of the company, minutes of general meetings and the company’s audited financial statements, which must be presented in the annual general meeting. The register of members of a company is also open to inspection by shareholders and by members of the general public without charge. The register of members is required to be open for inspection for not less than two hours in any business day (subject to the ability of a company to close the register of members for not more than thirty days in a year). A company is required to maintain its share register in Bermuda but may, subject to the provisions of the Companies Act establish a branch register outside of Bermuda. A company is required to keep at its registered office a register of directors and officers that is open for inspection for not less than two hours in any business day by members of the public without charge.
Bermuda law does not, however, provide a general right for shareholders to inspect or obtain copies of any other corporate records.

**Election and removal of directors**

Our amended and restated bye-laws will provide that our board of directors shall consist of such number of directors (not being less than five directors or more than seven directors) as the board of directors may determine. Upon the closing of this offering, our board of directors will consist of a single class of five directors. Prior to the first date on which RSL ceases to hold at least 25% of the aggregate voting power of our issued and outstanding shares, RSL will be entitled to appoint two directors, or the RSL Directors, by notice to us, each of whom will have three votes for each matter presented to the board of directors or any duly authorized committee thereof, other than our audit committee. Each member of our audit committee will have one vote on all matters presented. All other duly executed directors will have one vote for each matter presented to the board of directors or any duly authorized committee thereof. Each member of our board of directors (other than an RSL Director), will serve a term as determined by our shareholders and each RSL Director will serve a term as determined by RSL. In either case, if no such determination is made, each such director will serve a one-year term expiring at our next annual meeting of shareholders, subject to his or her office being vacated sooner pursuant to our amended and restated bye-laws.

A shareholder holding at least 3% of the common shares in issue, or a group of not more than 20 shareholders holding at least an aggregate 3% of the common shares in issue, who in each case have held such shares for at least three years, may propose for election as a director (other than an RSL Director) someone who is not an existing director or is not proposed by our board of directors. Where a director is to be elected at an annual general meeting, notice of any such proposal for election must be given not less than 90 days nor more than 120 days before the anniversary of the last annual general meeting prior to the giving of the notice or, in the event the annual general meeting is called for a date that is not less than 30 days before or after such anniversary the notice must be given not later than ten days following the earlier of the date on which notice of the annual general meeting was posted to shareholders or the date on which public disclosure of the date of the annual general meeting was made. Where a director is to be elected at a special general meeting, that notice must be given not later than seven days following the earlier of the date on which notice of the special general meeting was posted to shareholders or the date on which public disclosure of the date of the special general meeting was made; or, alternatively, if the special general meeting is held upon the request of shareholders holding not less than 10% of the paid-up capital of the company carrying the right to vote at general meetings, must be given in the requisition of special general meeting.

A director (other than an RSL Director) may be removed, with or without cause, by the shareholders, either by a notice to that effect signed by the holders of a majority of the aggregate voting rights of the issued and outstanding shares, and delivered to us, or by a resolution passed in a shareholders meeting convened on notice to remove the director given to the director. The notice must contain a statement of the intention to remove the director and a summary of the facts justifying the removal and must be served on the director not less than 14 days before the meeting. The director is entitled to attend the meeting and be heard on the motion for his removal. Prior to the first date on which RSL ceases to hold at least 25% of the aggregate voting power of our issued and outstanding shares, directors appointed by RSL may be removed, with or without cause, by RSL upon written notice to us. On or after the date on which RSL ceases to hold at least 25% of the aggregate voting power of our issued and outstanding shares, any director may be removed, with or without cause, by the shareholders, either by a joint written notice to us to that effect signed by the holders of a majority of the aggregate voting power of our issued and outstanding shares or by a resolution passed in a shareholders meeting convened on notice to remove the director and given to the director, as set out above.
Proceedings of board of directors

Our amended and restated bye-laws provide that our business is to be managed and conducted by our board of directors. Bermuda law permits individual and corporate directors and there is no requirement in our bye-laws or Bermuda law that directors hold any of our shares. There is also no requirement in our amended and restated bye-laws or Bermuda law that our directors must retire at a certain age.

The compensation of our directors will be determined by the board of directors, and there is no requirement that a specified number or percentage of “independent” directors must approve any such determination. Our directors may also be paid all travel, hotel and other reasonable out-of-pocket expenses properly incurred by them in connection with our business or their duties as directors.

A director who discloses a direct or indirect interest in any contract or arrangement with us as required by Bermuda law will not be entitled to vote in respect of any such contract or arrangement in which he or she is interested unless the chairman of the relevant meeting of the board of directors determines that such director is not disqualified from voting.

The chairperson of our board of directors will chair all meetings of the board of directors at which such individual is present. Prior to the date on which RSL ceases to hold at least 25% of the aggregate voting power of our issued and outstanding shares, the chairperson of our board of directors will be an RSL Director designated to us by duly executed notice from RSL. On or after the date on which RSL ceases to hold at least 25% of the aggregate voting power of our issued and outstanding shares, the chairperson of our board of directors will be elected by the directors.

Indemnification of directors and officers

Section 98 of the Companies Act provides generally that a Bermuda company may indemnify its directors, officers and auditors against any liability which by virtue of any rule of law would otherwise be imposed on them in respect of any negligence, default, breach of duty or breach of trust, except in cases where such liability arises from fraud or dishonesty of which such director, officer or auditor may be guilty in relation to the company. Section 98 further provides that a Bermuda company may indemnify its directors, officers and auditors against any liability incurred by them in defending any proceedings, whether civil or criminal, in which judgment is awarded in their favor or in which they are acquitted or granted relief by the Supreme Court of Bermuda pursuant to Section 281 of the Companies Act.

Our amended and restated bye-laws provide that we shall indemnify our officers and directors in respect of their actions and omissions, except in respect of their fraud or dishonesty, and that we shall advance funds to our officers and directors for expenses incurred in their defense upon receipt of an undertaking to repay the funds if any allegation of fraud or dishonesty is proved. Our amended and restated bye-laws provide that the shareholders waive all claims or rights of action that they might have, individually or in right of the company, against any of the company’s directors or officers for any act or failure to act in the performance of such director’s or officer’s duties, except in respect of any fraud or dishonesty of such director or officer. Section 98A of the Companies Act permits us to purchase and maintain insurance for the benefit of any officer or director in respect of any loss or liability attaching to him in respect of any negligence, default, breach of duty or breach of trust, whether or not we may otherwise indemnify such officer or director. We have purchased and maintain a directors’ and officers’ liability policy for such purpose.

Amendment of memorandum of association and bye-laws

Bermuda law provides that the memorandum of association of a company may be amended by a resolution passed at a general meeting of shareholders. Our amended and restated bye-laws provide that no bye-law shall
be rescinded, altered or amended, and no new bye-law shall be made, unless it shall have been approved by a resolution of our board of directors and by a resolution of our shareholders.

Under Bermuda law, the holders of an aggregate of not less than 20% in par value of a company’s issued share capital or any class thereof have the right to apply to the Supreme Court of Bermuda for an annulment of any amendment of the memorandum of association adopted by shareholders at any general meeting, other than an amendment that alters or reduces a company’s share capital as provided in the Companies Act. Where such an application is made, the amendment becomes effective only to the extent that it is confirmed by the Supreme Court of Bermuda. An application for an annulment of an amendment of the memorandum of association must be made within 21 days after the date on which the resolution altering the company’s memorandum of association is passed and may be made on behalf of persons entitled to make the application by one or more of their number as they may appoint in writing for the purpose. No application may be made by shareholders voting in favor of the amendment.

**Amalgamations and mergers**

The amalgamation or merger of a Bermuda company with another company or corporation (other than certain affiliated companies) requires the amalgamation or merger agreement to be approved by the company's board of directors and by its shareholders. Unless the company’s bye-laws provide otherwise, the approval of 75% of the shareholders voting at such meeting is required to approve the amalgamation or merger agreement, and the quorum for such meeting must be two or more persons holding or representing more than one-third of the issued shares of the company. Our amended and restated bye-laws provide that the approval of the amalgamation or merger agreement by 75% of the voting power of holders of common shares voting at a meeting shall be sufficient (other than in respect of any amalgamation or merger constituting a “business combination”), and the quorum for such meeting shall be persons holding or representing more than 50% of the issued voting shares.

Under Bermuda law, in the event of an amalgamation or merger of a Bermuda company with another company or corporation, a shareholder of the Bermuda company who did not vote in favor of the amalgamation or merger and who is not satisfied that fair value has been offered for such shareholder's shares may, within one month of notice of the shareholders meeting, apply to the Supreme Court of Bermuda to appraise the fair value of those shares.

**Business combinations**

Although the Companies Act does not contain specific provisions regarding "business combinations" between companies organized under the laws of Bermuda and “interested shareholders,” we have included these provisions in our bye-laws. Specifically, our bye-laws contain provisions which prohibit us from engaging in a business combination with an interested shareholder for a period of three years after the date of the transaction in which the person became an interested shareholder, unless, in addition to any other approval that may be required by applicable law:

- prior to the date of the transaction that resulted in the shareholder becoming an interested shareholder, our board of directors approved either the business combination or the transaction that resulted in the shareholder becoming an interested shareholder;

- upon consummation of the transaction that resulted in the shareholder becoming an interested shareholder, the interested shareholder owned at least 85% of our issued and voting shares outstanding at the time the transaction commenced; or
after the date of the transaction that resulted in the shareholder becoming an interested shareholder, the business combination is approved by our board of directors and authorized at an annual general meeting or special general meeting of shareholders by the affirmative vote of at least 66 2/3% of our issued and outstanding voting shares voted at the general meeting that are not owned by the interested shareholder.

For purposes of these provisions, a “business combination” includes recapitalizations, mergers, amalgamations, consolidations, exchanges, asset sales, leases, certain issues or transfers of shares or other securities and other transactions resulting in a financial benefit to the interested shareholder. An “interested shareholder” is any person or entity that beneficially owns 15% or more of our issued and outstanding voting shares and any person or entity affiliated with or controlling or controlled by that person or entity.

Shareholder suits
Class actions and derivative actions are generally not available to shareholders under Bermuda law. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company’s memorandum of association or by-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company’s shareholders than that which actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some part of the shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company’s affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company.

Our amended and restated bye-laws contain a provision by virtue of which our shareholders waive any claim or right of action that they have, both individually and on our behalf, against any director or officer in relation to any action or failure to take action by such director or officer, except in respect of any fraud or dishonesty of such director or officer. We have been advised by the SEC that in the opinion of the SEC, the operation of this provision as a waiver of the right to sue for violations of federal securities laws would likely be unenforceable in U.S. courts.

Capitalization of profits and reserves
Pursuant to our amended and restated by-laws, our board of directors may (1) capitalize any part of the amount of our share premium or other reserve accounts or any amount credited to our profit and loss account or otherwise available for distribution by applying such sum in paying up unissued shares to be allotted as fully paid bonus shares pro rata (except in connection with the conversion of shares) to the shareholders; or (2) capitalize any sum standing to the credit of a reserve account or sums otherwise available for dividend or distribution by paying up in full, partly paid or nil paid shares of those shareholders who would have been entitled to such sums if they were distributed by way of dividend or distribution.

Untraced shareholders
Our amended and restated by-laws provide that our board of directors may forfeit any dividend or other monies payable in respect of any shares that remain unclaimed for six years from the date when such monies became due for payment. In addition, we are entitled to cease sending dividend warrants and checks by post or otherwise to a shareholder if such instruments have been returned undelivered to, or left uncashed by, such shareholder on at least two consecutive occasions or, following one such occasion, reasonable enquires have
failed to establish the shareholder’s new address. This entitlement ceases if the shareholder claims a dividend or cashes a dividend check or a warrant.

**Certain provisions of Bermuda law**

We have been designated by the Bermuda Monetary Authority as a non-resident for Bermuda exchange control purposes. This designation allows us to engage in transactions in currencies other than the Bermudian dollar, and there are no restrictions on our ability to transfer funds (other than funds denominated in Bermudian dollars) in and out of Bermuda or to pay dividends to U.S. residents who are holders of our common shares.

The Bermuda Monetary Authority has given its consent for the issue and free transferability of all of the common shares that are the subject of this offering to and between residents and non-residents of Bermuda for exchange control purposes, provided our shares remain listed on an appointed stock exchange, which includes Nasdaq. Approvals or permissions given by the Bermuda Monetary Authority do not constitute a guarantee by the Bermuda Monetary Authority as to our performance or our creditworthiness. Accordingly, in giving such consent or permissions, neither the Bermuda Monetary Authority nor the Registrar of Companies in Bermuda shall be liable for the financial soundness, performance or default of our business or for the correctness of any opinions or statements expressed in this prospectus. Certain issues and transfers of common shares involving persons deemed resident in Bermuda for exchange control purposes require the specific consent of the Bermuda Monetary Authority. We have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer.

In accordance with Bermuda law, share certificates are only issued in the names of companies, partnerships or individuals. In the case of a shareholder acting in a special capacity (for example as a trustee), certificates may, at the request of the shareholder, record the capacity in which the shareholder is acting. Notwithstanding such recording of any special capacity, we are not bound to investigate or see to the execution of any such trust.

**Registration rights**

In July 2018, we entered into a registration rights agreement with RSL, which provides RSL with certain registration rights. The registration of our common shares pursuant to the exercise of registration rights described below would enable RSL to sell these common shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and transfer taxes, of the shares registered pursuant to the piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specific conditions, to limit the number of shares shareholders may include pursuant to such registration rights. The piggyback and Form S-3 registration rights described below will expire upon the earlier of (1) five years after the effective date of the registration statement, of which this prospectus forms a part, (2) at such time as a shareholder can sell all of its shares under Rule 144 of the Securities Act during any three-month period or (3) in the event of a change of control or liquidation of our company.

**Piggyback registration rights**

In connection with this offering, RSL is entitled to, and has waived, its right to include their common shares in this offering. If we propose to register the offer and sale of any of our securities under the Securities Act either
for our own account or for the account of other shareholders, RSL will be entitled to certain “piggyback” registration rights allowing it to include its common shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, including a registration statement on Form S-3 as discussed below, RSL is entitled to notice of the registration and has the right, subject to limitations that the underwriters may impose on the number of common shares included in the registration, to include its common shares in the registration. This does not include any registration statements relating to the sale of our securities to employees pursuant to an equity incentive plan, relating to an SEC Rule 145 transaction, or where the registration statement would not include substantially the same information required to offer such securities.

**Form S-3 registration rights**

RSL is entitled to certain Form S-3 registration rights. RSL may request that we register their common shares on Form S-3 if we are qualified to file a registration statement on Form S-3. Such request for registration on Form S-3 must cover securities with an aggregate offering price of at least $5.0 million, before payment of underwriting discounts, commissions and transfer taxes.

**Transfer Agent and Registrar**

A register of holders of the common shares will be maintained by Conyers Corporate Services (Bermuda) Limited in Bermuda, and a branch register will be maintained in the United States by American Stock Transfer & Trust Company, LLC, which will also serve as transfer agent. The transfer agent’s address is 6201 15th Avenue, Brooklyn, New York 11219.

**Listing**

We have applied to list our common shares on The Nasdaq Global Market under the trading symbol "UROV."
Shares eligible for future sale

Prior to this offering, no public market existed for our common shares. Future sales of our common shares in the public market after this offering, or the perception that these sales could occur, could adversely affect prevailing market prices for our common shares and could impair our future ability to raise equity capital.

Based on the number of common shares outstanding as of June 30, 2018, upon the closing of this offering and assuming no exercise by the underwriters of their option to purchase additional common shares,  common shares will be outstanding. All of the common shares sold in this offering will be freely tradable without restrictions or further registration under the Securities Act of 1933, except for any shares sold to our affiliates, as defined in Rule 144 under the Securities Act. The remaining common shares held by existing shareholders are restricted securities, as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 promulgated under the Securities Act.

As a result of contractual restrictions described below and the provisions of Rules 144 and 701, the common shares sold in this offering and the restricted securities will be available for sale in the public market as follows:

• all the common shares sold in this offering will be eligible for immediate sale upon the closing of this offering; and
• common shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Rule 144

In general, persons who have beneficially owned our common shares for at least six months, and any affiliate of the company who owns our common shares, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of common shares under Rule 144 if:

• the common shares have been held for at least six months, including the holding period of any prior owner other than one of our affiliates;
• we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
• we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the common shares for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of common shares without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to
additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

• 1% of the number of our common shares then outstanding, which will equal approximately shares immediately after the closing of this offering based on the number of shares outstanding as of June 30, 2018; or

• the average weekly trading volume of our common shares on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

Rule 701
Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Our employees, executive officers or directors who purchase shares under a written compensatory plan or contract will be entitled to rely on the resale provisions of Rule 701, but any holders of Rule 701 shares will be required to wait until 90 days after the date of this prospectus before selling their shares. However, all our Rule 701 shares are subject to lock-up agreements as described below and in the section titled “Underwriting” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 registration statements
As soon as practicable after the closing of this offering, we intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register the our common shares that are issuable pursuant to our 2017 Plan. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

Lock-up agreements
We and the holders of all of our common shares outstanding on the date of this prospectus, including each of our executive officers, directors and option holders, have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our common shares, any options or warrants to purchase our common shares, or any securities convertible into, or exchangeable for or that represent the right to receive our common shares, without the prior written consent of J.P. Morgan Securities LLC and Jefferies LLC for a period of 180 days from the date of this prospectus. See the section titled “Underwriting—Lock-up agreements” for more information on the lock-up agreements.
## Bermuda company considerations

Our corporate affairs are governed by our memorandum of association and bye-laws and by the laws of Bermuda. The provisions of the Companies Act, which applies to us, differ in certain material respects from laws generally applicable to U.S. companies incorporated in the State of Delaware and their stockholders. The following is a summary of significant differences between the Companies Act (including modifications adopted pursuant to our bye-laws) and Bermuda common law applicable to us and our shareholders and the provisions of the Delaware General Corporation Law applicable to U.S. companies organized under the laws of Delaware and their stockholders.

<table>
<thead>
<tr>
<th>Shareholder meetings</th>
<th>Bermuda</th>
<th>Delaware</th>
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<tbody>
<tr>
<td>• May be called by the board of directors and must be called upon the request of shareholders holding not less than 10% of the paid-up capital of the company carrying the right to vote at general meetings.</td>
<td></td>
<td>• May be held at such time or place as designated in the certificate of incorporation or the bylaws, or if not so designated, as determined by the board of directors.</td>
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<tr>
<td>• May be held in or outside Bermuda.</td>
<td></td>
<td>• May be held in or outside Delaware.</td>
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<tr>
<td>• Notice:</td>
<td>• Notice:</td>
<td>• Written notice shall be given not less than ten nor more than 60 days before the meeting.</td>
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<tr>
<td>• Shareholders must be given at least five days’ advance notice of a general meeting, but the unintentional failure to give notice to any person does not invalidate the proceedings at a meeting.</td>
<td>• Notice of general meetings must specify the place, the day and hour of the meeting and in the case of special general meetings, the general nature of the business to be considered.</td>
<td>• Whenever stockholders are required to take any action at a meeting, a written notice of the meeting shall be given, which shall state the place, if any, date and hour of the meeting, and the means of remote communication, if any.</td>
</tr>
<tr>
<td>• Our bye-laws provide that at least 14 days’ notice of an annual general meeting and 10 days’ notice of a special general meeting must be given to each shareholder entitled to vote at such meeting.</td>
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## Shareholders’ voting rights

- Shareholders may act by written consent to elect directors.
  Shareholders may not act by written consent to remove a director or auditor.

- Generally, except as otherwise provided in the bye-laws, or the Companies Act, any action or resolution requiring approval of the shareholders may be passed by a simple majority of votes cast. Any person authorized to vote may authorize another person or persons to act for him or her by proxy.

- With limited exceptions, stockholders may act by written consent to elect directors unless prohibited by the certificate of incorporation.

- Any person authorized to vote may authorize another person or persons to act for him or her by proxy.
The voting rights of shareholders are regulated by a company’s bye-laws and, in certain circumstances, by the Companies Act. The bye-laws may specify the number to constitute a quorum and if the bye-laws permit, a general meeting of the shareholders of a company may be held with only one individual present if the requirement for a quorum is satisfied.

Subject to the rules of Nasdaq, our bye-laws provide that the quorum required for a general meeting of shareholders is persons present in person at the start of the meeting and representing in person or by proxy in excess of 50% of all issued and outstanding voting shares.

Our bye-laws provide that when a quorum is once present in general meeting it is broken by the subsequent withdrawal of any shareholders required for quorum.

The bye-laws may provide for cumulative voting, although our bye-laws do not.

The amalgamation or merger of a Bermuda company with another company or corporation (other than certain affiliated companies) requires the amalgamation or merger agreement to be approved by the company’s board of directors and by its shareholders. Unless the company’s bye-laws provide otherwise, the approval of 75% of the shareholders voting at such meeting is required to approve the amalgamation or merger agreement, and the quorum for such meeting must be two or more persons holding or representing more than one-third of the issued shares of the company.

Every company may at any meeting of its board of directors sell, lease or exchange all or substantially all of its property and assets as its board of directors deems expedient and in the best interests of the company to do so when authorized by a resolution adopted by the holders of a majority of issued and outstanding shares of a company entitled to vote.

Any company that is the wholly owned subsidiary of a holding company, or one or more companies which are wholly owned subsidiaries of the same holding company, may amalgamate or merge without the vote or consent of shareholders provided that the amalgamation or merger does not involve any transfer of property or assets to any corporation which is not a wholly owned subsidiary of the holding company.

For stock corporations, the certificate of incorporation or bylaws may specify the number to constitute a quorum, but in no event shall a quorum consist of less than one-third of shares entitled to vote at a meeting. In the absence of such specifications, a majority of shares entitled to vote shall constitute a quorum.

When a quorum is once present to organize a meeting, it is not broken by the subsequent withdrawal of any stockholders.

The certificate of incorporation may provide for cumulative voting.

Any two or more corporations existing under the laws of the state may merge into a single corporation pursuant to a board resolution and upon the majority vote by stockholders of each constituent corporation at an annual or special meeting.

Every corporation may at any meeting of the board sell, lease or exchange all or substantially all of its property and assets as its board deems expedient and for the best interests of the corporation when so authorized by a resolution adopted by the holders of a majority of the outstanding stock of a corporation entitled to vote.

Any corporation owning at least 90% of the outstanding shares of each class of another corporation may merge the other corporation into itself and assume all of its obligations without the vote or consent of stockholders; however, in case
approval of the board of directors is obtained and that a director or officer of each such company signs a statutory solvency declaration in respect of the relevant company.

- Any mortgage, charge or pledge of a company’s property and assets may be authorized without the consent of shareholders subject to any restrictions under the bye-laws.

**Directors**

- The board of directors must consist of at least one director.
- The number of directors is fixed by the bye-laws, and any changes to such number must be approved by the board of directors and/or the shareholders in accordance with the company’s bye-laws.
- Removal:
  - Under our bye-laws, any or all directors (other than an RSL Director) may be removed with or without cause by the holders of a majority of the shares entitled to vote either by joint written notice or at a special meeting convened and held in accordance with the bye-laws for the purpose of such removal. RSL Directors may be removed only with or without cause by RSL.

**Duties of directors**

- The Companies Act authorizes the directors of a company, subject to its bye-laws, to exercise all powers of the company except those that are required by the Companies Act or the company’s bye-laws to be exercised by the shareholders of the company. Our bye-laws provide that our business is to be managed and conducted by our Board of Directors. At common law, members of a board of directors owe a fiduciary duty to the company to act in good faith in their dealings with or on behalf of the company and exercise their powers and fulfill the duties of their office honestly. This duty includes the following essential elements:
  - a duty to act in good faith in the best interests of the company;
- Under Delaware law, the business and affairs of a corporation are managed by or under the direction of its board of directors. In exercising their powers, directors are charged with a fiduciary duty of care to protect the interests of the corporation and a fiduciary duty of loyalty to act in the best interests of its stockholders. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to stockholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he...
• a duty not to make a personal profit from opportunities that arise from the office of director;
• a duty to avoid conflicts of interest; and
• a duty to exercise powers for the purpose for which such powers were intended.

The Companies Act imposes a duty on directors and officers of a Bermuda company:
• to act honestly and in good faith with a view to the best interests of the company; and
• to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

The Companies Act also imposes various duties on directors and officers of a company with respect to certain matters of management and administration of the company. Under Bermuda law, directors and officers generally owe fiduciary duties to the company itself, not to the company’s individual shareholders, creditors or any class thereof. Our shareholders may not have a direct cause of action against our directors.

Takeovers

• An acquiring party is generally able to acquire compulsorily the common shares of minority holders of a company in the following ways:
  • By a procedure under the Companies Act known as a "scheme of arrangement." A scheme of arrangement could be effected by obtaining the agreement of the company and of holders of common shares, representing in the aggregate a majority in number and at least 75% in value of the common shareholders present and voting at a court ordered meeting held to consider the scheme of arrangement. The scheme of arrangement must then be sanctioned by the Bermuda Supreme Court. If a scheme of arrangement receives all necessary agreements reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its stockholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the stockholders generally.

• In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

• Delaware law provides that a parent corporation, by resolution of its board of directors and without any stockholder vote, may merge with any subsidiary of which it owns at least 90% of each class of its capital stock. Upon any such merger, and in the event the parent corporate does not own all of the stock of the subsidiary, dissenting stockholders of the subsidiary are entitled to certain appraisal rights.

• Delaware law also provides, subject to certain exceptions, that if a person acquires 15% of voting stock of a company, the person is an “interested stockholder” and may not engage in “business combinations” with the company for a period of
and sanctions, upon the filing of the court order with the Registrar of Companies in Bermuda, all holders of common shares could be compelled to sell their shares under the terms of the scheme of arrangement.

- By acquiring pursuant to a tender offer 90% of the shares or class of shares not already owned by, or by a nominee for, the acquiring party (the offeror), or any of its subsidiaries. If an offeror has, within four months after the making of an offer for all the shares or class of shares not owned by, or by a nominee for, the offeror, or any of its subsidiaries, obtained the approval of the holders of 90% or more of all the shares to which the offer relates, the offeror may, at any time within two months beginning with the date on which the approval was obtained, by notice compulsorily acquire the shares of any nontendering shareholder on the same terms as the original offer unless the Supreme Court of Bermuda (on application made within a one-month period from the date of the offeror's notice of its intention to acquire such shares) orders otherwise.

- Where the acquiring party or parties hold not less than 95% of the shares or a class of shares of the company, by acquiring, pursuant to a notice given to the remaining shareholders or class of shareholders, the shares of such remaining shareholders or class of shareholders. When this notice is given, the acquiring party is entitled and bound to acquire the shares of the remaining shareholders on the terms set out in the notice, unless a remaining shareholder, within one month of receiving such notice, applies to the Supreme Court of Bermuda for an appraisal of the value of their shares. This provision only applies where the acquiring party offers the same terms to all holders of shares whose shares are being acquired.

**Dissenter's rights of appraisal**

- A dissenting shareholder (that did not vote in favor of the amalgamation or merger) of a Bermuda exempted company is entitled to be paid the fair

- With limited exceptions, appraisal rights shall be available for the shares of any class or series of stock of a corporation in a merger or consolidation.
value of his or her shares in an amalgamation or merger.

• The certificate of incorporation may provide that appraisal rights are available for shares as a result of an amendment to the certificate of incorporation, any merger or consolidation or the sale of all or substantially all of the assets.

Dissolution

• Under Bermuda law, a solvent company may be wound up by way of a shareholders’ voluntary liquidation. Prior to the company entering liquidation, a majority of the directors shall each make a statutory declaration, which states that the directors have made a full enquiry into the affairs of the company and have formed the opinion that the company will be able to pay its debts within a period of 12 months of the commencement of the winding up and must file the statutory declaration with the Registrar of Companies in Bermuda. The general meeting will be convened primarily for the purposes of passing a resolution that the company be wound up voluntarily and appointing a liquidator. The winding up of the company is deemed to commence at the time of the passing of the resolution.

• Under Delaware law, a corporation may voluntarily dissolve (1) if a majority of the board of directors adopts a resolution to that effect and the holders of a majority of the issued and outstanding shares entitled to vote thereon vote for such dissolution; or (2) if all stockholders entitled to vote thereon consent in writing to such dissolution.

Shareholders’ derivative actions

• Class actions and derivative actions are generally not available to shareholders under Bermuda law. Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company’s memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company’s shareholders than that which actually approved it.

• In any derivative suit instituted by a stockholder of a corporation, it shall be averred in the complaint that the plaintiff was a stockholder of the corporation at the time of the transaction of which he complains or that such stockholder’s stock thereafter devolved upon such stockholder by operation of law.
Material Bermuda, U.K. and U.S. federal income tax considerations

The following is a discussion of the material Bermuda, U.K. and U.S. federal income tax considerations that may be relevant to an investment decision by a potential investor with respect to our common shares.

Bermuda tax considerations

At the present time, there is no Bermuda income or profits tax, withholding tax, capital gains tax, capital transfer tax, estate duty or inheritance tax payable by us or by our shareholders in respect of our common shares. We have obtained an assurance from the Minister of Finance of Bermuda under the Exempted Undertakings Tax Protection Act 1966 that, in the event that any legislation is enacted in Bermuda imposing any tax computed on profits or income, or computed on any capital asset, gain or appreciation or any tax in the nature of estate duty or inheritance tax, such tax shall not, until March 31, 2035, be applicable to us or to any of our operations or to our shares, debentures or other obligations except insofar as such tax applies to persons ordinarily resident in Bermuda or is payable by us in respect of real property owned or leased by us in Bermuda.

U.K. tax considerations

The following is a general summary of certain U.K. tax considerations relating to the ownership and disposal of our common shares and does not address all possible tax consequences relating to an investment in our common shares. It is based on current U.K. tax law and published HM Revenue & Customs, or HMRC, practice (which may not be binding on HMRC), as of the date of this prospectus, both of which are subject to change, possibly with retrospective effect.

This summary is intended to address only certain U.K. tax consequences for holders of our common shares who are tax resident in (and only in) the United Kingdom, and in the case of individuals, domiciled in (and only in) the United Kingdom (except where expressly stated otherwise) who are the absolute beneficial owners of common shares and any dividends paid on them and who hold common shares as investments (other than in an individual savings account or a self-invested personal pension). This summary does not address the U.K. tax consequences which may be relevant to certain classes of holders of common shares such as traders, brokers, dealers, banks, financial institutions, insurance companies, investment companies, collective investment schemes, tax-exempt organisations, trustees, persons connected with us or a member of our group, persons holding our common shares as part of hedging or conversion transactions and holders of our common shares who have (or are deemed to have) acquired our common shares by virtue of an office or employment.

The following is intended only as a general guide and is not intended to be, nor should it be considered to be, legal or tax advice to any particular prospective subscriber for, or purchaser of, our common shares. Accordingly, prospective subscribers for, or purchasers of, our common shares who are in any doubt as to their tax position regarding the acquisition, ownership and disposition of our common shares or who are subject to tax in a jurisdiction other than the United Kingdom should consult their own tax advisers.

Taxation of dividends

Withholding tax

Dividends paid by us to holders of our common shares will not be subject to withholding or deduction for or on account of U.K. tax.

Income tax

An individual holder of our common shares who is resident for tax purposes in the United Kingdom may, depending on his or her particular circumstances, be subject to U.K. tax on dividends received from us. An
individual holder of our common shares who is not resident for tax purposes in the United Kingdom should not be chargeable to U.K. income tax on dividends received from us unless he or she carries on (whether solely or in partnership) any trade, profession or vocation in the United Kingdom through a branch or agency to which our common shares are attributable. There are certain exceptions for trading in the United Kingdom through independent agents, such as some brokers and investment managers.

All dividends received by a U.K. resident individual holder of our common shares from us or from other sources will form part of that holder’s total income for income tax purposes and will constitute the top slice of that income. A nil rate of income tax will apply to the first £2,000 of taxable dividend income received by the holder of our common shares in a tax year. Income within the nil rate band will be taken into account in determining whether income in excess of the nil rate band falls within the basic rate, higher rate or additional rate tax bands.

Dividend income in excess of the £2,000 tax-free allowance will (subject to the availability of any income tax personal allowance) be taxed at 7.5% to the extent that the excess amount falls within the basic rate tax band, 32.5% to the extent that the excess amount falls within the higher rate tax band and 38.1% to the extent that the excess amount falls within the additional rate tax band.

Corporation tax

Corporate holders of our common shares which are resident for tax purposes in the United Kingdom should not be subject to U.K. corporation tax on any dividend received from us so long as the dividends qualify for exemption, which should be the case although certain conditions must be met (including anti-avoidance conditions). If the conditions for the exemption are not satisfied, or such holder of common shares elects for an otherwise exempt dividend to be taxable, U.K. corporation tax will be chargeable on the amount of any dividends (at the current rate of 19%).

Corporate holders of our common shares who are not resident in the United Kingdom will not generally be subject to U.K. corporation tax on dividends unless they are carrying on a trade, profession or vocation in the United Kingdom through a permanent establishment in connection with which such shares are attributable.

Taxation of capital gains

U.K. resident holders of our common shares

A disposal or deemed disposal of our common shares by an individual or corporate holder of such shares who is tax resident in the United Kingdom may, depending on that holder’s circumstances and subject to any available exemptions or reliefs, give rise to a chargeable gain or allowable loss for the purposes of U.K. taxation of chargeable gains. If an individual holder of our common shares who is subject to U.K. income tax at either the higher or the additional rate is liable to U.K. capital gains tax on the disposal of common shares, the current applicable rate will be 20%. For an individual U.K. holder who is subject to U.K. income tax at the basic rate and liable to U.K. capital gains tax on such disposal, the current applicable rate would be 10%, save to the extent that any capital gains exceed the unused basic rate tax band. In that case, the rate currently applicable to the excess would be 20%.

If a corporate holder becomes liable to U.K. corporation tax on the disposal of our common shares, the main rate of U.K. corporation tax (currently 19%) would apply. Indexation allowance is not available in respect of disposals of our common shares acquired on or after January 1, 2018 (and only covers the movement in the retail prices index up until December 31, 2017, in respect of common shares acquired prior to that date).

Non-U.K. holders of our common shares

Holders of our common shares who are not resident in the United Kingdom and, in the case of an individual holder of our common shares, not temporarily non-resident, should not be liable for U.K. tax on capital gains.
realised on a sale or other disposal of our common shares unless such shares are attributable to a trade, profession or vocation carried on in the United Kingdom through a branch or agency or, in the case of a corporate holder of our common shares, through a permanent establishment.

Generally, an individual holder of our common shares who has ceased to be resident in the United Kingdom for tax purposes for a period of five years or less and who disposes of our common shares during that period may be liable on their return to the United Kingdom to U.K. taxation on any capital gain realized (subject to any available exemption or relief).

**U.K. stamp duty and U.K. stamp duty reserve tax**

The discussion below relates to the holders of our common shares wherever resident, however it should be noted that special rules may apply to certain persons such as market makers, brokers, dealers or intermediaries. No U.K. stamp duty or U.K. stamp duty reserve tax, or SDRT, will be payable on the issue or transfer of the common shares, subject to the comments below.

U.K. stamp duty will in principle be payable on any instrument of transfer of common shares (where the amount or value of the consideration is more than £1,000) that is executed in the United Kingdom or that relates to any property situated, or to any matter or thing done or to be done, in the United Kingdom. No U.K. stamp duty should be payable on the transfer of the common shares, provided that any transfer documents are executed and retained outside the United Kingdom. Holders of common shares should be aware that, even where an instrument of transfer is in principle subject to stamp duty, stamp duty is not required to be paid unless it is necessary to rely on the instrument for legal purposes, for example to register a change of ownership by updating a share register held in the United Kingdom or in litigation in a U.K. court.

Provided that common shares are not registered in any register maintained in the United Kingdom by us or on our behalf and are not paired with any shares issued by a U.K. incorporated company, any agreement to transfer common shares will not be subject to SDRT. We currently do not intend that any register of common shares will be maintained in the United Kingdom and the summary above (which is intended as a general guide only) assumes that our common shares will not be registered on any register in the United Kingdom by us or on our behalf.

**U.S. federal income tax consequences for U.S. holders**

The following discussion describes the material U.S. federal income tax consequences for U.S. holders (as defined below) of the purchase, ownership and disposition of our common shares. This summary is based upon provisions of the U.S. Internal Revenue Code of 1986, as amended, which is referred to herein as the Code, applicable Treasury Regulations, administrative rulings and judicial decisions in effect as of the date hereof, any of which may subsequently be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. This summary deals only with our common shares held as capital assets for tax purposes (i.e., our common shares held for investment). This summary is general in nature, does not address all aspects of U.S. federal income taxes (such as the alternative minimum tax) and does not address state, local, estate, gift or non-U.S. tax consequences. In addition, it does not deal with all tax consequences that may be relevant to holders in light of their personal circumstances or particular situations, such as:

- holders who may be subject to special tax treatment, including dealers in securities or currencies, banks, financial institutions, regulated investment companies, real estate investment trusts, retirement plans, tax-exempt entities, and certain former citizens or long-term residents of the United States, insurance companies, governmental organizations, or traders in securities that elect to use a mark-to-market method of tax accounting for their securities;
• persons holding common shares as a part of an integrated or conversion transaction or a straddle or persons deemed to sell common shares under the constructive sale provisions of the Code;
• U.S. holders whose “functional currency” is not the U.S. dollar;
• S corporations, partnerships or other entities classified as partnerships for U.S. federal income tax purposes or other pass through entities, or investors in such pass-through entities holding common shares;
• holders that own, directly, indirectly or through attribution, 10% or more of the voting power or value of our equity; and
• persons who are subject to Section 451(b) of the Code.

If an entity or arrangement treated as a partnership holds common shares, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. Any such partnership and a partner in any such partnership should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it (and, as applicable, its partners) of the purchase, ownership and disposition of our ordinary shares.

We have not sought, nor will we seek, a ruling from the U.S. Internal Revenue Service, or the IRS, with respect to the matters discussed below. There can be no assurance that the IRS will not take a different position concerning the tax consequences of the purchase, ownership or disposition of the common shares or that any such position would not be sustained.

THIS SUMMARY OF CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY AND IS NOT TAX ADVICE. YOU SHOULD CONSULT YOUR TAX ADVISOR WITH RESPECT TO THE APPLICATION OF U.S. FEDERAL INCOME TAX LAWS TO YOUR PARTICULAR SITUATION AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF THE COMMON SHARES ARISING UNDER U.S. FEDERAL ESTATE OR GIFT TAX RULES OR UNDER THE LAWS OF ANY STATE, LOCAL, NON-U.S. OR ANY OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.

U.S. holders

As used herein, the term “U.S. holder” means a beneficial owner of common shares that is, for U.S. federal income tax purposes:
• an individual who is a citizen or resident of the United States;
• a corporation created or organized in or 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 taxation regardless of its source; or
• a trust, if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (2) has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on common shares

Subject to the discussion in “—Passive foreign investment company,” the gross amount of distributions (including any foreign taxes withheld therefrom), if any, made on our common shares generally will be included in a U.S. holder’s income as foreign source ordinary dividend income (and generally will constitute passive category income for foreign tax credit purposes) to the extent of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes.
We believe we are resident in the United Kingdom for U.K. corporate income tax purposes and that we qualify as a resident of the United Kingdom for purposes of the United States-United Kingdom Income Tax Convention entered into force on April 25, 2001, as amended and currently in force, which is referred to herein as the U.S.-U.K. Tax Treaty, although there can be no assurance in this regard. If the U.S.-U.K. Tax Treaty is applicable or our common shares are readily tradable on an established securities market in the United States, and we are not classified as a PFIC for the taxable year in which a dividend is paid or the preceding taxable year (as discussed below under “—Passive foreign investment company”), dividend income will generally be “qualified dividend income” in the hands of individual U.S. holders, which is generally taxed at the lower applicable long-term capital gains rates provided certain holding period and other requirements for treatment of such dividends as “qualified dividend income” are satisfied. Our common shares will generally be considered to be readily tradable on an established securities market in the United States if they are listed on Nasdaq, as we intend our common shares will be. U.S. holders should consult their own tax advisors regarding the availability of the lower rate for dividends paid with respect to our common shares. Distributions in excess of our current and accumulated earnings and profits will be treated as a return of capital to the extent of a U.S. holder’s tax basis in the common shares and thereafter as capital gain from the sale or exchange of such common shares. Because we do not maintain complete calculations of our earnings and profits in accordance with U.S. federal income tax principles, U.S. holders should assume that any distribution by us with respect to common shares will constitute ordinary dividend income. Any dividends we pay or are deemed to pay will not be eligible for the dividend-received deductions allowed to corporations in respect of dividends received from other U.S. corporations.

Certain U.S. holders generally may claim any foreign taxes withheld from distributions either as a deduction from gross income or as a credit against U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. U.S. holders should consult their own tax advisors regarding the foreign tax credit rules.

Sale or other taxable disposition of common shares

Subject to the discussion in “—Passive foreign investment company,” upon the sale or other taxable disposition of common shares, a U.S. holder generally will recognize U.S.-source capital gain or loss equal to the difference between (1) the amount of cash and the fair market value of all other property received upon such disposition (including the amount of any foreign taxes withheld therefrom) and (2) the U.S. holder’s tax basis in the common shares. Such capital gain or loss will be long-term capital gain or loss if a U.S. holder’s holding period in the common shares is more than one year at the time of the taxable disposition. Long-term capital gains recognized by certain non-corporate U.S. holders (including individuals) will generally be subject to reduced rates of U.S. federal income tax. A U.S. holder’s ability to deduct capital losses may be limited.

Passive foreign investment company

In general, a corporation organized outside the United States will be a passive foreign investment company, or PFIC, in any taxable year in which either (1) at least 75% of its gross income is “passive income” or (2) on average at least 50% of the value of its assets is attributable to assets that produce passive income or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from commodities transactions and from the sale or exchange of property that gives rise to passive income. Assets that produce or are held for the production of passive income may include cash, even if held as working capital or raised in a public offering, marketable securities and other assets that may produce passive income. In determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.
Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets from time to time. The 50% passive asset test described above is generally based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our common shares, which may be volatile. If we are a CFC and not publicly traded throughout the relevant taxable year, however, the test may be applied based on the adjusted basis of our assets. Our status may also depend, in part, on how quickly we utilize the cash proceeds from this offering in our business and whether we earn primarily passive income (such as interest income) in the current taxable year or future taxable years. We believe that we were classified as a CFC prior to this offering in the current taxable year beginning on April 1, 2018. Based on this belief, and the current and expected adjusted basis of our assets, we may be classified as a PFIC with respect to the current taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Our status as a PFIC is a fact intensive determination made on an annual basis after the end of each taxable year. Accordingly, no assurances can be made regarding our PFIC status in one or more subsequent years, and our U.S. counsel expresses no opinion with respect to our PFIC status in the taxable year that ended March 31, 2018 or the current taxable year ending March 31, 2019, and also expresses no opinion with respect to our predictions or past determinations regarding our PFIC status in the past or in the future. We will determine whether we were a PFIC or not for each taxable year and make such determination available to U.S. holders.

If we are a PFIC in any taxable year during which a U.S. holder owns common shares, such U.S. holder could be liable for additional taxes and interest charges upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. holder’s holding period for the common shares, and (2) any gain recognized on a sale, exchange or other taxable disposition, including a pledge, of the common shares, whether or not we continue to be a PFIC. In these circumstances, the tax will be determined by allocating such distribution or gain ratably over the U.S. holder’s holding period for the common shares. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax. If we are a PFIC for any year during which a U.S. holder holds the common shares, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. holder holds the common shares, unless we cease to meet the requirements for PFIC status and the U.S. holder makes a “deemed sale” election with respect to the common shares. If such election is made, the U.S. holder will be deemed to have sold the common shares it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences described above. After the deemed sale election, the U.S. holder’s common shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently again become a PFIC.

If we are a PFIC for any taxable year during which a U.S. holder holds the common shares and one of our non-United States subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be subject to the rules described above on certain distributions by the lower-tier PFIC and a disposition of shares of the lower-tier PFIC even though such U.S. holder would not receive the proceeds of those distributions or dispositions. Each U.S. holder is advised to consult its tax advisors regarding the application of the PFIC rules to any of our subsidiaries.
The tax consequences that would apply if we were a PFIC would be different from those described above if a timely and valid "mark-to-market" election is made by a U.S. holder for the common shares held by such U.S. holder. An electing U.S. holder generally would take into account as ordinary income each year, the excess of the fair market value of the common shares held at the end of the taxable year over the adjusted tax basis of such common shares. The U.S. holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such common shares over their fair market value at the end of the taxable year, but only to the extent of the excess of amounts previously included in income over ordinary losses deducted in prior years as a result of the mark-to-market election. The U.S. holder's tax basis in the common shares would be adjusted to reflect any income or loss recognized as a result of the mark-to-market election. Any gain from a sale, exchange or other taxable disposition of the common shares in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other taxable disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss. If, after having been a PFIC for a prior taxable year, we cease to be classified as a PFIC, the U.S. holder would not be required to take into account any latent gain or loss in the manner described above and any gain or loss recognized on the sale or exchange of the common shares would be classified as a capital gain or loss.

A mark-to-market election is available to a U.S. holder only for "marketable stock." Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury Regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. The common shares will be marketable stock as long as they remain listed on a qualified exchange, such as Nasdaq, and are regularly traded. A mark-to-market election will not apply to the common shares for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any subsidiary that we own. Accordingly, a U.S. holder may continue to be subject to the PFIC rules with respect to any lower-tier PFICs notwithstanding the U.S. holder's mark-to-market election for the common shares.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a U.S. holder were able to make a valid "qualified electing fund," or QEF, election. As we do not expect to provide U.S. holders with the information required in order to permit a QEF election, prospective investors should assume that a QEF election will not be available.

Each U.S. holder who is a shareholder of a PFIC must file an annual information report on IRS Form 8621 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.

The U.S. federal income tax rules relating to PFICs are very complex. Prospective U.S. investors are strongly urged to consult their own tax advisors with respect to the impact of these rules on the purchase, ownership and disposition of our common shares, the consequences to them of an investment in a PFIC, any elections available with respect to the common shares and the IRS information reporting obligations with respect to the purchase, ownership and disposition of the common shares.

Medicare tax on net investment income

Certain U.S. holders who are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which generally includes dividends on the common shares and net gains from the disposition of the common shares. U.S. holders that are individuals, estates or trusts should consult their tax advisors regarding the applicability of the Medicare tax to them.
U.S. information reporting and backup withholding

U.S. holders of common shares may be subject to information reporting and may be subject to backup withholding on distributions on common shares or on the proceeds from a sale or other disposition of common shares paid within the United States. Payments of distributions on common shares, or the proceeds from the sale or other disposition of common shares to or through a foreign office of a broker generally will not be subject to backup withholding, although information reporting may apply to those payments in certain circumstances. Backup withholding will generally not apply, however, to a U.S. holder who:

- furnishes a correct taxpayer identification number and certifies that the U.S. holder is not subject to backup withholding on IRS Form W-9, Request for Taxpayer Identification Number and Certification (or substitute form); or
- is otherwise exempt from backup withholding.

Backup withholding is not an additional tax. Any amounts withheld from a payment to a U.S. holder under the backup withholding rules may be credited against the U.S. holder’s U.S. federal income tax liability, and a U.S. holder may obtain a refund of any excess amounts withheld by filing the appropriate claim for refund (typically a tax return) with the IRS in a timely manner.

Foreign asset reporting

Certain U.S. holders who are individuals are required to report information relating to an interest in the common shares, subject to certain exceptions (including an exception for common shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the common shares.
Underwriting

We are offering the common shares described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of common shares listed next to its name in the following table:

<table>
<thead>
<tr>
<th>Name</th>
<th>Number of common shares</th>
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<tbody>
<tr>
<td>J.P. Morgan Securities LLC</td>
<td></td>
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<tr>
<td>Jefferies LLC</td>
<td></td>
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<tr>
<td>Cowen and Company, LLC</td>
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<td>Total</td>
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The underwriters are committed to purchase all the common shares offered by us if they purchase any common shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $\_\_\_ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $\_\_\_ per share from the initial public offering price. After the initial offering of the common shares to the public, if all of the common shares are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of common shares made outside of the United States may be made by affiliates of the underwriters.

Option to purchase additional common shares

The underwriters have an option to buy up to additional common shares from us to cover sales of common shares by the underwriters which exceed the number of common shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional common shares. If any common shares are purchased with this option to purchase additional common shares, the underwriters will purchase common shares in approximately the same proportion as shown in the table above. If any additional common shares are purchased, the underwriters will offer the additional common shares on the same terms as those on which the common shares are being offered.

Underwriting discount and expenses

The underwriting fee is equal to the public offering price per common share less the amount paid by the underwriters to us per common share. The underwriting fee is $\_\_\_ per common share. The following table shows the per common share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters’ option to purchase additional common shares.
We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $\text{[value]}$. We have also agreed to reimburse the underwriters for reasonable fees and expenses of counsel related to the review by the Financial Industry Regulatory Authority of the terms of sale of the common shares offered hereby in an amount not to exceed $25,000.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of common shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

**Lock-up agreements**

We have agreed, subject to specified limited exceptions, that we will not (1) offer, pledge, announce the intention to sell, 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 dispose of, directly or indirectly, or file with the SEC a registration statement under the Securities Act relating to, any of our common shares or securities convertible into or exchangeable or exercisable for any of our common shares, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (2) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any common shares or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of common shares or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and Jefferies LLC for a period of 180 days after the date of this prospectus.

Our directors, executive officers and holders of all of our common shares outstanding have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, for a period of 180 days after the date of this prospectus, may not, subject to specified limited exceptions, without the prior written consent of J.P. Morgan Securities LLC and Jefferies LLC, (1) 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 of our common shares or any securities convertible into or exercisable or exchangeable for our common shares (including, without limitation, common shares or such other securities which may be deemed to be beneficially owned by such directors, executive officers, managers and members in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a share option or warrant), (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common shares or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common shares or such other securities, in cash or otherwise, (3) make any demand for or exercise any right with respect to the registration of any of our common shares or any security convertible into or exercisable or exchangeable for our common shares, or (4) publicly announce any intention to do any of the foregoing.
Indemnification
We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Listing
We have applied to have our common shares approved for listing on The Nasdaq Global Market under the symbol "UROV."

Price stabilization and short positions
In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling common shares in the open market for the purpose of preventing or retarding a decline in the market price of the common shares while this offering is in progress. These stabilizing transactions may include making short sales of the common shares, which involves the sale by the underwriters of a greater number of common shares than they are required to purchase in this offering, and purchasing common shares on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. 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 the common shares in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase common shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common shares, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common shares in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those common shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common shares or preventing or retarding a decline in the market price of the common shares, and, as a result, the price of the common shares may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on Nasdaq, in the over-the-counter market or otherwise.

New issue of securities
Prior to this offering, there has been no public market for our common shares. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

• the information set forth in this prospectus and otherwise available to the representatives;
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• our prospects and the history and prospects for the industry in which we compete;

• an assessment of our management;

• our prospects for future earnings;

• the general condition of the securities markets at the time of this offering;

• the recent market prices of, and demand for, publicly traded common shares of generally comparable companies; and

• other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the common shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in Canada

The common shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the common shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) 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 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.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a “Relevant Member State”), no offer of common shares may be made to the public in that Relevant Member State other than:

A. to any legal entity which is a qualified investor as defined in the Prospectus Directive;
B. to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 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; or

C. in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common shares shall require the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who initially acquires any common shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a “qualified investor” within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive. In the case of any common shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the common shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any common shares to the public other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

The Company, the representatives and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of common shares in any Relevant Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of common shares. Accordingly any person making or intending to make an offer in that Relevant Member State of common shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the underwriters have authorized, nor do they authorize, the making of any offer of common shares in circumstances in which an obligation arises for the Company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression “an offer to the public” in relation to any common shares 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 common shares to be offered so as to enable an investor to decide to purchase or subscribe the common shares, as the same may be varied in the Relevant Member State by any measure implementing the Prospectus Directive in the Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC (including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Notice to prospective investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended.
(the “Order”) and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”).

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons. 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.

Notice to prospective investors in France

Neither this prospectus nor any other offering material relating to the common shares described in this prospectus has been submitted to the clearance procedures of the Autorité des Marchés Financiers or of the competent authority of another member state of the European Economic Area and notified to the Autorité des Marchés Financiers. The common shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the common shares has been or will be (i) released, issued, distributed or caused to be released, issued or distributed to the public in France; or (ii) used in connection with any offer for subscription or sale of the common shares to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (investisseurs qualifiés) and/or to a restricted circle of investors (cercle restraint d’investisseurs), in each case investing for their own account, all as defined in, and in accordance with, articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier;
- to investment services providers authorized to engage in portfolio management on behalf of third parties;
- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (Règlement Général) of the Autorité des Marchés Financiers, does not constitute a public offer (appel public à l’épargne).

The common shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L412-1 and L.621-8 through L.621-8-3 of the French Code monétaire et financier.

Notice to prospective investors in Hong Kong

The common shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the common shares 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 in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to common shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

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Notice to prospective investors in Japan

The common shares have not been and will not be registered under the Financial Instruments and Exchange Act. Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means 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 or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to prospective investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common shares may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons 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 pursuant to Section 275(1), or any person pursuant to Section 275(1A), 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, in each case subject to compliance with the conditions set forth in the SFA.

Where the common shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is: (a) a corporation (which is not an accredited investor (as defined in 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 (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, common shares, debentures and units of shares and debentures of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except: (i) to an institutional investor (for corporations, 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 common 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 S$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; (ii) where no consideration is or will be given for the transfer; or (iii) where the transfer is by operation of law.

Notice to prospective investors in Australia

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or Corporations Act) in relation to the common shares has been or will be lodged with the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia: (a) you confirm and warrant that you are either: (i) a “sophisticated investor” under section 708(8)(a) or (b) of the Corporations Act; (ii) a “sophisticated investor” under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to us 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; (iii) a person associated with the
company under section 708(12) of the Corporations Act; or (iv) a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and (b) you warrant and agree that you will not offer any of the common shares for resale in Australia within 12 months of that common shares being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Notice to prospective investors in the Dubai International Financial Centre, or DIFC

This prospectus relates to an Exempt Offer in accordance with the Market Rules 2012 of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Market Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for this prospectus. The common shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the common shares offered should conduct their own due diligence on the common shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

In relation to its use in the DIFC, this prospectus is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to prospective investors in China

This prospectus does not constitute a public offer of the shares offered by this prospectus, whether by sale or subscription, in the People’s Republic of China, or the PRC. The common shares are not being offered or sold directly or indirectly in the PRC to or for the benefit of, legal or natural persons of the PRC.

Further, no legal or natural persons of the PRC may directly or indirectly purchase any of the common shares without obtaining all prior PRC’s governmental approvals that are required, whether statutorily or otherwise. Persons who come into possession of this prospectus are required by the issuer and its representatives to observe these restrictions.

Notice to prospective investors in Switzerland

This prospectus is not intended to constitute an offer or solicitation to purchase or invest in the common shares described herein. The common shares may not be publicly offered, sold or advertised, directly or indirectly, in, into or from Switzerland and will not be listed on the SIX Swiss Exchange or on any other exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the common shares constitutes a prospectus as such term is understood pursuant to article 652a or article 1156 of the Swiss Code of Obligations and neither this prospectus nor any other offering or marketing material relating to the common shares may be publicly distributed or otherwise made publicly available in Switzerland.

Other relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and
other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Legal matters

The validity of the common shares and certain other matters of Bermuda law will be passed upon for us by Conyers Dill & Pearman Limited, our special Bermuda counsel. Certain other legal matters will be passed upon for us by Cooley LLP, Palo Alto, California, and for the underwriters by Latham & Watkins LLP.

Experts

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at March 31, 2017 and 2018, and for each of the two years in the period ended March 31, 2018, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company’s ability to continue as a going concern as described in Note 1[B] to the consolidated financial statements). We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP’s report, given on their authority as experts in accounting and auditing.

Where you can find additional information

We have confidentially submitted with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the common shares being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common shares offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC’s website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at www.urovant.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.
Exchange controls

The permission of the Bermuda Monetary Authority is required, pursuant to the provisions of the Exchange Control Act 1972 and related regulations, for all issuances and transfers of shares (which includes our common shares) of Bermuda companies to or from a non-resident of Bermuda for exchange control purposes, other than in cases where the Bermuda Monetary Authority has granted a general permission. The Bermuda Monetary Authority, in its notice to the public dated June 1, 2005, has granted a general permission for the issue and subsequent transfer of any securities of a Bermuda company from or to a non-resident of Bermuda for exchange control purposes for so long as any “Equity Securities” of the company (which would include our common shares) are listed on an “Appointed Stock Exchange” (which would include Nasdaq). Certain issues and transfers of common shares involving persons deemed resident in Bermuda for exchange control purposes require the specific consent of the Bermuda Monetary Authority. We have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer.
Enforcement of civil liabilities under U.S. federal securities laws

We are a Bermuda exempted company. As a result, the rights of holders of our common shares will be governed by Bermuda law and our memorandum of association and bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in other jurisdictions. It may be difficult for investors to enforce in the United States judgments obtained in U.S. courts against us based on the civil liability provisions of the U.S. securities laws. Our principal office is located at Suite 1, 3rd Floor, 11-12 St. James’s Square, London SW1Y 4LB, United Kingdom, and our registered office is located in Bermuda at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. We also have business operations at 5151 California Avenue, Suite 250, Irvine, California 92617.

We have been advised by our special Bermuda counsel that there is no treaty in force between the United States and Bermuda providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. As a result, whether a U.S. judgment would be enforceable in Bermuda against us or our directors and officers depends on whether the U.S. court that entered the judgment is recognized by a Bermuda court as having jurisdiction over us or our directors and officers, as determined by reference to Bermuda conflict of law rules. The courts of Bermuda would recognize as a valid judgment, a final and conclusive judgment in personam obtained in a U.S. court pursuant to which a sum of money is payable (other than a sum of money payable in respect of multiple damages, taxes or other charges of a like nature or in respect of a fine or other penalty). The courts of Bermuda would give a judgment based on such a U.S. judgment as long as (1) the U.S. court had proper jurisdiction over the parties subject to the judgment; (2) the U.S. court did not contravene the rules of natural justice of Bermuda; (3) the U.S. judgment was not obtained by fraud; (4) the enforcement of the U.S. judgment would not be contrary to the public policy of Bermuda; (5) no new admissible evidence relevant to the action is submitted prior to the rendering of the judgment by the courts of Bermuda; (6) there is due compliance with the correct procedures under the laws of Bermuda; and (7) the U.S. judgment is not inconsistent with any judgment of the courts of Bermuda in respect of the same matter.

In addition, and irrespective of jurisdictional issues, the Bermuda courts will not enforce a U.S. federal securities law that is either penal or contrary to Bermuda public policy. We have been advised that an action brought pursuant to a public or penal law, the purpose of which is the enforcement of a sanction, power or right at the instance of the state in its sovereign capacity, is unlikely to be entertained by a Bermuda court. Certain remedies available under the laws of U.S. jurisdictions, including certain remedies under U.S. federal securities laws, would not be available under Bermuda law or enforceable in a Bermuda court, as they are likely to be contrary to Bermuda public policy. Further, it may not be possible to pursue direct claims in Bermuda against us or our directors and officers for alleged violations of U.S. federal securities laws because these laws are unlikely to have extraterritorial effect and do not have force of law in Bermuda. A Bermuda court may, however, impose civil liability on us or our directors and officers if the facts alleged and proved in the Bermuda proceedings constitute or give rise to a cause of action under the applicable governing law, not being a foreign public, penal or revenue law.
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Report of independent registered public accounting firm

To the Shareholder and the Board of Directors of Urovant Sciences Ltd.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Urovant Sciences Ltd. (the Company) as of March 31, 2017 and 2018, the related consolidated statements of operations, comprehensive loss, shareholder’s equity and cash flows for each of the two years in the period ended March 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2017 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2018, in conformity with U.S. generally accepted accounting principles.

The Company’s ability to continue as a going concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1[B] to the financial statements, the Company has recurring losses from operations, has insufficient capital to fund its operations, and has stated that substantial doubt exists about the Company’s ability to continue as a going concern. Management’s evaluation of the events and conditions and management’s plans regarding these matters are also described in Note 1[B]. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2018.

Iselin, New Jersey
June 4, 2018

F-2
# Urovant Sciences Ltd.
## Consolidated balance sheets

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2017</th>
<th>March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash</td>
<td>$4,767,471</td>
<td>$7,193,962</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>8,628</td>
<td>5,196,332</td>
</tr>
<tr>
<td>Total current assets</td>
<td>$4,776,099</td>
<td>$12,390,294</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>—</td>
<td>509,567</td>
</tr>
<tr>
<td>Other assets</td>
<td>—</td>
<td>83,595</td>
</tr>
<tr>
<td>Total assets</td>
<td>$4,776,099</td>
<td>$12,983,456</td>
</tr>
<tr>
<td><strong>Liabilities and Shareholder’s Equity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>$15,943</td>
<td>$832,797</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>8,027</td>
<td>3,594,714</td>
</tr>
<tr>
<td>Due to Rovant Sciences Ltd.</td>
<td>842,432</td>
<td>1,481,960</td>
</tr>
<tr>
<td>Total liabilities</td>
<td>866,402</td>
<td>5,909,471</td>
</tr>
<tr>
<td>Commitments and contingencies (Note 9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common shares, par value $0.00001 per share, 1,000,000,000 shares authorized, 10,000,000 and 75,000,000 issued and outstanding at March 31, 2017 and 2018, respectively</td>
<td>100</td>
<td>750</td>
</tr>
<tr>
<td>Common shares subscribed</td>
<td>(100)</td>
<td>(750)</td>
</tr>
<tr>
<td>Shareholder receivable</td>
<td>—</td>
<td>(1,310,000)</td>
</tr>
<tr>
<td>Accumulated other comprehensive (loss) income</td>
<td>(24,505)</td>
<td>7,014</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>31,045,676</td>
<td>72,562,119</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(27,111,474)</td>
<td>(64,185,148)</td>
</tr>
<tr>
<td>Total shareholder’s equity</td>
<td>3,909,697</td>
<td>7,073,985</td>
</tr>
<tr>
<td>Total liabilities and shareholder’s equity</td>
<td>$4,776,099</td>
<td>$12,983,456</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these audited consolidated financial statements.
### Urovant Sciences Ltd.
#### Consolidated statements of operations

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31, 2017</th>
<th>Year Ended March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development (includes $441,269 and $2,477,492 of share-based compensation expense, respectively)(^1)</td>
<td>$26,047,370</td>
<td>$32,359,078</td>
</tr>
<tr>
<td>General and administrative (includes $439,169 and $694,036 of share-based compensation expense, respectively)(^2)</td>
<td>1,016,166</td>
<td>4,639,900</td>
</tr>
<tr>
<td><strong>Total operating expenses</strong></td>
<td>27,063,536</td>
<td>36,998,978</td>
</tr>
<tr>
<td><strong>Other income (expense):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other income (expense)</td>
<td>93,454</td>
<td>(37,467)</td>
</tr>
<tr>
<td><strong>Loss before provision for income taxes</strong></td>
<td>(26,970,082)</td>
<td>(37,036,445)</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>0</td>
<td>37,229</td>
</tr>
<tr>
<td><strong>Net loss</strong></td>
<td>$ (26,970,082)</td>
<td>$ (37,073,674)</td>
</tr>
<tr>
<td><strong>Net loss per common share—basic and diluted</strong></td>
<td>$ (2.70)</td>
<td>$ (0.58)</td>
</tr>
<tr>
<td><strong>Weighted average common shares outstanding—basic and diluted</strong></td>
<td>10,000,000</td>
<td>64,136,986</td>
</tr>
</tbody>
</table>

\(^1\) Includes $1,056,736 and $7,712,896 of costs allocated from RSL during the years ended March 31, 2017 and 2018, respectively.

\(^2\) Includes $860,913 and $1,376,894 of costs allocated from RSL during the years ended March 31, 2017 and 2018, respectively.

The accompanying notes are an integral part of these audited consolidated financial statements.
Urovant Sciences Ltd.
Consolidated statements of comprehensive loss

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31, 2017</th>
<th>Year Ended March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>$ (26,970,082)</td>
<td>$ (37,073,674)</td>
</tr>
<tr>
<td>Other comprehensive (loss) income:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustment</td>
<td>(24,505)</td>
<td>31,519</td>
</tr>
<tr>
<td>Total other comprehensive (loss) income</td>
<td>(24,505)</td>
<td>31,519</td>
</tr>
<tr>
<td>Comprehensive loss</td>
<td>$ (26,994,587)</td>
<td>$ (37,042,155)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these audited consolidated financial statements.
Urovant Sciences Ltd.
Consolidated statements of shareholder’s equity

<table>
<thead>
<tr>
<th>Common Shares</th>
<th>Shares</th>
<th>Amount</th>
<th>Common shares subscribed</th>
<th>Shareholder receivable</th>
<th>Additional paid-in capital</th>
<th>Accumulated deficit</th>
<th>Accumulated other comprehensive (loss) income</th>
<th>Total shareholder’s equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at March 31, 2016</td>
<td>10,000,000</td>
<td>$ 100</td>
<td>$ (100)</td>
<td>$ —</td>
<td>$ 141,392</td>
<td>$ (141,392)</td>
<td>$ —</td>
<td>$ —</td>
</tr>
<tr>
<td>Capital contributions</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>30,023,846</td>
<td>—</td>
<td>—</td>
<td>30,023,846</td>
</tr>
<tr>
<td>Capital contribution—share-based compensation expense</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>880,438</td>
<td>—</td>
<td>—</td>
<td>880,438</td>
</tr>
<tr>
<td>Foreign currency translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(24,505)</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(26,970,082)</td>
</tr>
<tr>
<td>Balance at March 31, 2017</td>
<td>10,000,000</td>
<td>$ 100</td>
<td>$ (100)</td>
<td>—</td>
<td>31,045,676</td>
<td>(27,111,474)</td>
<td>(24,505)</td>
<td>3,909,697</td>
</tr>
<tr>
<td>Common shares issued to Roivant Sciences Ltd.</td>
<td>65,000,000</td>
<td>650</td>
<td>(650)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Capital contributions</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(1,310,000)</td>
<td>38,344,915</td>
<td>—</td>
<td>—</td>
<td>37,034,915</td>
</tr>
<tr>
<td>Foreign currency translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>31,519</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(37,073,674)</td>
</tr>
<tr>
<td>Balance at March 31, 2018</td>
<td>75,000,000</td>
<td>$ 750</td>
<td>$ (750)</td>
<td>(1,310,000)</td>
<td>72,562,119</td>
<td>(84,185,148)</td>
<td>7,014</td>
<td>7,073,985</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these audited consolidated financial statements.
Urovant Sciences Ltd.
Consolidated statements of cash flows

<table>
<thead>
<tr>
<th>Year Ended March 31</th>
<th>Year Ended March 31</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2017</td>
</tr>
</tbody>
</table>

**Cash flows from operating activities:**

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>$(26,970,082)</td>
<td>$(37,073,674)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>—</td>
<td>12,419</td>
</tr>
<tr>
<td>Share-based compensation expense</td>
<td>880,438</td>
<td>3,171,528</td>
</tr>
<tr>
<td>Unrealized foreign currency translation adjustment</td>
<td>(24,505)</td>
<td>31,519</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(8,628)</td>
<td>(5,187,704)</td>
</tr>
<tr>
<td>Other assets</td>
<td>—</td>
<td>(83,595)</td>
</tr>
<tr>
<td>Due to Roivant Sciences Ltd.</td>
<td>842,432</td>
<td>639,528</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>15,943</td>
<td>816,854</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>8,027</td>
<td>3,586,687</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>(25,256,375)</td>
<td>(34,086,438)</td>
</tr>
</tbody>
</table>

**Cash flows used in investing activities:**

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchases of property and equipment</td>
<td>—</td>
<td>(521,986)</td>
</tr>
<tr>
<td>Cash flows provided by financing activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from capital contributions from Roivant Sciences Ltd.</td>
<td>30,023,846</td>
<td>37,034,915</td>
</tr>
<tr>
<td>Net change in cash</td>
<td>4,767,471</td>
<td>2,426,491</td>
</tr>
<tr>
<td>Cash—beginning of year</td>
<td>—</td>
<td>4,767,471</td>
</tr>
<tr>
<td>Cash—end of year</td>
<td>$4,767,471</td>
<td>$7,193,962</td>
</tr>
</tbody>
</table>

**Supplemental disclosure of cash paid:**

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income taxes</td>
<td>—</td>
<td>$20,000</td>
</tr>
</tbody>
</table>

**Non-cash financing activities:**

<table>
<thead>
<tr>
<th></th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shareholder receivable for the sale of intellectual property rights in China recorded as a deemed capital contribution (see Note 5[B])</td>
<td>$ —</td>
<td>$1,310,000</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these audited consolidated financial statements.
Urovant Sciences Ltd.
Notes to consolidated financial statements

Note 1—Description of business and liquidity

[A] Description of business:

Urovant Sciences Ltd. and its subsidiaries (collectively, the “Company”) is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. The Company’s product candidate, vibegron, is an oral, once-daily, small molecule that was observed to be highly selective for the human beta-3 adrenergic receptor in in vitro assays. The Company is developing for the treatment of overactive bladder, or OAB. The Company is also developing vibegron for the treatment of two additional potential indications: OAB in men with benign prostatic hyperplasia and pain associated with irritable bowel syndrome. The Company was founded on January 27, 2016 as a Bermuda Exempted Limited Company and a wholly owned subsidiary of Roivant Sciences Ltd. In November 2016, the Company incorporated as its wholly owned subsidiaries (1) Urovant Holdings Ltd. (“UHL”), a private limited company incorporated under the laws of England and Wales, (2) Urovant Sciences GmbH (“USG”), a company with limited liability formed under the laws of Switzerland and the Company’s principal operating subsidiary and (3) Urovant Sciences, Inc. (“USI”), a Delaware corporation based in the United States of America.

Since its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, acquiring its product candidate, vibegron, and preparing for and advancing vibegron into clinical development. Vibegron was licensed from Merck Sharp & Dohme Corp. (“Merck”), a subsidiary of Merck & Co., in February 2017. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

[B] Liquidity:

The Company has not been capitalized with sufficient funding to conduct its operations. Certain other costs of conducting the Company’s operations were paid by Roivant Sciences Ltd., inclusive of its wholly owned subsidiaries (“RSL”), and will be reimbursed by the Company upon receipt of additional external funding pursuant to services agreements with Roivant Sciences, Inc. (“RSI”) and Roivant Sciences GmbH (“RSG”). The Company has not generated any revenues and does not anticipate generating any revenues unless and until it successfully completes development and obtains regulatory approval for vibegron or any future product candidate. Since the Company has limited cash on hand to complete its clinical development and no credit facilities, the Company is dependent upon RSL and its affiliates to provide services and funding to support the operations of the Company until, at least, such time as an external financing is completed.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. The Company anticipates incurring additional losses until such time, if ever, it can obtain marketing approval to sell, and then generate significant sales from, vibegron or any future product candidate. Substantial additional financing will be needed by the Company to fund its operations and to develop and commercialize vibegron or any future product candidate. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The Company will seek to obtain additional capital through equity financings, the sale of debt or other arrangements; however, there can be no assurance that the Company will be able to raise additional capital.
Urovant Sciences Ltd.
Notes to consolidated financial statements (continued)

when needed or under acceptable terms, if at all. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the Company’s ability to pay dividends or make other distributions to shareholders. If the Company is unable to obtain such additional financing, operations would need to be scaled back or discontinued. The Company is currently exploring external financing alternatives which will be needed by the Company to fund its operations.

The Company’s future operations are highly dependent on a combination of factors, including (1) the timely and successful completion of additional financing discussed above; (2) the success of its research and development programs; (3) the development of competitive therapies by other biotechnology and pharmaceutical companies, (4) the Company’s ability to manage growth of the organization; (5) the Company’s ability to protect its technology and products; and, ultimately (6) regulatory approval and market acceptance of vibegron or any future product candidate.

Note 2—Summary of significant accounting policies

[A] Basis of presentation:
The Company’s fiscal year ends on March 31. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). The consolidated financial statements include the accounts of USL and UHL, USG, and USI, USL’s wholly-owned subsidiaries. USL has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”) was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Effective June 1, 2017, upon approval of the Board of Directors and the Company’s sole shareholder, RSL, the Company effected a share split of the authorized, issued and outstanding shares of the Company at a ratio of 100,000-to-1. The share split increased the total number of authorized shares from 10,000 to 1,000,000,000, increased the total number of shares issued and outstanding as of March 31, 2017 from 100 to 10,000,000, and decreased par value from $1.00 to $0.00001. All information in the accompanying consolidated financial statements and notes thereto regarding amounts of the common shares and prices per share of the common shares has been adjusted to reflect the application of the share split on a retroactive basis.

[B] Use of estimates:
The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets, liabilities,
Urovant Sciences Ltd.
Notes to consolidated financial statements (continued)

costs, expenses and compensation expense allocated to the Company under its services agreements with RSI and RSG, as well as share-based compensation, research and development costs and income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

[C] Risks and uncertainties:
The Company is subject to risks common to early stage companies in the biopharmaceutical industry including, but not limited to, uncertainties related to commercialization of products, regulatory approvals, dependence on key products, third-party service providers such as contract research organizations, protection of intellectual property rights and the ability to make milestone, royalty or other payments due under any license, collaboration or supply agreements.

[D] Concentrations of credit risk:
Financial instruments that potentially subject the Company to concentration of credit risk include cash. At March 31, 2018, substantially all of the cash balance is deposited in three banking institutions that the Company believes are of high credit quality and are in excess of federally insured levels. The Company maintains its cash with accredited financial institutions and accordingly, such funds are subject to minimal credit risk. The Company has not experienced any losses on its cash deposits.

[E] Property and equipment:
Property and equipment, consisting of computers, equipment, furniture and fixtures and leasehold improvements, is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement or sale, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the consolidated results of operations. Depreciation will be recorded for property and equipment using the straight-line method over the estimated useful lives of three to seven years, once the asset is installed and placed in service. Leasehold improvements are amortized using the straight-line method over the estimated useful life or remaining lease term, whichever is shorter.

The Company reviews the recoverability of all long-lived assets, including the related useful lives, whenever events or changes in circumstances indicate that the carrying amount of a long-lived asset might not be recoverable. Recoverability is measured by comparison of the book values of the assets to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

[F] Contingencies:
The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. In accordance with the guidance of the FASB on accounting for contingencies, the Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be
Urovant Sciences Ltd.
Notes to consolidated financial statements (continued)

reasonably estimated. If the estimate of a probable loss is a range and no amount within the range is more likely than another, the Company
accrues the minimum of the range. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses
the facts and circumstances of the litigation, including an estimable range, if possible.

[G] Research and development expense:
Research and development costs are expensed as incurred. Payments for a product license prior to regulatory approval of the product and
payments for milestones achieved prior to regulatory approval of the product are expensed in the period incurred as research and
development. Milestone payments made in connection with regulatory approvals are capitalized and amortized to cost of product sales over
the remaining useful life of the asset. Research and development expenses primarily consist of the intellectual property and research and
development materials acquired from Merck (see Note 3), certain costs charged by RSI and RSG under their services agreements with the
Company (see Note 5[A]) and expenses from third parties who conduct research and development activities on behalf of the Company. The
estimated costs of research and development activities conducted by third-party service providers, which primarily include the conduct of
clinical trials and contract manufacturing activities, are accrued over the service periods specified in the contracts and adjusted as
necessary based upon an ongoing review of the level of effort and costs actually incurred. The estimate of the work completed is developed
through discussions with internal personnel and external services providers as to the progress of stage of completion of the services and the
agreed-upon fee to be paid for such services. As actual costs become known, the accrued estimates are adjusted. Such estimates are not
expected to be materially different from amounts actually incurred, however the Company’s understanding of the status and timing of
services performed, the number of subjects enrolled, and the rate of subject enrollment may vary from estimates and could result in reporting
amounts that are higher or lower than incurred in any particular period. The estimate of accrued research and development expense is
dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service
providers.

[H] Income taxes:
The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and
liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this
method, deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statement and
tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect
of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.
The Company recognizes deferred tax assets to the extent that it believes these assets are more likely than not to be realized. In making
such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable
temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines
that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an
adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely
than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits
of the tax position as well as consideration of the
available facts and circumstances. The Company’s policy is to recognize interest and/or penalties related to income tax matters in income
tax expense.

[1] Share-based compensation:

Share-based awards to employees and directors are valued at fair value on the date of the grant and that fair value is recognized as share-
based compensation expense over the requisite service period. The Company values its stock options that only have service vesting
requirements or performance-based awards without market conditions using the Black-Scholes option pricing model. For performance-based
awards with market conditions, the Company determines the fair value of awards as of the grant date using a Monte Carlo simulation model.

Certain assumptions need to be made with respect to utilizing the Black-Scholes option pricing model, including the expected life of the
award, volatility of the underlying shares, the risk-free interest rate and the fair value of the Company’s common shares. Since the Company
has limited option exercise history, it has generally elected to estimate the expected life of an award based upon the Securities and
Exchange Commission (“SEC”) approved “simplified method” noted under the provisions of Staff Accounting Bulletin (“SAB”) No. 107 with
the continued use of this method extended under the provisions of SAB No. 110. The risk-free interest rate is based on the rates paid on
securities issued by the U.S. Treasury with a term approximating the expected life of the equity award. The expected share price volatility for
the Company’s common shares is estimated by taking the average historical price volatility for industry peers. As a result of the adoption of
ASU 2016-09 on April 1, 2017, the Company has made an entity-wide accounting policy election to account for pre-vesting award forfeitures
when they occur. The impact of this adoption was immaterial and has been reflected in the Company’s consolidated statement of operations
for the year ended March 31, 2018.

As part of the valuation of share-based compensation under the Black-Scholes option pricing model, it is necessary for the Company to
estimate the fair value of its common shares. Given the absence of a public trading market, and in accordance with the American Institute of
Certified Public Accountants’ Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, the Company
exercised reasonable judgment and considered numerous objective and subjective factors to determine its best estimate of the fair value of
its common shares. The estimation of the fair value of the common shares considered factors including the following: the estimated present
value of the Company’s future cash flows; the Company’s business, financial condition and results of operations; the Company’s forecasted
operating performance; the illiquid nature of the Company’s common shares; industry information such as market size and growth; market
capitalization of comparable companies and the estimated value of transactions such companies have engaged in; and macroeconomic
conditions.

Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment.
The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are
made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance
goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

The Company accounts for share-based payments to non-employees issued in exchange for services based upon the fair value of the equity
instruments issued. Compensation expense for stock options issued to non-employees is calculated using the Black-Scholes option pricing
model and is recorded over the service
performance period. Options subject to vesting are required to be periodically remeasured over their service performance period, which is generally the same as the vesting period.

[J] Financial instruments:
The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. There are three levels of inputs that may be used to measure fair value:

- **Level 1**—Quoted prices in active markets for identical assets or liabilities.
- **Level 2**—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves.
- **Level 3**—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company’s financial instruments consist of cash, accounts payable, accrued expenses and amounts due to and from RSL, RSI and RSG. These financial instruments are stated at their respective historical carrying amounts, which approximates fair value due to their short-term nature.

[K] Foreign currency:
The Company has operations in the United States, the United Kingdom and Switzerland. The results of its non-U.S. dollar based functional currency operations are translated to U.S. dollars at the average exchange rates during the period. The Company’s assets and liabilities are translated using the current exchange rate as of the consolidated balance sheet date and shareholder’s equity is translated using historical rates. Adjustments resulting from the translation of the consolidated financial statements of the Company’s foreign functional currency subsidiaries into U.S. dollars are excluded from the determination of net loss and are accumulated in a separate component of shareholder’s equity. Foreign exchange transaction gains and losses are included in other income (expense) in the Company’s consolidated results of operations.

[L] Net loss per common share:
Basic net loss per common share is computed by dividing net loss applicable to common shareholder by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss applicable to common shareholder by the diluted weighted-average
number of common shares outstanding during the period calculated in accordance with the treasury stock method. For the year ended March 31, 2017, there were no instruments outstanding that were dilutive. For the year ended March 31, 2018, 6,508,750 options to purchase common shares were not included in the calculation of diluted weighted-average number of common shares outstanding because they were anti-dilutive given the net loss of the Company.

[M] Recently issued accounting pronouncements:

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU No. 2016-02”), which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 will require lessees to present the assets and liabilities that arise from leases on their consolidated balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the new standard and its impact on the Company’s consolidated financial position, results of operations and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“ASU No. 2016-09”). This ASU makes several modifications to Topic 718 related to the accounting for forfeitures, employer tax withholding on share-based compensation, and the consolidated financial statement presentation of excess tax benefits or deficiencies. ASU No. 2016-09 also clarifies the consolidated statement of cash flows presentation for certain components of share-based awards. The standard is effective for interim and annual reporting periods beginning after December 15, 2016, with early adoption permitted. The Company adopted this guidance on April 1, 2017 and the adoption of ASU No. 2016-09 did not have a material impact on the Company’s consolidated financial statements, results of operations and related disclosures.

In October 2016, the FASB issued ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory (“ASU No. 2016-16”), which eliminates the exception in existing guidance which defers the recognition of the tax effects of intra-entity asset transfers other than inventory until the transferred asset is sold to a third party. Rather, the amended guidance requires an entity to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. This guidance is effective for interim and annual periods beginning after December 15, 2017, with early adoption permitted as of the beginning of an annual reporting period. Entities must apply the guidance on a modified retrospective basis though a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the new standard and its impact on the Company’s consolidated financial position, results of operations and related disclosures.

In January 2017, the FASB issued ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business (“ASU No. 2017-01”), which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU No. 2017-01 is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those years, with early adoption permitted. The Company will apply the guidance to applicable transactions after the adoption date. The impact on the Company’s consolidated financial position, results of operations and related disclosures will depend on the facts and circumstances of any specific future transactions.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes* (Topic 740): *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* ("ASU No. 2018-05"). ASU No. 2018-05 amends certain SEC material in ASC Topic 740 for the income tax accounting implications of the recently issued Tax Cuts and Jobs Act. ASU No. 2018-05 is effective immediately. The Company evaluated the impact of the Tax Cuts and Jobs Act as well as the guidance of SAB No. 118 and incorporated the changes into the determination of a reasonable estimate of deferred taxes and appropriate disclosures in the notes to the Company’s consolidated financial statements (see Note 7). The Company will continue to evaluate the impact this tax reform legislation may have on its consolidated financial position, results of operations and related disclosures.

**Note 3—License agreement**

On February 3, 2017, the Company’s wholly-owned subsidiary, USG, entered into an exclusive license agreement with Merck for the development and commercialization of vibegron in exchange for the following consideration:

- Initial one-time, non-refundable, non-creditable payment of $25.0 million within ten days of the agreement;
- Up to an aggregate of $44.0 million upon the achievement of certain regulatory milestones;
- Up to an aggregate of $80.0 million upon the achievement of certain annual sales-based milestones; and
- An escalating low double-digit royalty on annual net sales which may be reduced by a portion of royalty payments, and in certain cases other payments, made to third parties, as well as, on a country-by-country basis, if generic products achieve a certain market share. Our royalty obligations with respect to vibegron will end, on a country-by-country basis, on the latest of 15 years from first commercial sale or the expiration of marketing exclusivity or enforceable Merck patents.

The Territory for our exclusive license for vibegron is worldwide, except for Japan, Brunei, Cambodia, Hong Kong, Indonesia, Korea, Laos, Malaysia, Myanmar, Philippines, Singapore, Taiwan, Thailand, and Vietnam.

For the consideration above, the Company also received a small quantity of inventory of vibegron, and certain research and development historical records. The Company did not hire, or receive, any Merck employees working on vibegron, or any research, clinical or manufacturing equipment. Additionally, the Company did not assume from Merck any contracts, licenses or agreements between Merck and any third party with respect to vibegron. The Company will need to develop independently all clinical processes and procedures for its clinical trials through the use of internal and external resources once appropriate and acceptable resources have been identified and obtained.

The Company has evaluated the in-license agreement of vibegron from Merck based on the applicable guidance in ASC No. 805, *Business Combinations*, and has determined that the in-process research and development asset ("IPR&D") licensed did not meet the definition of a business and thus the transaction was not considered a business combination. The Company then evaluated, pursuant to ASC 730, *Research and Development*, whether
the IPR&D asset had an alternative future use and concluded it did not. As a result, the Company recorded the initial payment under the license agreement of $25,000,000 as research and development expense in the accompanying consolidated statement of operations for the year ended March 31, 2017. There were no amounts due to Merck for the year ended March 31, 2018.

Note 4—Accrued expenses

Accrued expenses at March 31, 2017 and 2018 consist of the following:

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2017</th>
<th>March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development expenses</td>
<td>$ -</td>
<td>$2,482,098</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>-</td>
<td>429,207</td>
</tr>
<tr>
<td>Bonuses and other compensation expenses</td>
<td>-</td>
<td>549,409</td>
</tr>
<tr>
<td>Professional services expenses</td>
<td>8,027</td>
<td>89,875</td>
</tr>
<tr>
<td>Other expenses</td>
<td>-</td>
<td>44,125</td>
</tr>
<tr>
<td><strong>Total accrued expenses</strong></td>
<td><strong>$8,027</strong></td>
<td><strong>$3,594,714</strong></td>
</tr>
</tbody>
</table>

Note 5—Related party transactions

[A] Services agreements:

In May 2017, the Company entered into a formal services agreement with RSI, a wholly owned subsidiary of RSL, effective January 17, 2017 under which RSI agreed to provide certain administrative and research and development services to the Company during the formative period of the Company. Under this services agreement, the Company will pay or reimburse RSI for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI employees, RSI will charge back the employee compensation expense plus a pre-determined markup. RSI also provided such services prior to the formalization of this services agreement, and such costs have been recognized by the Company in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs will be billed back at cost. The consolidated financial statements also include third-party expenses that have been paid by RSI and RSL since the inception of the Company.

During the years ended March 31, 2017 and 2018, RSL and RSI provided certain administrative and research and development services on behalf of the Company. Total compensation expense, inclusive of base salary and fringe benefits, is proportionately allocated to the Company based upon the relative percentage of time utilized on the Company’s matters. The term of the RSI services agreement will continue until terminated upon 60 days’ written notice by RSI or by either USI or USG with respect to the services either such party receives thereunder.

In May 2017, USG entered into a separate services agreement with RSG, a wholly owned subsidiary of RSL, effective as of January 17, 2017 for the provision of services by RSG to USG in relation to the identification of potential product candidates and assistance with clinical trials, as well as other services related to clinical development, administrative and financial activities. Under the terms of the services agreement, the Company is obligated to pay or reimburse RSG for the costs they, or third parties acting on their behalf, incur in providing services to USG, including administrative and support services, as well as research and development services. In
addition, the Company is obligated to pay to RSG a pre-determined mark-up on the costs incurred directly by RSG in connection with any general and administrative and research and development services. The term of the RSG services agreement will continue until terminated by RSG or USG upon 60 days’ written notice.

Under the RSI and RSG services agreements, for the years ended March 31, 2017 and 2018, the Company incurred expenses of $1,037,211 and $6,334,618, respectively, inclusive of the mark-up. Based upon the service performed under the services agreements, amounts included in research and development expenses totaled $615,467 and $5,240,173, and amounts included in general and administrative expenses totaled $421,744 and $1,094,445 during the years ended March 31, 2017 and 2018, respectively.

[B] China intellectual property purchase agreement:

On June 12, 2017, USG and RSG entered into an intellectual property purchase agreement, as amended on May 22, 2018, pursuant to which USG assigned to RSG all of its rights, titles, claims and interests in and to all intellectual property rights under the Merck license agreement, solely as it relates to USG’s rights and obligations in China. The assignment is subject to the terms of the Merck license agreement, and RSG is obligated to make royalty and milestone payments owed under the Merck license agreement to USG, to the extent such payment obligations arise from the development, regulatory approval or sales of any vibegron product in China. The consideration for the assignment of the rights to China under the Merck license agreement was $1,810,000 plus applicable Swiss VAT and was determined based on an independent third-party valuation. As described in Note 3 above, since the IPR&D asset acquired from Merck was expensed during the year ended March 31, 2017, the carrying value of the intellectual property rights transferred to RSG was $0. Since the assignment of such intellectual property rights from USG to RSG were between entities under common control with no carrying value, the Company accounted for the consideration of $1,810,000 as a deemed capital contribution from its parent, RSL. During the year ended March 31, 2018, the Company received payment of $500,000 under such agreement and the remaining consideration due of $1,310,000 was classified within equity as a shareholder receivable in the accompanying consolidated balance sheet as of March 31, 2018.

[C] Data sharing agreement:

On May 22, 2018, USG entered into a data sharing agreement (the “Data Sharing Agreement”) with Datavant, Inc. (“Datavant”), a subsidiary of the Company’s parent company, RSL. Pursuant to this Data Sharing Agreement, USG granted to Datavant a royalty-free, worldwide (excluding jurisdictions prohibited by the United States government), non-exclusive, irrevocable license to all data, subject to certain exceptions set forth in the Data Sharing Agreement, collected as part of clinical trials (but not prior to completion of such clinical trials and the publication or presentation of the data generated in connection with such clinical trials) or other patient-level data that is owned or licensed by USG and all other data mutually agreed by USG and Datavant, solely for Datavant to (1) use such data to develop its data or other analytics products (the “Datavant Products”), or (2) provide such data to third parties, subject to the limitations and conditions set forth in the Data Sharing Agreement, including limitations on providing such data to any third party that competes with USG. Pursuant to the Data Sharing Agreement, Datavant granted to USG a royalty-free, worldwide (excluding jurisdictions prohibited by the United States government), nonexclusive, irrevocable license to use all data, subject to certain exceptions set forth in the Data Sharing Agreement, owned or licensed by Datavant and applicable Datavant Products for such specified purposes as set forth in the Data Sharing Agreement. The Data Sharing Agreement has an initial term of two years and will automatically renew annually thereafter, subject to 30 days’ written notice of termination by either party. In addition, either party may terminate (1) upon a change of control of
Note 6—Shareholder’s equity

[A] Overview:
The Company’s Memorandum of Association, filed on January 27, 2016 in Bermuda, authorized the creation of one class of shares. As of March 31, 2018, the Company had 1,000,000,000 shares authorized with a par value of $0.00001 per share.

[B] Transactions:
Upon the Company’s formation, RSL subscribed for 10,000,000 shares of the Company’s share capital.

In February 2017, RSL made a cash capital contribution of $30.0 million. No additional common shares of the Company were issued in connection with this capital contribution as RSL owned 100% of the shares issued and outstanding.

On June 1, 2017, upon approval of the Board of Directors, the Company issued an additional 65,000,000 shares for consideration of $650 or par value of $0.00001 to RSL, increasing the total number of issued and outstanding shares to 75,000,000.

For the year ended March 31, 2018, RSL made cash capital contributions of $36.5 million. No additional common shares of the Company were issued in connection with these capital contributions as RSL owned 100% of the shares issued and outstanding.

In connection with the China intellectual property purchase agreement with RSG, USG assigned all of its rights, titles, claims and interests in and to all intellectual property rights under the Merck license agreement, solely as it relates to USG’s rights and obligations in China to RSG for cash consideration of $1,810,000. As RSG and USG are under common control, the consideration was recorded as a capital contribution from the Company’s parent, RSL (see Note 5[B]).
Note 7—Income taxes

The loss before income taxes and the related tax provision are as follows:

<table>
<thead>
<tr>
<th>Loss before income taxes:</th>
<th>Year Ended March 31, 2017</th>
<th>Year Ended March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>$—</td>
<td>$(159,303)</td>
</tr>
<tr>
<td>Switzerland</td>
<td>$(26,955,211)</td>
<td>$(36,805,234)</td>
</tr>
<tr>
<td>Bermuda</td>
<td>$(14,871)</td>
<td>$(80,459)</td>
</tr>
<tr>
<td>Other*</td>
<td>—</td>
<td>8,551</td>
</tr>
<tr>
<td>Total loss before income taxes</td>
<td>$(26,970,082)</td>
<td>$(37,036,445)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Current taxes:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>United States—Federal</td>
<td>$—</td>
<td>$36,429</td>
</tr>
<tr>
<td>United States—State</td>
<td>—</td>
<td>800</td>
</tr>
<tr>
<td>Switzerland</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Bermuda</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Other</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total current tax expense</td>
<td>—</td>
<td>37,229</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deferred taxes:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>United States—Federal</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Switzerland</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Bermuda</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Other</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total deferred tax expense</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total income tax provision</td>
<td>$—</td>
<td>$37,229</td>
</tr>
</tbody>
</table>

* Mainly related to operations in the United Kingdom.

As of March 31, 2018, the Company had an aggregate income tax payable of $17,229 to various federal, state, and local jurisdictions which is included in accrued expenses in the accompanying consolidated balance sheet.

A reconciliation of income tax provision computed at the Bermuda statutory rate to income tax provision reflected in the consolidated financial statements is as follows:

<table>
<thead>
<tr>
<th>Income tax provision at Bermuda statutory rate</th>
<th>Year Ended March 31, 2017</th>
<th>Year Ended March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign rate differential*</td>
<td>(2,868,618)</td>
<td>(4,176,646)</td>
</tr>
<tr>
<td>Tax reform</td>
<td>—</td>
<td>38,916</td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>2,868,618</td>
<td>4,174,959</td>
</tr>
<tr>
<td>Total income tax provision</td>
<td>$—</td>
<td>$37,229</td>
</tr>
</tbody>
</table>

* Mainly related to current tax on U.S. operations including permanent and temporary differences as well as operations in Switzerland and the United Kingdom at rates different than the Bermuda rate.
Urovant Sciences Ltd.
Notes to consolidated financial statements (continued)

The Company’s effective tax rate for the years ended March 31, 2017 and 2018 was 0.00% and (0.10)%, respectively, driven by the Company's jurisdictional earnings by location and a valuation allowance that eliminates the Company’s global net deferred tax assets.

On December 22, 2017, the Tax Cuts and Jobs Act (the “Act”) was enacted which introduced a comprehensive set of tax reform. The Act revises the U.S. corporate income tax by, among other things, lowering the corporate income tax rate from 35% to 21%, adopting a quasi-territorial income tax system and imposing a one-time transition tax on foreign unremitted earnings, and setting limitations on deductibility of certain costs (e.g. interest expense).

The effects of changes in tax laws are required to be recognized in the period in which the legislation is enacted. However, due to the complexity and significance of the Act’s provisions, the SEC staff issued SAB No. 118, which allows companies to record the tax effects of the Act on a provisional basis based on a reasonable estimate, and then, if necessary, subsequently adjust such amounts during a limited measurement period as more information becomes available. The measurement period ends when a company has obtained, prepared, and analyzed the information necessary to finalize its accounting, but cannot extend beyond one year from enactment.

The Act did not have a material impact on the Company’s consolidated financial statements since its global net deferred tax assets are fully offset by a valuation allowance and the Company does not have any off-shore earnings from which to record the mandatory transition tax. However, given the significant complexity of the Act, anticipated guidance from the U.S. Treasury about implementing the Act, and the potential for additional guidance from the SEC or the FASB related to the Act, these estimates may be adjusted during the measurement period. The provisional amounts were based on the Company’s present interpretations of the Act and currently available information, including assumptions and expectations about future events, such as its projected financial performance, and are subject to further refinement as additional information becomes available (such as potential new or interpretative guidance issued by the FASB or the Internal Revenue Service and other tax agencies) and further analyses are completed. The Company continues to analyze the changes in certain income tax deductions and gather additional data to compute the full impacts on the Company’s current and deferred tax assets and liabilities (deferred tax assets and liabilities will be subject to a valuation allowance if adjusted).

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the deferred tax assets (liabilities) at March 31, 2017 and 2018 are as follows:

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31, 2017</th>
<th>Year Ended March 31, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred tax assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research tax credits</td>
<td>$</td>
<td>$ 527,575</td>
</tr>
<tr>
<td>Intangibles</td>
<td>2,748,970</td>
<td>2,685,170</td>
</tr>
<tr>
<td>Net operating losses</td>
<td>119,648</td>
<td>3,745,044</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td></td>
<td>87,113</td>
</tr>
<tr>
<td>Other</td>
<td>—</td>
<td>105,684</td>
</tr>
<tr>
<td>Subtotal</td>
<td>2,868,618</td>
<td>7,150,586</td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>(2,868,618)</td>
<td>(7,043,577)</td>
</tr>
<tr>
<td>Deferred tax liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation</td>
<td>—</td>
<td>(107,009)</td>
</tr>
<tr>
<td>Total net deferred taxes</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

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Urovant Sciences Ltd.
Notes to consolidated financial statements (continued)

The Company has net operating losses in Switzerland and the United Kingdom in the amount of $33,907,429 and $80,017, respectively. The net operating losses in Switzerland will begin to expire in fiscal year 2024. The net operating losses in the United Kingdom can be carried forward indefinitely with an annual usage limitation. The Company has research and development credit carryforwards in the United States in the amount of $527,575 which will begin to expire in fiscal year 2037.

The Company assesses the realizability of the net deferred tax assets at each balance sheet date based on available positive and negative evidence in order to determine the amount which is more likely than not to be realized and record a valuation allowance as necessary. Due to the Company’s cumulative loss position which provides significant negative evidence difficult to overcome, the Company has recorded a valuation allowance of $2,868,618 and $7,043,577 as of March 31, 2017 and 2018, respectively, representing the portion of the net deferred tax assets that is not more likely than not to be realized. During the years ended March 31, 2017 and 2018, the Company recorded an increase to its valuation allowance of $2,868,618 and $4,174,959, respectively. The amount of the net deferred tax assets considered realizable, could be adjusted for future factors that would impact the assessment of the objective and subjective evidence of the Company. The Company will continue to assess the realizability of net deferred tax assets at each consolidated balance sheet date in order to determine the proper amount, if any, required for a valuation allowance.

There are outside basis differences related to our investment in subsidiaries for which no deferred taxes have been recorded as these would not be subject to tax on repatriation as Bermuda has no tax regime for Bermuda exempted limited companies, and the United Kingdom tax regime relating to company distributions generally provides for exemption from tax for most overseas profits, subject to certain exceptions.

The Company is subject to tax and will file income tax returns in the United Kingdom, Switzerland, and United States federal, state, and local jurisdictions. The Company is subject to tax examinations for fiscal year 2016 and forward in all applicable income tax jurisdictions. Tax audits and examinations can involve complex issues, interpretations and judgments. The resolution of matters may span multiple years particularly if subject to litigation or negotiation. The Company believes it has appropriately recorded its tax position using reasonable estimates and assumptions, however the potential tax benefits may impact the consolidated results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire. There are no uncertain tax benefits recorded as of March 31, 2017 and 2018.

Note 8—Share-based compensation

Stock options:

On June 1, 2017, the Company adopted its 2017 Equity Incentive Plan (the “2017 Plan”), under which 7,500,000 common shares are reserved for grant. The Company’s employees, directors and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance cash awards, and other stock awards under the plan. Options granted to consultants and employees generally vest over four years and have a 10-year contractual term and each option will have an exercise price equal to the fair market value of the Company’s common shares on the date of grant. For grants of incentive stock options, if the grantee owns, or is deemed to own, 10% or more of the total voting power of the Company, then the exercise price shall be 110% of the fair market value of the Company’s common shares on the date of grant and the option will have a five-year contractual term. Options that are forfeited or expire are available for future grants.

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Stock options granted under the 2017 Plan may provide option holders, if approved by the Board of Directors, the right to exercise their options prior to vesting. In the event that an option holder exercises the unvested portion of any option, such unvested portion will be subject to a repurchase option held by the Company at the lower of (1) the fair market value of its common shares on the date of repurchase and (2) the exercise price of the options. Any common shares underlying such unvested portion will continue to vest in accordance with the original vesting schedule of the option.

At March 31, 2018, a total of 991,250 common shares were available for future issuance under the 2017 Plan.

The Company estimated the fair value of each option on the date of grant using the Black-Scholes option pricing model applying the weighted average assumptions in the following table:

<table>
<thead>
<tr>
<th>Risk-free interest rate</th>
<th>2.15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected term, in years</td>
<td>6.28</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>69.7%</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>—%</td>
</tr>
</tbody>
</table>

The following table presents a summary of option activity and data under the Company’s 2017 Plan through March 31, 2018:

<table>
<thead>
<tr>
<th></th>
<th>Number of Options</th>
<th>Weighted Average Exercise Price</th>
<th>Weighted Average Grant Date Fair Value</th>
<th>Weighted Average Remaining Contractual Life</th>
<th>Aggregate Intrinsic Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Options outstanding at March 31, 2017</td>
<td>—</td>
<td>$ —</td>
<td>$ —</td>
<td>$ —</td>
<td>$ —</td>
</tr>
<tr>
<td>Granted</td>
<td>6,508,750</td>
<td>1.02</td>
<td>0.66</td>
<td>9.58</td>
<td>$ —</td>
</tr>
<tr>
<td>Options outstanding at March 31, 2018</td>
<td>6,508,750</td>
<td>$ 1.02</td>
<td>$ 0.66</td>
<td>9.58</td>
<td>$ —</td>
</tr>
<tr>
<td>Options expected to vest at March 31, 2018</td>
<td>6,508,750</td>
<td>$ 1.02</td>
<td>$ 0.66</td>
<td>9.58</td>
<td>$ —</td>
</tr>
</tbody>
</table>

At March 31, 2018, there were no vested or exercisable options outstanding.

[A] Stock options granted to employees and non-employees:

There were no stock options granted to employees and consultants during the year ended March 31, 2017. During the year ended March 31, 2018, the Company granted options to purchase 6,454,750 common shares to certain employees of the Company and options to purchase 54,000 common shares to certain consultants, who are also employees of RSI, with a weighted-average exercise price of $1.02 under the 2017 Plan. The fair value of the stock options granted to RSI employees is accounted for by the Company in accordance with the authoritative guidance for non-employee equity awards and is remeasured on each reporting date until performance is complete using the Black-Scholes option pricing model. Each award is subject to a specified vesting schedule. Compensation expense will be recognized by the Company over the required service period to earn each award.
In connection with his employment agreement, the Company granted to its Principal Executive Officer a stock option to purchase 750,000 common shares at an exercise price of $1.03 per common share which vests upon the satisfaction of both a time-based vesting condition and a performance vesting condition. As of March 31, 2018, the performance condition is not probable of occurring and as a result no expense has been recognized for this option during the year ended March 31, 2018. In addition, on each six-month anniversary of his employment start date, he is eligible to receive a stock option award equal to 5% of the net positive number of equity awards that were granted by the Company to individuals (other than him) in the prior six-month period less any such equity awards that were forfeited during that period, provided that the cumulative net number of equity grants issued since his start date (excluding the awards issued to him) compared to the number of such equity awards forfeited is positive at the time of measurement, and until such time as the Company has raised $200 million (including capital contributions from RSL or otherwise). The number of shares underlying the options and the exercise price will be established at the date of each grant. Such options will vest over a period of four years, with 25% of the common shares underlying the options vesting on the first anniversary of the option grant date and the remaining common shares vesting in 12 equal quarterly installments thereafter. The first such award granted pursuant to the terms of this provision in his employment agreement was in March 2018 and the Company granted him a stock option to purchase 92,250 common shares at an exercise price of $1.07 per common share.

For the year ended March 31, 2018, the Company recorded share-based compensation expense related to stock options issued to employees and consultants of $416,356. This share-based compensation expense is included in general and administrative expenses and research and development expenses in the accompanying consolidated statement of operations.

At March 31, 2018, total unrecognized compensation expense related to non-vested options for employees and consultants was $3.9 million and is expected to be recognized over the remaining weighted-average service period of 3.53 years.

[B] Share-based compensation allocated to the company by RSL:

In relation to the RSL common share awards and options issued by RSL to RSL, RSI and RSG employees, the Company recorded share-based compensation expense of $880,438 and $2,755,172 for the years ended March 31, 2017 and 2018, respectively.

Share-based compensation expense is allocated to the Company by RSL based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.

The RSL common share awards and RSL options are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. Significant judgment and estimates were used to estimate the fair value of these RSL awards and RSL options, as they are not publicly traded. RSL common share awards and RSL options are subject to specified vesting schedules and requirements (a mix of time-based and performance-based events). The fair value of each RSL common share award is based on various corporate event-based considerations, including targets for RSL’s post-IPO market capitalization and future financing events. The fair value of each RSL option on the date of grant is estimated using the Black-Scholes option-pricing model.

Compensation expense will be allocated to the Company over the required service period over which these RSL common share awards and RSL options would vest and is based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.
Urovant Sciences Ltd.
Notes to consolidated financial statements (continued)

[3] RSL restricted stock unit (“RSUs”): 
In connection with his employment agreement, the Company’s Principal Executive Officer was granted 66,845 RSUs of the Company’s parent company, RSL, during the year ended March 31, 2018. The RSUs have a requisite service period of eight years and have no dividend rights. The RSUs will vest upon the achievement of both a performance and market condition, if both are achieved within the requisite service period. As of March 31, 2018, the performance condition had not been met and was deemed not probable of being met.

For the year ended March 31, 2018, the Company recorded no share-based compensation expense related to the RSUs that were issued. At March 31, 2018, there was $0.9 million of unrecognized compensation expense related to non-vested RSUs. The Company will recognize the expense upon the probable achievement of the performance condition through the requisite service period.

Note 9—Commitments and contingencies

The Company entered into certain commitments under the Merck license agreement (see Note 3), the Codexis enzyme supply agreement (see Note 9[A]), the Kyorin information sharing collaboration agreement (see Note 9[B]), and the services agreements with RSI and RSG (see Note 5[A]). In addition, the Company has entered into services agreements with third parties for pharmaceutical research and development and manufacturing activities and has a lease agreement for office space located in Irvine, California. Expenditures to contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, represent significant costs in the Company’s clinical development of its product candidates. Subject to required notice periods, a nominal early termination fee, in certain cases, and the Company’s remaining obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional commitments as the business further develops. As of March 31, 2018, the Company did not have any additional ongoing material financial commitments.

The Company leases 8,038 square feet of office space located in Irvine, California, pursuant to an operating lease agreement that expires in February of 2020.

Approximate future operating lease obligations as of March 31, 2018 are as follows:

<table>
<thead>
<tr>
<th>Years Ended March 31,</th>
<th>Operating Lease</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>$193,000</td>
</tr>
<tr>
<td>2020</td>
<td>177,000</td>
</tr>
<tr>
<td>Thereafter</td>
<td></td>
</tr>
<tr>
<td>Total minimum operating lease payments</td>
<td>$370,000</td>
</tr>
</tbody>
</table>

Rent expense for the year ended March 31, 2018 was approximately $55,000. The Company had no rent expense for the year ended March 31, 2017.

[A] Codexis:

On September 1, 2017, the Company entered into a supply agreement (the “Codexis Agreement”) with Codexis, Inc. (“Codexis”), pursuant to which Codexis agreed to supply its proprietary enzyme, currently used in the production of vibegron, to the Company on a non-exclusive basis. Pursuant to the Codexis Agreement, the
Company agreed to purchase from Codexis all of the Company’s requirements for such enzyme for use in the clinical and commercial production of vibegron for the first six years after the first approved vibegron product in any of the United States, Europe or Canada. The Company could be required to make minimum purchase commitments of up to $3.75 million and a milestone payment of $0.5 million, subject to the first regulatory approval of vibegron in any of the United States, Europe or Canada.

[B] Kyorin information sharing collaboration agreement:

On August 24, 2017, the Company entered into an information sharing collaboration agreement (the "Kyorin Agreement") with Kyorin Pharmaceutical Co., Ltd. ("Kyorin"). Under the Kyorin Agreement, the Company and Kyorin have agreed to share with each other certain information, including clinical study reports, and have granted each other rights of reference to the others’ regulatory materials for the purposes of developing and commercializing vibegron in their respective territories. Additionally, Kyorin has agreed to share with the Company its statistical analysis system datasets and relevant sections of its trial master file. The Kyorin Agreement does not include any joint operating activities between the parties and is solely for the purpose of sharing certain information and granting each other rights of reference to regulatory materials as it relates to vibegron.

Pursuant to this agreement, the Company’s maximum obligation to Kyorin is $11.5 million, of which $1.0 million was paid during the year ended March 31, 2018 and is included in research and development expense in the accompanying consolidated statement of operation. The remaining obligations under this agreement will be due upon achievement of certain regulatory milestones by Kyorin in Japan and the Company in the United States, subject to certain conditions. Additionally, the Company has granted Kyorin a right of first review and negotiation if the Company acquires the Japanese rights to any urology asset(s), which right expires in 2027.

[C] Indemnities and guarantees:

The Company has made certain indemnities, under which the Company may be required to make payments to an indemnified party, in relation to certain transactions. We indemnify our officers and directors to the maximum extent permitted under applicable laws. The duration of these indemnities varies and, in certain cases, is indefinite. These indemnities do not provide for any limitation of the maximum potential future payments we could be obligated to make. Historically, we have not been obligated to make any payments for these obligations and no liabilities have been recorded for these indemnities in the accompanying consolidated balance sheets.

Note 10—Subsequent events

The Company has evaluated subsequent events through June 4, 2018, the date that the consolidated financial statements were available to be issued and determined that no subsequent events have occurred that would require recognition in the consolidated financial statements or disclosures in the notes thereto other than as disclosed in the accompanying notes to the consolidated financial statements.

[A] Shareholder’s equity:

For the period April 2018 through June 2018, RSL made cash capital contributions of $8,500,000. No additional common shares of the Company were issued in connection with these capital contributions as RSL owned 100% of the shares issued and outstanding.
Urovant Sciences Ltd.
Notes to consolidated financial statements (continued)

[B] Share-based compensation:
In April 2018, the Company granted options to purchase 595,000 common shares to certain employees of the Company, with a weighted-average exercise price of $1.07 under the 2017 Plan.

[C] Related party transactions:
On May 22, 2018, USG and RSG entered into amendment of the intellectual property purchase agreement dated June 12, 2017, pursuant to which USG assigned to RSG all of its rights, titles, claims and interests in and to all intellectual property rights under the Merck license agreement, solely as it relates to USG’s rights and obligations in China (see Note 5[B]).

On May 22, 2018, USG and Datavant, a subsidiary of the Company’s parent company, RSL, entered into a Data Sharing Agreement which requires the sharing of certain information between the parties, among other things (see Note 5[C]).

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## Urovant Sciences Ltd.
### Condensed consolidated balance sheets

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2018</th>
<th>June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash</td>
<td>$7,193,962</td>
<td>$4,252,962</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>5,196,332</td>
<td>5,887,933</td>
</tr>
<tr>
<td>Deferred initial public offering costs</td>
<td>(852,650)</td>
<td></td>
</tr>
<tr>
<td>Total current assets</td>
<td>12,390,294</td>
<td>10,993,545</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>509,567</td>
<td>585,244</td>
</tr>
<tr>
<td>Other assets</td>
<td>83,595</td>
<td>83,595</td>
</tr>
<tr>
<td>Total assets</td>
<td>$12,983,456</td>
<td>$11,662,384</td>
</tr>
<tr>
<td><strong>Liabilities and Shareholder’s Equity (Deficit)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts payable</td>
<td>$832,797</td>
<td>$5,329,372</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>3,594,714</td>
<td>8,791,889</td>
</tr>
<tr>
<td>Due to Roivant Sciences Ltd.</td>
<td>1,481,960</td>
<td>2,676,248</td>
</tr>
<tr>
<td>Total liabilities</td>
<td>5,909,471</td>
<td>16,797,509</td>
</tr>
<tr>
<td>Commitments and contingencies (Note 7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shareholder’s equity (deficit):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common shares, par value $0.00001 per share, 1,000,000,000 shares authorized, 75,000,000 issued and outstanding at March 31, 2018 and June 30, 2018</td>
<td>750</td>
<td>750</td>
</tr>
<tr>
<td>Common shares subscribed</td>
<td>(750)</td>
<td>(750)</td>
</tr>
<tr>
<td>Shareholder receivable</td>
<td>(1,310,000)</td>
<td>(1,310,000)</td>
</tr>
<tr>
<td>Accumulated other comprehensive income (loss)</td>
<td>7,014</td>
<td>(212,736)</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td>72,562,119</td>
<td>91,867,863</td>
</tr>
<tr>
<td>Accumulated deficit</td>
<td>(64,185,148)</td>
<td>(95,480,252)</td>
</tr>
<tr>
<td>Total shareholder’s equity (deficit)</td>
<td>7,073,985</td>
<td>(5,135,125)</td>
</tr>
<tr>
<td>Total liabilities and shareholder’s equity (deficit)</td>
<td>$12,983,456</td>
<td>$11,662,384</td>
</tr>
</tbody>
</table>

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

F-27
# Urovant Sciences Ltd.

## Condensed consolidated statements of operations

(Unaudited)

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended June 30, 2017</th>
<th>Three Months Ended June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development (includes $838,726 and $451,468 of share-based compensation expense, respectively)</td>
<td>$3,131,553</td>
<td>$27,964,780</td>
</tr>
<tr>
<td>General and administrative (includes $44,823 and $354,276 of share-based compensation expense, respectively)</td>
<td>334,125</td>
<td>3,504,256</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>3,465,678</td>
<td>31,469,036</td>
</tr>
<tr>
<td><strong>Other (expense) income:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (expense) income</td>
<td>(146,711)</td>
<td>229,361</td>
</tr>
<tr>
<td>Loss before provision for income taxes</td>
<td>(3,612,389)</td>
<td>(31,239,675)</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>2,103</td>
<td>55,429</td>
</tr>
<tr>
<td>Net loss</td>
<td>$3,614,492</td>
<td>$31,295,104</td>
</tr>
<tr>
<td>Net loss per common share—basic and diluted</td>
<td>$(0.12)</td>
<td>$(0.42)</td>
</tr>
<tr>
<td>Weighted average common shares outstanding—basic and diluted</td>
<td>31,428,571</td>
<td>75,000,000</td>
</tr>
</tbody>
</table>

(1) Includes $2,287,155 and $2,431,279 of costs allocated from RSL during the three months ended June 30, 2017 and 2018, respectively.

(2) Includes $224,098 and $893,354 of costs allocated from RSL during the three months ended June 30, 2017 and 2018, respectively.

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

F-28
<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended June 30, 2017</th>
<th>Three Months Ended June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>$ (3,614,492)</td>
<td>$ (31,295,104)</td>
</tr>
<tr>
<td>Other comprehensive income (loss):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustment</td>
<td>144,123</td>
<td>(219,700)</td>
</tr>
<tr>
<td>Total other comprehensive income (loss)</td>
<td>144,123</td>
<td>(219,700)</td>
</tr>
<tr>
<td>Comprehensive loss</td>
<td>$ (3,470,369)</td>
<td>$ (31,514,854)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these condensed consolidated financial statements.
### Urovant Sciences Ltd.

**Condensed consolidated statement of shareholder’s equity (deficit)**

(Unaudited)

<table>
<thead>
<tr>
<th>Common Shares</th>
<th>Shares</th>
<th>Amount</th>
<th>Common Shares Subscribed</th>
<th>Shareholder Receivable</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Deficit</th>
<th>Accumulated Other Comprehensive Income (Loss)</th>
<th>Total Shareholder’s Equity (Deficit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at March 31, 2018</td>
<td>75,000,000</td>
<td>$ 750</td>
<td>(750) $ (1,310,000)</td>
<td>$72,562,119</td>
<td>$ (64,185,148)</td>
<td>$ 7,014</td>
<td>$ 7,073,985</td>
<td></td>
</tr>
<tr>
<td>Capital contributions</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>18,500,000</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>18,500,000</td>
</tr>
<tr>
<td>Share-based compensation expense</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>320,050</td>
<td>—</td>
<td>—</td>
<td>320,050</td>
</tr>
<tr>
<td>Capital contribution—share-based compensation expense</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>485,694</td>
<td>—</td>
<td>—</td>
<td>485,694</td>
</tr>
<tr>
<td>Foreign currency translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(219,750)</td>
<td>—</td>
<td>(219,750)</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(31,295,104)</td>
<td>—</td>
</tr>
<tr>
<td>Balance at June 30, 2018</td>
<td>75,000,000</td>
<td>$ 750</td>
<td>(750) $ (1,310,000)</td>
<td>$91,867,863</td>
<td>$ (95,480,252)</td>
<td>$ (212,736)</td>
<td>$ (5,135,125)</td>
<td></td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these condensed consolidated financial statements.
### Urovant Sciences Ltd.
**Condensed consolidated statements of cash flows**  
(Unaudited)

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended June 30, 2017</th>
<th>Three Months Ended June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cash flows from operating activities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$(3,614,492)</td>
<td>$(31,295,104)</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss to net cash used in operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depreciation and amortization</td>
<td>—</td>
<td>39,690</td>
</tr>
<tr>
<td>Share-based compensation expense</td>
<td>883,549</td>
<td>805,744</td>
</tr>
<tr>
<td>Unrealized foreign currency translation adjustment</td>
<td>144,123</td>
<td>(219,750)</td>
</tr>
<tr>
<td><strong>Changes in operating assets and liabilities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(215,332)</td>
<td>(691,601)</td>
</tr>
<tr>
<td>Due to Roivant Sciences Ltd.</td>
<td>1,468,326</td>
<td>1,194,288</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>114,243</td>
<td>4,209,075</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>618,986</td>
<td>5,197,175</td>
</tr>
<tr>
<td><strong>Net cash used in operating activities</strong></td>
<td>(600,597)</td>
<td>(20,760,483)</td>
</tr>
<tr>
<td><strong>Cash flows used in investing activities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>—</td>
<td>(115,367)</td>
</tr>
<tr>
<td><strong>Cash flows from financing activities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from capital contributions from Roivant Sciences Ltd.</td>
<td>34,882</td>
<td>18,500,000</td>
</tr>
<tr>
<td>Initial public offering costs paid</td>
<td>—</td>
<td>(565,150)</td>
</tr>
<tr>
<td><strong>Net cash provided by financing activities</strong></td>
<td>34,882</td>
<td>17,934,850</td>
</tr>
<tr>
<td><strong>Net change in cash</strong></td>
<td>(565,715)</td>
<td>(2,941,000)</td>
</tr>
<tr>
<td>Cash—beginning of period</td>
<td>4,767,471</td>
<td>7,193,962</td>
</tr>
<tr>
<td><strong>Cash—end of period</strong></td>
<td>$4,201,756</td>
<td>$4,252,962</td>
</tr>
<tr>
<td><strong>Non-cash financing activities:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unpaid initial public offering costs included in accounts payable</td>
<td>$ —</td>
<td>$287,500</td>
</tr>
<tr>
<td>Shareholder receivable for the sale of intellectual property rights in China recorded as a deemed capital contribution (see Note 4[B])</td>
<td>$1,810,000</td>
<td>—</td>
</tr>
</tbody>
</table>

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

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Urovant Sciences Ltd.
Notes to condensed consolidated financial statements
(Unaudited)

Note 1—Description of business and liquidity

[A] Description of business:

Urovant Sciences Ltd. and its subsidiaries (collectively, the “Company”) is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. The Company’s product candidate, vibegron, is an oral, once-daily, small molecule beta-3 agonist. The Company is currently developing vibegron for the treatment of overactive bladder, or OAB. The Company is also developing vibegron for the treatment of two additional potential indications; OAB in men with benign prostatic hyperplasia and pain associated with irritable bowel syndrome. The Company was founded on January 27, 2016 as a Bermuda Exempted Limited Company and a wholly owned subsidiary of Roivant Sciences Ltd. In November 2016, the Company incorporated as its wholly owned subsidiaries (1) Urovant Holdings Ltd. (“UHL”), a private limited company incorporated under the laws of England and Wales, (2) Urovant Sciences GmbH (“USG”), a company with limited liability formed under the laws of Switzerland and the Company’s principal operating subsidiary and (3) Urovant Sciences, Inc. (“USI”), a Delaware corporation based in the United States of America.

Since its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, acquiring its product candidate, vibegron, and preparing for and advancing vibegron into clinical development. Vibegron was licensed from Merck Sharp & Dohme Corp. (“Merck”), a subsidiary of Merck & Co., in February 2017. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

[B] Liquidity:

The Company has not been capitalized with sufficient funding to conduct its operations. Certain other costs of conducting the Company’s operations were paid by Roivant Sciences Ltd., inclusive of its wholly owned subsidiaries (“RSL”), and will be reimbursed by the Company upon receipt of additional external funding pursuant to services agreements with Roivant Sciences, Inc. (“RSI”) and Roivant Sciences GmbH (“RSG”). The Company has not generated any revenues and does not anticipate generating any revenues unless and until it successfully completes development and obtains regulatory approval for vibegron or any future product candidate. Since the Company has limited cash on hand to complete its clinical development and no credit facilities, the Company is dependent upon RSL and its affiliates to provide services and funding to support the operations of the Company until, at least, such time as an external financing is completed.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. The Company anticipates incurring additional losses until such time, if ever, it can obtain marketing approval to sell, and then generate significant sales from, vibegron or any future product candidate. Substantial additional financing will be needed by the Company to fund its operations and to develop and commercialize vibegron or any future product candidate. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The Company will seek to obtain additional capital through equity financings, the sale of debt or other arrangements; however, there can be no assurance that the Company will be able to raise additional capital.

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when needed or under acceptable terms, if at all. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the Company’s ability to pay dividends or make other distributions to shareholders. If the Company is unable to obtain such additional financing, operations would need to be scaled back or discontinued. The Company is currently exploring external financing alternatives which will be needed by the Company to fund its operations.

The Company’s future operations are highly dependent on a combination of factors, including (1) the timely and successful completion of additional financing discussed above; (2) the success of its research and development programs; (3) the development of competitive therapies by other biotechnology and pharmaceutical companies, (4) the Company’s ability to manage growth of the organization; (5) the Company’s ability to protect its technology and products; and, ultimately (6) regulatory approval and market acceptance of vibegron or any future product candidate.

Note 2—Summary of significant accounting policies

[A] Basis of presentation:

The Company’s fiscal year ends on March 31. The accompanying interim condensed consolidated balance sheet as of June 30, 2018, the condensed consolidated statements of operations, comprehensive loss and cash flows for the three months ended June 30, 2017 and 2018 and the condensed consolidated statement of shareholder’s equity (deficit) for the three months ended June 30, 2018 are unaudited. The accompanying interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and follow the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements as certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These interim condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and notes thereto for the fiscal year ended March 31, 2018 included elsewhere in this prospectus.

The condensed consolidated balance sheet at March 31, 2018 has been derived from the audited consolidated financial statements at that date. In the opinion of management, the interim consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of our consolidated financial position at June 30, 2018 and the consolidated results of operations and cash flows for the three months ended June 30, 2017 and 2018. The results for the three months ended June 30, 2018 are not necessarily indicative of the results to be expected for the year ending March 31, 2019 or for any future period.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of USL and UHL, USG, and USI, USL’s wholly-owned subsidiaries. USL has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period.
for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting
standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this
extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which
adoption of such standards is required for other public companies.

Effective June 1, 2017, upon approval of the Board of Directors and the Company’s sole shareholder, RSL, the Company effected a share
split of the authorized, issued and outstanding shares of the Company at a ratio of 100,000-to-1. The share split increased the total number
of authorized shares from 10,000 to 1,000,000,000 and decreased par value from $1.00 to $0.00001. All information in the accompanying
condensed consolidated financial statements and notes thereto regarding amounts of the common shares and prices per share of the
common shares has been adjusted to reflect the application of the share split on a retroactive basis.

[B] Use of estimates:
The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and
assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. The Company
regularly evaluates estimates and assumptions related to assets, liabilities, costs, expenses and compensation expense allocated to the
Company under its services agreements with RSI and RSG, as well as share-based compensation, research and development costs and
income taxes. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to
be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and
liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

[C] Financial instruments:
The Company applies a fair value framework in order to measure and disclose its financial assets and liabilities. Fair value is defined as the
exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market
for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an
entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.
There are three levels of inputs that may be used to measure fair value:

• Level 1—Quoted prices in active markets for identical assets or liabilities.

• Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that
  are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the
  assets or liabilities. Fair values are determined by utilizing quoted prices for similar assets and liabilities in active markets or other market
  observable inputs such as interest rates and yield curves.

• Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or
  liabilities.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair
value requires more judgment. Accordingly, the degree of judgment exercised
by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company’s financial instruments consist of cash, accounts payable, accrued expenses and amounts due to and from RSL. These financial instruments are stated at their respective historical carrying amounts, which approximates fair value due to their short-term nature.

[D] Deferred initial public offering costs:
Deferred offering costs, which consisted of direct costs related to the Company’s initial public offering of its common shares, are being capitalized in other current assets until the consummation of the initial public offering. These offering costs will be reclassified to additional paid-in capital upon the closing of the Company’s initial public offering.

[E] Net loss per common share:
Basic net loss per common share is computed by dividing net loss applicable to common shareholder by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss applicable to common shareholder by the diluted weighted-average number of common shares outstanding during the period calculated in accordance with the treasury stock method. For the three months ended June 30, 2017, there were no instruments outstanding that were dilutive. For the three months ended June 30, 2018, 9,071,750 options to purchase common shares were not included in the calculation of diluted weighted-average number of common shares outstanding because they were anti-dilutive given the net loss of the Company.

[F] Recently issued accounting pronouncements:
In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU No. 2016-02”), which is a comprehensive new lease standard that amends various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 will require lessees to present the assets and liabilities that arise from leases on their consolidated balance sheets. ASU No. 2016-02 is effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the new standard and its impact on the Company’s consolidated financial position, results of operations and related disclosures.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement-Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (“ASU No. 2018-02”). ASU No. 2018-02 allows companies to reclassify stranded tax effects resulting from the Tax Cuts and Jobs Act, from accumulated other comprehensive (loss) income to retained earnings. ASU No. 2018-02 is effective for interim and annual reporting periods beginning after December 15, 2017 and early adoption is permitted. The adoption of ASU 2018-02 on April 1, 2018 did not have a material impact on the Company’s condensed consolidated financial position, results of operations and related disclosures.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting (“ASU No. 2018-07”). ASU No. 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees.
Urovant Sciences Ltd.
Notes to condensed consolidated financial statements (continued)
(Unaudited)

ASU No. 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. Entities must apply the guidance retrospectively with a cumulative effect adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the new standard and its impact on the Company’s consolidated financial position, results of operations and related disclosures.

Note 3—Accrued expenses

Accrued expenses at March 31, 2018 and June 30, 2018 consist of the following:

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2018</th>
<th>June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development expenses</td>
<td>$2,482,098</td>
<td>$7,730,072</td>
</tr>
<tr>
<td>General and administrative expenses</td>
<td>429,207</td>
<td>308,696</td>
</tr>
<tr>
<td>Bonuses and other compensation expenses</td>
<td>549,409</td>
<td>498,081</td>
</tr>
<tr>
<td>Professional services expenses</td>
<td>89,875</td>
<td>158,533</td>
</tr>
<tr>
<td>Other expenses</td>
<td>44,125</td>
<td>96,507</td>
</tr>
<tr>
<td><strong>Total accrued expenses</strong></td>
<td><strong>$3,594,714</strong></td>
<td><strong>$8,791,889</strong></td>
</tr>
</tbody>
</table>

Note 4—Related party transactions

[A] Services agreements:

In May 2017, the Company entered into a formal services agreement with RSI effective January 17, 2017, as amended on July 9, 2018, under which RSI agreed to provide certain administrative and research and development services to the Company during the formative period of the Company. Under this services agreement, the Company will pay or reimburse RSI for any expenses it, or third parties acting on its behalf, incurs for the Company. For any general and administrative and research and development activities performed by RSI employees, RSI will charge back the employee compensation expense plus a pre-determined markup. RSI also provided such services prior to the formalization of this services agreement, and such costs have been recognized by the Company in the period in which the services were rendered. Employee compensation expense, inclusive of base salary and fringe benefits, is determined based upon the relative percentage of time utilized on Company matters. All other costs will be billed back at cost. The condensed consolidated financial statements also include third-party expenses that have been paid by RSI and RSL since the inception of the Company.

During the three months ended June 30, 2017 and 2018, RSL and RSI provided certain administrative and research and development services on behalf of the Company. Total compensation expense, inclusive of base salary, fringe benefits and share-based compensation, is proportionately allocated to the Company based upon the relative percentage of time utilized on the Company’s matters. A significant component of total compensation expense allocated back to the Company relates to the RSL common share awards and RSL options issued by RSL to RSL and RSI employees. The term of the RSI services agreement will continue until terminated upon 90 days’ written notice by RSI or by either USI or USG with respect to the services either such party receives thereunder.
Urovant Sciences Ltd.

Notes to condensed consolidated financial statements (continued)
(Unaudited)

In May 2017, USG entered into a separate services agreement with RSG effective as of January 17, 2017, as amended on July 9, 2018, for the provision of services by RSG to USG in relation to the identification of potential product candidates and project management of clinical trials, as well as other services related to clinical development, administrative and financial activities. Under the terms of the services agreement, the Company is obligated to pay or reimburse RSG for the costs they, or third parties acting on their behalf, incur in providing services to USG, including administrative and support services, as well as research and development services. In addition, the Company is obligated to pay to RSG a predetermined mark-up on the costs incurred directly by RSG in connection with any general and administrative and research and development services. The term of the RSG services agreement will continue until terminated by RSG or USG upon 90 days’ written notice.

Under the RSI and RSG services agreements, for the three months ended June 30, 2017 and 2018, the Company incurred expenses of $1,627,704 and $2,838,939, respectively, inclusive of the mark-up. Based upon the service performed under the services agreements, amounts included in research and development expenses totaled $1,448,429 and $2,041,805, and amounts included in general and administrative expenses totaled $179,275 and $797,134 during the three months ended June 30, 2017 and 2018, respectively.

[B] China intellectual property purchase agreement:

On June 12, 2017, USG and RSG entered into an intellectual property purchase agreement, as amended on May 22, 2018, pursuant to which USG assigned to RSG all of its rights, titles, claims and interests in and to all intellectual property rights under the Merck license agreement, solely as it relates to USG’s rights and obligations in China. The assignment is subject to the terms of the Merck license agreement, and RSG is obligated to make royalty and milestone payments owed under the Merck license agreement to USG, to the extent such payment obligations arise from the development, regulatory approval or sales of any vibegron product in China. In connection with this assignment, the Company also entered into a separate collaboration agreement with RSG on June 1, 2018, setting forth the parties’ respective rights and obligations to each other in connection with the development of vibegron in their respective territories.

The consideration for the assignment of the rights to China under the Merck license agreement was $1,810,000 plus applicable Swiss VAT and was determined based on an independent third-party valuation. Since the in-process research and development asset acquired from Merck was expensed during the year ended March 31, 2017, the carrying value of the intellectual property rights transferred to RSG was $0. Since the assignment of such intellectual property rights from USG to RSG were between entities under common control with no carrying value, the Company accounted for the consideration of $1,810,000 as a deemed capital contribution from its parent, RSL. In July 2017, the Company received payment of $500,000 under such agreement and the remaining consideration due of $1,310,000 was classified within equity as a shareholder receivable in the accompanying condensed consolidated balance sheets as of March 31, 2018 and June 30, 2018.

[C] Information sharing and cooperation agreement:

On July 9, 2018, the Company entered into an information sharing and cooperation agreement (the “Cooperation Agreement”) with RSL. The Cooperation Agreement, among other things: (1) obligates the Company to deliver to RSL periodic financial statements and other information upon reasonable request and to comply with other specified financial reporting requirements; (2) requires the Company to supply certain material information to RSL to assist it in preparing any future SEC filings; and (3) requires the Company to implement and observe certain policies and procedures related to applicable laws and regulations. The
Urovant Sciences Ltd.
Notes to condensed consolidated financial statements (continued)
(Unaudited)

Company agreed to indemnify RSL and its affiliates and their respective officers, employees and directors against all losses arising out of,
due to or in connection with RSL’s status as a shareholder under the Cooperation Agreement and the operations of or services provided by
RSL or its affiliates or their respective officers, employees or directors to the Company or any of the Company’s subsidiaries, subject to
certain limitations set forth in the Cooperation Agreement. No amounts have been paid or received under this agreement; however, the
Company believes this agreement is material to its business and operations.

[D] Data sharing agreement:
On May 22, 2018, USG entered into a data sharing agreement (the “Data Sharing Agreement”) with Datavant, Inc. (“Datavant”), a subsidiary
of the Company’s parent company, RSL. Pursuant to this Data Sharing Agreement, USG granted to Datavant a royalty-free, worldwide
(excluding jurisdictions prohibited by the United States government), non-exclusive, irrevocable license to all data, subject to certain
exceptions set forth in the Data Sharing Agreement, collected as part of clinical trials (but not prior to completion of such clinical trials and
the publication or presentation of the data generated in connection with such clinical trials) or other patient-level data that is owned or
licensed by USG and all other data mutually agreed by USG and Datavant, solely for Datavant to (1) use such data to develop its data or
other analytics products (the “Datavant Products”), or (2) provide such data to third parties, subject to the limitations and conditions set forth
in the Data Sharing Agreement, including limitations on providing such data to any third party that competes with USG. Pursuant to the Data
Sharing Agreement, Datavant granted to USG a royalty-free, worldwide (excluding jurisdictions prohibited by the United States government),
nonexclusive, irrevocable license to use all data, subject to certain exceptions set forth in the Data Sharing Agreement, owned or licensed
by Datavant and applicable Datavant Products for such specified purposes as set forth in the Data Sharing Agreement. The Data Sharing
Agreement has an initial term of two years and will automatically renew annually thereafter, subject to 30 days’ written notice of termination
by either party. In addition, either party may terminate (1) upon a change of control of either party upon 60 days’ written notice or (2) upon 90
days’ written notice for an uncured material breach by the other party. No amounts have been paid or received under this agreement,
however, the Company believes this agreement is material to its business and operations.

Note 5—Shareholder’s equity (deficit)
For the three months ended June 30, 2018, RSL made cash capital contributions of $18.5 million. No additional common shares of the
Company were issued in connection with these capital contributions as RSL owned 100% of the shares issued and outstanding.

Note 6—Share-based compensation

Stock options:
On June 1, 2017, the Company adopted its 2017 Equity Incentive Plan (the “2017 Plan”), under which 7,500,000 common shares are
reserved for grant. On June 15, 2018, the Board of Directors approved an increase in the common shares reserved for grant under the 2017
Plan of 4,000,000 common shares.

At June 30, 2018, a total of 2,428,250 common shares were available for future issuance under the 2017 Plan.
The Company estimated the fair value of each option on the date of grant using the Black-Scholes option pricing model applying the weighted average assumptions in the following table:

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended June 30, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>2.91%</td>
</tr>
<tr>
<td>Expected term, in years</td>
<td>6.14</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>68.3%</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>— %</td>
</tr>
</tbody>
</table>

The following table presents a summary of option activity and data under the Company’s 2017 Plan through June 30, 2018:

<table>
<thead>
<tr>
<th>Options outstanding at March 31, 2018</th>
<th>6,508,750</th>
<th>$1.02</th>
<th>$0.66</th>
<th>—</th>
<th>—</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granted</td>
<td>2,563,000</td>
<td>1.86</td>
<td>1.18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Options outstanding at June 30, 2018</td>
<td>9,071,750</td>
<td>$1.26</td>
<td>$0.81</td>
<td>9.49</td>
<td>$ —</td>
</tr>
<tr>
<td>Options expected to vest at June 30, 2018</td>
<td>9,071,750</td>
<td>$1.26</td>
<td>$0.81</td>
<td>9.49</td>
<td>$ —</td>
</tr>
</tbody>
</table>

At June 30, 2018, there were no vested or exercisable options outstanding.

**[A] Stock options granted to employees and non-employees:**

During the three months ended June 30, 2018, the Company granted options to purchase 2,563,000 common shares to certain employees and directors of the Company with a weighted-average exercise price of $1.86 under the 2017 Plan.

For the three months ended June 30, 2018, the Company recorded share-based compensation expense related to stock options issued to employees, directors and consultants of $320,050. This share-based compensation expense is included in general and administrative expenses and research and development expenses in the accompanying condensed consolidated statement of operations.

At June 30, 2018, total unrecognized compensation expense related to non-vested options for employees, directors and consultants was $6.6 million and is expected to be recognized over the remaining weighted-average service period of 3.50 years.

**[B] Share-based compensation allocated to the company by RSL:**

In relation to the RSL common share awards and options issued by RSL to RSL, RSI and RSG employees, the Company recorded share-based compensation expense of $883,549 and $485,694 for the three months ended June 30, 2017 and 2018, respectively.
Share-based compensation expense is allocated to the Company by RSL based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.

The RSL common share awards and RSL options are valued at fair value on the date of grant and that fair value is recognized over the requisite service period. Significant judgment and estimates were used to estimate the fair value of these RSL awards and RSL options, as they are not publicly traded. RSL common share awards and RSL options are subject to specified vesting schedules and requirements (a mix of time-based and performance-based events). The fair value of each RSL common share award is based on various corporate event-based considerations, including targets for RSL’s post-IPO market capitalization and future financing events. The fair value of each RSL option on the date of grant is estimated using the Black-Scholes option-pricing model.

Compensation expense will be allocated to the Company over the required service period over which these RSL common share awards and RSL options would vest and is based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.

RSL restricted stock unit ("RSUs"):

In connection with his employment agreement, the Company’s Principal Executive Officer was granted 66,845 RSUs of the Company’s parent company, RSL, during the year ended March 31, 2018. The RSUs have a requisite service period of eight years and have no dividend rights. The RSUs will vest upon the achievement of both a performance and liquidity condition by RSL, if both are achieved within the requisite service period. As of June 30, 2018, the performance condition had not been met and was deemed not probable of being met.

For the three months ended June 30, 2018, the Company recorded no share-based compensation expense related to the RSUs that were issued. At June 30, 2018, there was $0.9 million of unrecognized compensation expense related to non-vested RSUs. The Company will recognize the expense upon the probable achievement of the performance condition through the requisite service period.

Note 7—Commitments and contingencies

The Company entered into certain commitments under the Merck license agreement, the Codexis enzyme supply agreement, the Kyorin information sharing collaboration agreement, and the services agreements with RSI and RSG (see Note 4[A]). In addition, the Company has entered into services agreements with third parties for pharmaceutical research and development and manufacturing activities and has a lease agreement for office space located in Irvine, California that expires in February 2020. Expenditures to contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, represent significant costs in the Company’s clinical development of its product candidates. Subject to required notice periods, a nominal early termination fee, in certain cases, and the Company’s remaining obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time. The Company expects to enter into additional commitments as the business further develops. As of June 30, 2018, the Company did not have any additional ongoing material financial commitments.

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company accrues for loss contingencies when available information indicates that it is probable that a liability has been incurred and the amount of such liability can be reasonably estimated. In the cases where the Company believes that a reasonably possible loss exists, the Company discloses the facts and circumstances of the loss contingency, including an estimable range, if possible.
During the three months ended June 30, 2018, there were no other material changes outside the ordinary course of business to the specified contractual obligations set forth in the commitments and contingencies footnote disclosure in the Company’s audited consolidated financial statements for the year ended March 31, 2018 included elsewhere in this prospectus.

Note 8—Subsequent events

The Company has evaluated subsequent events through August 30, 2018, the date that the condensed consolidated financial statements were available to be issued and determined that no subsequent events have occurred that would require recognition in the condensed consolidated financial statements or disclosures in the notes thereto other than as disclosed in the accompanying notes to the condensed consolidated financial statements.

[A] Shareholder's equity:

For the period July 2018 through August 2018, RSL made cash capital contributions of $18,700,000. No additional common shares of the Company were issued in connection with these capital contributions as RSL owned 100% of the shares issued and outstanding.

[B] Share-based compensation:

In July 2018, the Company granted options to purchase 329,952 common shares to certain employees of the Company, with a weighted-average exercise price of $2.75 under the 2017 Plan.

[C] License agreement:

In August 2018, the Company entered into a license agreement with Ion Channel Innovations, LLC (“ICI”), to develop, manufacture and commercialize hMaxi-K, a novel gene therapy for patients with OAB who have failed oral pharmacological therapy, worldwide. Pursuant to this license agreement, the Company made an upfront payment of $250,000 to ICI. Additionally, the Company agreed to pay ICI up to an aggregate of $35.0 million upon the achievement of certain development and regulatory milestone events and up to an aggregate of $60.0 million upon the achievement of certain sales milestone events. Further, the Company agreed to pay ICI tiered royalties in the mid-to-high single digits on net sales of licensed products made by the Company, its affiliates or its sublicensees, subject to standard reductions as set forth in the license agreement.
Table of Contents

Shares

Common shares
Prospectus

J.P. Morgan
Jefferies
Cowen

, 2018

Through and including , 2018 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, 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 13. Other expenses of issuance and distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common shares being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and the Nasdaq initial listing fee.

<table>
<thead>
<tr>
<th>Description</th>
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<tbody>
<tr>
<td>SEC registration fee</td>
<td>$18,675</td>
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<tr>
<td>FINRA filing fee</td>
<td>23,000</td>
</tr>
<tr>
<td>Nasdaq listing fee</td>
<td>25,000</td>
</tr>
<tr>
<td>Legal fees and expenses</td>
<td>*</td>
</tr>
<tr>
<td>Accounting fees and expenses</td>
<td>*</td>
</tr>
<tr>
<td>Printing and engraving</td>
<td></td>
</tr>
<tr>
<td>expenses</td>
<td></td>
</tr>
<tr>
<td>Transfer agent and registrar</td>
<td></td>
</tr>
<tr>
<td>fees and expenses</td>
<td></td>
</tr>
<tr>
<td>Miscellaneous expenses</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>$*</td>
</tr>
</tbody>
</table>

* To be filed by amendment.


Section 98 of the Companies Act provides generally that a Bermuda company may indemnify its directors, officers and auditors against any liability which by virtue of any rule of law would otherwise be imposed on them in respect of any negligence, default, breach of duty or breach of trust, except in cases where such liability arises from fraud or dishonesty of which such director, officer or auditor may be guilty in relation to the company. Section 98 further provides that a Bermuda company may indemnify its directors, officers and auditors against any liability incurred by them in defending any proceedings, whether civil or criminal, in which judgment is awarded in their favor or in which they are acquitted or granted relief by the Supreme Court of Bermuda pursuant to section 281 of the Companies Act.

We have adopted provisions in our bye-laws that provide that we shall indemnify our officers and directors in respect of their actions and omissions, except in respect of their fraud or dishonesty. Our bye-laws provide that the shareholders waive all claims or rights of action that they might have, individually or in right of the company, against any of the company’s directors or officers for any act or failure to act in the performance of such director’s or officer’s duties, except in respect of any fraud or dishonesty of such director or officer. Section 98A of the Companies Act permits us to purchase and maintain insurance for the benefit of any officer or director in respect of any loss or liability attaching to him in respect of any negligence, default, breach of duty or breach of trust, whether or not we may otherwise indemnify such officer or director. We have purchased and maintain a directors’ and officers’ liability policy for such a purpose.

In connection with this offering, we expect to enter into indemnification agreements with each of our directors and executive officers. These indemnification agreements will provide the directors and executive officers with contractual rights to indemnification and expense advancement that are, in some cases, broader than the specific indemnification provisions contained under Bermuda law.
In addition, the underwriting agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act, or otherwise.

**Item 15. Recent sales of unregistered securities.**

**Issuances of share capital**

1. We issued 10,000,000 common shares for $0.00001 per common share on February 5, 2016 and 65,000,000 common shares for $0.00001 per common share on June 1, 2017, each to Roivant Sciences Ltd., our sole shareholder, for an aggregate consideration of $750. Each such offer, sale and issuance gives effect to the 100,000-to-1 stock split effected on June 1, 2017.

2. In September 2017, we issued options for an aggregate of 4,500,000 of our common shares under our 2017 Equity Incentive Plan, as amended, at an exercise price of $1.03 per share, to Keith A. Katkin, our Principal Executive Officer;

3. Between November 2017 and January 2018, we issued options for an aggregate of 1,145,000 of our common shares under our 2017 Equity Incentive Plan, as amended, at an exercise price of $0.97 per share, to our employees; and

4. Between February 2018 and April 2018, we issued options for an aggregate of 1,458,750 of our common shares under our 2017 Equity Incentive Plan, as amended, at an exercise price of $1.07 per share, to our employees and consultants;

5. In May 2018, we issued options for an aggregate of 1,560,500 of our common shares under our 2017 Equity Incentive Plan, as amended, at an exercise price of $2.01 per share, to our employees and a member of the board of directors of our wholly owned subsidiary, Urovant Sciences, Inc.; and

6. Between June 2018 and July 2018, we issued options for an aggregate of 737,452 of our common shares under our 2017 Equity Incentive Plan, as amended, at an exercise price of $2.58 per share, to our employees and a member of the board of directors of our wholly owned subsidiary, Urovant Sciences, Inc.

7. In August 2018, we issued options for an aggregate of 20,000 of our common shares under our 2017 Equity Incentive Plan, as amended, at an exercise price of $4.18 per share, to an employee of our wholly owned subsidiary, Urovant Sciences, Inc.

The offers, sales and issuances of the securities set forth in paragraph (1) above were deemed to be exempt from registration under Section 4(a)(2) of the Securities Act.

The offers, sales and issuances of the securities set forth in paragraphs (2) through (7) above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 thereunder as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. All of these options remain outstanding.

**Item 16. Exhibits and financial statement schedules.**

(a) **Exhibits.**

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Exhibit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Form of Underwriting Agreement</td>
</tr>
<tr>
<td>3.1††</td>
<td>Certificate of Incorporation</td>
</tr>
<tr>
<td>3.2††</td>
<td>Memorandum of Association</td>
</tr>
<tr>
<td>3.3††</td>
<td>Amended and Restated Bye-laws</td>
</tr>
</tbody>
</table>

II-2
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description of Exhibit</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1†</td>
<td>Opinion of Conyers Dill &amp; Pearman Limited as to legality.</td>
</tr>
<tr>
<td>10.4††</td>
<td>Collaboration Agreement, dated June 1, 2018, by and between Urovant Sciences GmbH and Roivant Sciences GmbH.</td>
</tr>
<tr>
<td>10.5††</td>
<td>Enzyme Supply Agreement, effective as of September 1, 2017, by and between Urovant Sciences GmbH and Codexis, Inc.</td>
</tr>
<tr>
<td>10.7††</td>
<td>Amended and Restated Services Agreement, effective as of July 9, 2018, by and among Roivant Sciences GmbH and Urovant Sciences GmbH.</td>
</tr>
<tr>
<td>10.8††</td>
<td>Information Sharing and Cooperation Agreement, dated as of July 9, 2018, by and between Roivant Sciences Ltd. and the Registrant.</td>
</tr>
<tr>
<td>10.9††</td>
<td>Registration Rights Agreement, dated as of July 7, 2018, by and between Roivant Sciences Ltd. and the Registrant.</td>
</tr>
<tr>
<td>10.10††*</td>
<td>Data Sharing Agreement, effective as of May 22, 2018, by and between Urovant Sciences GmbH and Datavant, Inc.</td>
</tr>
<tr>
<td>10.11*</td>
<td>License Agreement, dated August 24, 2018, by and between Urovant Sciences GmbH and Ion Channel Innovations, LLC.</td>
</tr>
<tr>
<td>10.12+</td>
<td>Form of Indemnification Agreement with directors and executive officers.</td>
</tr>
<tr>
<td>10.13†+</td>
<td>2017 Equity Incentive Plan, as amended.</td>
</tr>
<tr>
<td>10.14†+</td>
<td>Forms of Option Grant Notice and Option Agreement under 2017 Equity Incentive Plan, as amended.</td>
</tr>
<tr>
<td>10.15†+</td>
<td>Form of Early Exercise Stock Purchase Agreement under 2017 Equity Incentive Plan, as amended.</td>
</tr>
<tr>
<td>21.1††</td>
<td>Subsidiaries of the Registrant.</td>
</tr>
<tr>
<td>23.1</td>
<td>Consent of Ernst &amp; Young LLP, independent registered public accounting firm.</td>
</tr>
<tr>
<td>23.2†</td>
<td>Consent of Conyers Dill &amp; Pearman Limited (included in Exhibit 5.1).</td>
</tr>
<tr>
<td>24.1</td>
<td>Powers of Attorney (included on the signature page to the original filing of this registration statement).</td>
</tr>
</tbody>
</table>

+ Indicates management contract or compensatory plan.
* Portions of this exhibit (indicated by asterisks) will be omitted pursuant to a request for confidential treatment and will be separately filed with the Securities and Exchange Commission.
† To be filed by amendment.
†† Previously filed.
(b) **Financial statement schedules.**

See Index to consolidated financial statements on Page F-1. All schedules have been omitted because they are not required or are not applicable.

**Item 17. 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 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.

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.

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Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Amendment No. 3 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Irvine, California, on the 30th day of August, 2018.

UROVANT SCIENCES LTD.

By: _______________________/s/ Keith A. Katkin____________________________
    Keith A. Katkin
    Principal Executive Officer

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Keith A. Katkin and Christine G. Ocampo, and each of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact and any of his or her substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 3 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ Keith A. Katkin</td>
<td>Principal Executive Officer and Director</td>
<td>August 30, 2018</td>
</tr>
<tr>
<td>Keith A. Katkin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Christine G. Ocampo</td>
<td>Principal Financial and Accounting Officer</td>
<td>August 30, 2018</td>
</tr>
<tr>
<td>Christine G. Ocampo</td>
<td>(Urovant’s authorized representative in the United States)</td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>Director</td>
<td>August 30, 2018</td>
</tr>
<tr>
<td>Myrtle S. Potter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>Director</td>
<td>August 30, 2018</td>
</tr>
<tr>
<td>Sef P. Kurstjens, M.D., Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>Director</td>
<td>August 30, 2018</td>
</tr>
<tr>
<td>Pierre Legault</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Frank M. Torti, M.D.</td>
<td>Director</td>
<td>August 30, 2018</td>
</tr>
<tr>
<td>Frank M. Torti, M.D.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Exhibit 1.1

UNDERWRITING AGREEMENT

UROVANT SCIENCES LTD.

[●] Shares of Common Shares

Underwriting Agreement

J.P. Morgan Securities LLC
Jefferies LLC
Cowen and Company, LLC

As Representatives of the several Underwriters listed in Schedule 1 hereto

c/o J.P. Morgan Securities LLC
383 Madison Avenue
New York, New York 10179

Jefferies LLC
520 Madison Avenue
New York, New York 10022

Cowen and Company, LLC
599 Lexington Avenue, 27th Floor
New York, New York 10022

Ladies and Gentlemen:

Urovant Sciences Ltd., a company incorporated and organized under the laws of Bermuda (the “Company”), proposes to issue and sell to the several underwriters listed in Schedule 1 hereto (the “Underwriters”), for whom J.P Morgan Securities LLC (“J.P. Morgan”), Jefferies LLC (“Jefferies”) and Cowen and Company, LLC (“Cowen”) are acting as representatives (the “Representatives”), an aggregate of [●] common shares, par value $0.00001 per share, of the Company (the “Underwritten Shares”) and, at the option of the Underwriters, up to an additional [●] common shares of the Company (the “Option Shares”). The Underwritten Shares and the Option Shares are herein referred to as the “Shares”. The common shares of the Company to be outstanding after giving effect to the sale of the Shares are referred to herein as the “Common Shares”.

__________, 2018
The Company hereby confirms its agreement with the several Underwriters concerning the purchase and sale of the Shares, as follows:

1. **Registration Statement.** The Company has prepared and filed with the Securities and Exchange Commission (the “Commission”) under the Securities Act of 1933, as amended, and the rules and regulations of the Commission thereunder (collectively, the “Securities Act”), a registration statement on Form S-1 (File No. 333-226169), including a prospectus, relating to the Shares. Such registration statement, as amended at the time it became effective, including the information, if any, deemed pursuant to Rule 430A, 430B or 430C under the Securities Act to be part of the registration statement at the time of its effectiveness (“Rule 430 Information”), is referred to herein as the “Registration Statement”; and as used herein, the term “Preliminary Prospectus” means each prospectus included in such registration statement (and any amendments thereto) before effectiveness, any prospectus filed with the Commission pursuant to Rule 424(a) under the Securities Act and the prospectus included in the Registration Statement at the time of its effectiveness that omits Rule 430 Information, and the term “Prospectus” means the prospectus in the form first used (or made available upon request of purchasers pursuant to Rule 173 under the Securities Act) in connection with confirmation of sales of the Shares. If the Company has filed an abbreviated registration statement pursuant to Rule 462(b) under the Securities Act (the “Rule 462 Registration Statement”), then any reference herein to the term “Registration Statement” shall be deemed to include such Rule 462 Registration Statement. Capitalized terms used but not defined herein shall have the meanings given to such terms in the Registration Statement and the Prospectus.

At or prior to the Applicable Time (as defined below), the Company had prepared the following information (collectively with the pricing information set forth on Annex A, the “Pricing Disclosure Package”): a Preliminary Prospectus dated [●], 2018 and each “free-writing prospectus” (as defined pursuant to Rule 405 under the Securities Act) listed on Annex A hereto.

“Applicable Time” means [●] [A/P] M., New York City time, on [●], 2018.

2. **Purchase of the Shares.**

(a) On the basis of the representations, warranties and agreements set forth herein and subject to the conditions set forth herein, the Company agrees to issue and sell the Underwritten Shares to the several Underwriters as provided in this underwriting agreement (this “Agreement”), and each Underwriter agrees, severally and not jointly, to purchase at a price per share of $[●] (the “Purchase Price”) from the Company the respective number of Underwritten Shares set forth opposite such Underwriter’s name in Schedule 1 hereto.

In addition, the Company agrees to issue and sell the Option Shares to the several Underwriters as provided in this Agreement, and the Underwriters, on the basis of the representations, warranties and agreements set forth herein and subject to the conditions set forth herein, shall have the option to purchase, severally and not jointly, from the Company the Option Shares at the Purchase Price less an amount per share equal to any dividends or distributions declared by the Company and payable on the Underwritten Shares but not payable on the Option Shares.
If any Option Shares are to be purchased, the number of Option Shares to be purchased by each Underwriter shall be the number of Option Shares which bears the same ratio to the aggregate number of Option Shares being purchased as the number of Underwritten Shares set forth opposite the name of such Underwriter in Schedule 1 hereto (or such number increased as set forth in Section 10 hereof) bears to the aggregate number of Underwritten Shares being purchased from the Company by the several Underwriters, subject, however, to such adjustments to eliminate any fractional Shares as the Representatives in their sole discretion shall make.

The Underwriters may exercise the option to purchase Option Shares at any time in whole, or from time to time in part, on or before the thirtieth day following the date of the Prospectus, by written notice from the Representatives to the Company. Such notice shall set forth the aggregate number of Option Shares as to which the option is being exercised and the date and time when the Option Shares are to be delivered and paid for, which may be the same date and time as the Closing Date (as hereinafter defined) but shall not be earlier than the Closing Date nor later than the tenth full business day (as hereinafter defined) after the date of such notice (unless such time and date are postponed in accordance with the provisions of Section 10 hereof). Any such notice shall be given at least two business days prior to the date and time of delivery specified therein.

(b) The Company understands that the Underwriters intend to make a public offering of the Shares, and initially to offer the Shares on the terms set forth in the Pricing Disclosure Package. The Company acknowledges and agrees that the Underwriters may offer and sell Shares to or through any affiliate of an Underwriter.

(c) Payment for the Shares shall be made by wire transfer in immediately available funds to the account specified by the Company to the Representatives in the case of the Underwritten Shares, at the offices of Latham & Watkins LLP at 10:00 A.M. New York City time on [●], 2018, or at such other time or place on the same or such other date, not later than the fifth business day thereafter, as the Representatives and the Company may agree upon in writing or, in the case of the Option Shares, on the date and at the time and place specified by the Representatives in the written notice of the Underwriters’ election to purchase such Option Shares. The time and date of such payment for the Underwritten Shares is referred to herein as the “Closing Date”, and the time and date for such payment for the Option Shares, if other than the Closing Date, is herein referred to as the “Additional Closing Date”.

Payment for the Shares to be purchased on the Closing Date or the Additional Closing Date, as the case may be, shall be made against delivery to the Representatives for the respective accounts of the several Underwriters of the Shares to be purchased on such date or the Additional Closing Date, as the case may be, with any transfer taxes payable in connection with the sale of such Shares duly paid by the Company. Delivery of the Shares shall be made through the facilities of The Depository Trust Company unless the Representatives shall otherwise instruct.

(d) The Company acknowledges and agrees that the Representatives and the other Underwriters are acting solely in the capacity of an arm’s length contractual counterparty to the Company with respect to the offering of Shares contemplated hereby (including in connection with determining the terms of the offering) and not as a financial advisor or a fiduciary to, or an agent of, the Company or any other person. Additionally, neither the Representatives nor any
other Underwriter is advising the Company or any other person as to any legal, tax, investment, accounting or regulatory matters in any jurisdiction. The Company shall consult with its own advisors concerning such matters and shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby, and neither the Representatives nor the other Underwriters shall have any responsibility or liability to the Company with respect thereto. Any review by the Representatives and the other Underwriters of the Company, the transactions contemplated hereby or other matters relating to such transactions will be performed solely for the benefit of the Underwriters and shall not be on behalf of the Company.

3. Representations and Warranties of the Company. The Company represents and warrants to each Underwriter that:

(a) Preliminary Prospectus. No order preventing or suspending the use of any Preliminary Prospectus has been issued by the Commission, and each Preliminary Prospectus included in the Pricing Disclosure Package, at the time of filing thereof, complied in all material respects with the Securities Act, and no Preliminary Prospectus, at the time of filing thereof, contained any untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by or on behalf of such Underwriter through the Representatives expressly for use in any Preliminary Prospectus, it being understood and agreed that the only such information furnished by or on behalf any Underwriter consists of the information described as such in Section 7(b) hereof.

(b) Pricing Disclosure Package. The Pricing Disclosure Package as of the Applicable Time did not, and as of the Closing Date and as of the Additional Closing Date, as the case may be, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by or on behalf of such Underwriter through the Representatives expressly for use in such Pricing Disclosure Package, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the information described as such in Section 7(b) hereof. No statement of material fact included in the Prospectus has been omitted from the Pricing Disclosure Package and no statement of material fact included in the Pricing Disclosure Package that is required to be included in the Prospectus has been omitted therefrom.

(c) Issuer Free Writing Prospectus. Other than the Registration Statement, the Preliminary Prospectus and the Prospectus, the Company (including its agents and representatives, other than the Underwriters in their capacity as such) has not prepared, made, used, authorized, approved or referred to and will not prepare, make, use, authorize, approve or refer to any “written communication” (as defined in Rule 405 under
the Securities Act) that constitutes an offer to sell or solicitation of an offer to buy the Shares (each such communication by the Company or its agents and representatives (other than a communication referred to in clause (i) below) an “Issuer Free Writing Prospectus”) other than (i) any document not constituting a prospectus pursuant to Section 2(a)(10)(a) of the Securities Act or Rule 134 under the Securities Act or (ii) the documents listed on Annex A hereto, each electronic road show and any other written communications approved in writing in advance by the Representatives, which approval shall not be unreasonably withheld, delayed or conditioned. Each such Issuer Free Writing Prospectus complies in all material respects with the Securities Act, has been or will be (within the time period specified in Rule 433) filed in accordance with the Securities Act (to the extent required thereby) and does not conflict with the information contained in the Registration Statement or the Pricing Disclosure Package, and, when taken together with the Preliminary Prospectus accompanying, or delivered prior to delivery of, such Issuer Free Writing Prospectus, did not, and as of the Closing Date and as of the Additional Closing Date, as the case may be, will not, contain any untrue statement of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in each such Issuer Free Writing Prospectus or Preliminary Prospectus in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by or on behalf of such Underwriter through the Representatives expressly for use in such Issuer Free Writing Prospectus or Preliminary Prospectus, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 7(b) hereof.

(d) **Emerging Growth Company.** From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an “emerging growth company,” as defined in Section 2(a) of the Securities Act (an “Emerging Growth Company”). “Testing-the-Waters Communication” means any oral or written communication by the Company or any person authorized to act on behalf of the Company with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(e) **Testing-the-Waters Materials.** Except as disclosed to the Representatives, the Company (i) has not alone engaged in any Testing-the-Waters Communications other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications by virtue of a writing substantially in the form of Exhibit A hereto. The Company has not distributed or approved for distribution any Written
Testing-the-Waters Communications other than those listed on Annex B hereto. “Written Testing-the-Waters Communication” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act. Any individual Written Testing-the-Waters Communication does not conflict with the information contained in the Registration Statement or the Pricing Disclosure Package, complied in all material respects with the Securities Act, and when taken together with the Pricing Disclosure Package as of the Applicable Time, did not, and as of the Closing Date and as of the Additional Closing Date, as the case may be, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(f) Registration Statement and Prospectus. The Registration Statement has been declared effective by the Commission. No order suspending the effectiveness of the Registration Statement has been issued by the Commission, and no proceeding for that purpose or pursuant to the Securities Act against the Company or related to the offering of the Shares has been initiated or, to the knowledge of the Company, threatened by the Commission; as of the applicable effective date of the Registration Statement and any post-effective amendment thereto, the Registration Statement and any such post-effective amendment complied and will comply in all material respects with the Securities Act, and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading; and as of the date of the Prospectus and any amendment or supplement thereto and as of the Closing Date and as of the Additional Closing Date, as the case may be, the Prospectus will comply in all material respects with the Securities Act and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in the Registration Statement and the Prospectus and any amendment or supplement thereto, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 7(b) hereof.

(g) Financial Statements. The financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries included in the Registration Statement, the Pricing Disclosure Package and the Prospectus comply in all material respects with the applicable requirements of the Securities Act and present fairly in all material respects the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in conformity with generally accepted accounting principles in the United States (“GAAP”) applied on a consistent basis throughout the periods covered thereby (except as otherwise noted therein); and the other financial information included in the Registration Statement, the Pricing Disclosure Package and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries and presents fairly in all material respects, on the basis stated therein, the information shown thereby.
(h) **No Material Adverse Change.** Since the date of the most recent financial statements of the Company included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (i) there has not been any change in the capital stock (other than the issuance of shares of Common Shares upon exercise of stock options and warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Registration Statement, the Pricing Disclosure Package and the Prospectus), material change in short-term debt or long-term debt of the Company and its consolidated subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development involving a prospective material adverse change, in or affecting the business, properties, management, financial position, stockholders’ equity, results of operations or prospects of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as otherwise disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(i) **Organization and Good Standing.** The Company and each of its subsidiaries have been duly organized and are validly existing and in good standing (or equivalent concept) under the laws of their respective jurisdictions of incorporation or organization, are duly qualified to do business and are in good standing in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification, and have all power and authority necessary to own or hold their respective properties and to conduct the businesses in which they are engaged, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the business, properties, financial position, management, shareholders’ equity, results of operations or prospects of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under this Agreement (a “Material Adverse Effect”). The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21 to the Registration Statement.

(j) **Capitalization.** The Company has an authorized capitalization as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus under the heading “Capitalization”; all the outstanding shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable
(k) **Stock Options.** With respect to the stock options (the “Stock Options”) granted pursuant to the stock-based compensation plans of the Company and its subsidiaries (the “Company Stock Plans”), (i) each Stock Option intended to qualify as an “incentive stock option” under Section 422 of the Internal Revenue Code of 1986, as amended (the “Code”), so qualifies, except where the failure to so qualify would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (ii) each grant of a Stock Option was duly authorized no later than the date on which the grant of such Stock Option was by its terms to be effective (the “Grant Date”) by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and, to the knowledge of the Company (other than with respect to the execution and delivery by the Company), the award agreement governing such grant (if any) was duly executed and delivered by each party thereto, (iii) each such grant was made, in all material respects, in accordance with the terms of the Company Stock Plans, the Exchange Act and all other applicable laws and regulatory rules or requirements, including the rules of the Nasdaq Global Market (the “Nasdaq Market”) and (iv) each such grant was properly accounted for in accordance with GAAP in the financial statements (including the related notes) of the Company.

(l) **Due Authorization.** The Company has full right, power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and all corporate action required to be taken for the due and proper authorization, execution and delivery by it of this Agreement and the consummation by it of the transactions contemplated hereby has been duly and validly taken.
(m) Underwriting Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(n) The Shares. The Shares to be issued and sold by the Company hereunder have been duly authorized by the Company and, when issued and delivered and paid for as provided herein, will be duly and validly issued, will be fully paid and nonassessable and will conform in all material respects to the descriptions thereof in the Registration Statement, the Pricing Disclosure Package and the Prospectus; and except as otherwise disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the issuance of the Shares is not subject to any preemptive or similar rights.

(o) Descriptions of the Underwriting Agreement. This Agreement conforms in all material respects to the description thereof contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(p) No Violation or Default. Neither the Company nor any of its subsidiaries is (i) in violation of its memorandum of association, bye-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any property or asset of the Company or any of its subsidiaries is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(q) No Conflicts. The execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Shares by the Company and the consummation by the Company of the transactions contemplated by this Agreement or the Pricing Disclosure Package and the Prospectus will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, result in the termination, modification or acceleration of, or result in the creation or imposition of any lien, charge or encumbrance upon any property, right or asset of the Company or any of its subsidiaries pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any property, right or asset of the Company or any of its subsidiaries is subject; (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or any of its subsidiaries or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation, default, lien, charge or encumbrance that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.
(r) **No Consents Required.** No consent, approval, authorization, order, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Shares and the consummation of the transactions contemplated by this Agreement, except for the registration of the Shares under the Securities Act and such consents, approvals, authorizations, orders and registrations or qualifications as may be required by the Financial Industry Regulatory Authority, Inc. (“FINRA”) and under applicable state securities laws in connection with the purchase and distribution of the Shares by the Underwriters.

(s) **Legal Proceedings.** Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no legal, governmental or regulatory investigations, actions, demands, claims, suits, arbitrations, inquiries or proceedings (“Actions”) pending to which the Company or any of its subsidiaries is or reasonably expects to be a party or to which any property of the Company or any of its subsidiaries is or is reasonably expected to be the subject that, individually or in the aggregate, if determined adversely to the Company or any of its subsidiaries, would reasonably be expected to have a Material Adverse Effect; no such Actions are, to the knowledge of the Company, threatened or contemplated by any governmental or regulatory authority or threatened by others; and (i) there are no current or pending Actions that are required under the Securities Act to be described in the Registration Statement, the Pricing Disclosure Package or the Prospectus that are not so described in the Registration Statement, the Pricing Disclosure Package and the Prospectus and (ii) there are no contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement or described in the Registration Statement, the Pricing Disclosure Package or the Prospectus that are not so filed as exhibits to the Registration Statement or described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(t) **Independent Accountants.** Ernst & Young LLP, who have certified certain financial statements of the Company and its subsidiaries, is an independent registered public accounting firm with respect to the Company and its subsidiaries within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act.

(u) **Title to Real and Personal Property.** The Company and its subsidiaries do not own any real property. The Company and its subsidiaries have valid rights to lease or otherwise use, all items of real and personal property that are material to the respective businesses of the Company and its subsidiaries, taken as a whole, in each case free and clear of all liens, encumbrances, claims and defects and imperfections of title except those that (i) do not materially interfere with the use made and proposed to be made by the Company and its subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(v) **Intellectual Property.** The Company or its subsidiaries own, or have obtained valid and enforceable licenses for, the inventions, patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual
property described in the Registration Statement, the Pricing Disclosure Package and the Prospectus as being owned or licensed by them or, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, which are necessary for the conduct of their respective businesses as currently conducted or as currently proposed to be conducted, except where the failure to so own or hold as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect (collectively, “Intellectual Property”). To the Company’s knowledge and, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (i) there are no third parties who have rights to any Intellectual Property, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus as licensed to the Company or its subsidiaries; (ii) the Company is not obligated to grant an option or license to any third party in connection with any Intellectual Property, and (iii) there is no infringement by third parties of any Intellectual Property, except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. There is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company’s ownership of, or rights in or to, any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim that, if asserted on the date hereof, would reasonably be expected to succeed; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim that, if asserted on the date hereof, would reasonably be expected to succeed; or (C) asserting that the Company or its subsidiaries infringe or otherwise violate, or would, upon the commercialization of any product or service described in the Registration Statement, the Pricing Disclosure Package or the Prospectus as under development, infringe or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim that, if asserted on the date hereof, would reasonably be expected to succeed. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, the Company and its subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or its subsidiaries, and all such agreements are in full force and effect. To the Company’s knowledge, the product candidates described in the Registration Statement, the Pricing Disclosure Package and the Prospectus as under development by the Company or its subsidiaries fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company or its subsidiaries and included in the Intellectual Property. To the knowledge of the Company, all patents and patent applications owned by, or exclusively licensed to, the Company have been duly and properly filed and maintained except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. To the knowledge of the Company, the parties prosecuting such patents and patent applications have complied with their duty of candor and disclosure to the U.S. Patent and Trademark Office, and the Company is not aware of any facts required to be disclosed to such office that were not disclosed to such office.
and, as such, which would preclude the grant of a patent in connection with any such application or would reasonably be expected to form the basis of a finding of invalidity with respect to any patents that have issued from such applications.

(w) *No Undisclosed Relationships.* No relationship, direct or indirect, exists between or among the Company or any of its subsidiaries, on the one hand, and the directors, officers, stockholders, customers, suppliers or other affiliates of the Company or any of its subsidiaries, on the other, that is required by the Securities Act to be described in each of the Registration Statement and the Prospectus and that is not so described in such documents and in the Pricing Disclosure Package.

(x) *Investment Company Act.* The Company is not and, after giving effect to the offering and sale of the Shares and the application of the proceeds thereof as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, will not be required to register as an “investment company” or an entity “controlled” by an “investment company” within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder (collectively, the “Investment Company Act”).

(y) *Taxes.* The Company and its subsidiaries have paid all material federal, state, local and foreign taxes (including any interest and penalties due and payable thereon) and promptly filed all tax returns required to be paid or filed through the date hereof; and except as otherwise disclosed in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus, there is no tax deficiency that has been, or would reasonably be expected to be, asserted against the Company or any of its subsidiaries or any of their respective properties or assets where such deficiency would reasonably be expected to have a Material Adverse Effect.

(z) *Licenses and Permits.* The Company and its subsidiaries possess all licenses, sub-licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are required and necessary for the ownership or lease of their respective properties or the conduct of their respective businesses and operations as described in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus, except where the failure to possess or make the same would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and except as described in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus, neither the Company nor any of its subsidiaries has received notice of any revocation or modification of any such license, sub-license, certificate, permit or authorization or has any reason to believe that any such license, sub-license, certificate, permit or authorization will not be renewed in the ordinary course.

(aa) *No Labor Disputes.* No labor disturbance by or dispute with employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, except as would not reasonably be expected to have a Material Adverse Effect.
(bb) **Certain Environmental Matters.** (i) The Company and its subsidiaries are in compliance with all, and have not violated any, applicable federal, state, local and foreign laws (including common law), rules, regulations, requirements, decisions, judgments, decrees, orders and other legally enforceable requirements relating to pollution or the protection of human health or safety, the environment, natural resources, hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "Environmental Laws"); (y) have received and are in compliance with all, and have not violated any, permits, licenses, certificates or other authorizations or approvals required of them under any Environmental Laws to conduct their respective businesses; and (z) have not received notice of any actual or potential liability or obligation under or relating to, or any actual or potential violation of, any Environmental Laws, including for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, and have no knowledge of any event or condition that would reasonably be expected to result in any such notice, and (ii) there are no costs or liabilities associated with Environmental Laws of or relating to the Company or its subsidiaries, except in the case of each of (i) and (ii) above, for any such matter as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) except as described in each of the Pricing Disclosure Package and the Prospectus, (x) there are no proceedings that are pending, or that are known by the Company to be contemplated, against the Company or any of its subsidiaries under any Environmental Laws in which a governmental entity is also a party, other than such proceeding regarding which it is reasonably believed no monetary sanctions of $100,000 or more will be imposed, (y) the Company and its subsidiaries are not aware of any facts or issues regarding compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that would reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company and its subsidiaries, and (z) none of the Company or its subsidiaries anticipates material capital expenditures relating to any Environmental Laws.

(cc) **Compliance with ERISA.** (i) Each employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), for which the Company or any member of its “Controlled Group” (defined as any entity, whether or not incorporated, that is under common control with the Company within the meaning of Section 4001(a)(14) of ERISA or any entity that would be regarded as a single employer with the Company under Section 414(b)(c),(m) or (o) of the Code) would have any liability (each, a “Plan”) has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan, excluding transactions effected pursuant to a statutory or administrative exemption; (iii) for each Plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no Plan has failed (whether or
not waived), or is reasonably expected to fail, to satisfy the minimum funding standards (within the meaning of Section 302 of ERISA or Section 412 of the Code) applicable to such Plan; (iv) no Plan is, or is reasonably expected to be, in "at risk status" (within the meaning of Section 303(i) of ERISA) and no Plan that is a "multiemployer plan" within the meaning of Section 4001(a)(3) of ERISA is in "endangered status" or "critical status" (within the meaning of Sections 304 and 305 of ERISA) (v) the fair market value of the assets of each Plan exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan); (vi) no "reportable event" (within the meaning of Section 4043(c) of ERISA and the regulations promulgated thereunder) has occurred or is reasonably expected to occur; (vii) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified, and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification; (viii) neither the Company nor any member of the Controlled Group has incurred, nor reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guarantee Corporation, in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan" within the meaning of Section 4001(a)(3) of ERISA); and (ix) none of the following events has occurred or is reasonably likely to occur: (A) a material increase in the aggregate amount of contributions required to be made to all Plans by the Company or its Controlled Group affiliates in the current fiscal year of the Company and its Controlled Group affiliates compared to the amount of such contributions made in the Company’s and its Controlled Group affiliates’ most recently completed fiscal year; or (B) a material increase in the Company and its subsidiaries’ “accumulated post-retirement benefit obligations” (within the meaning of Accounting Standards Codification Topic 715-60) compared to the amount of such obligations in the Company and its subsidiaries’ most recently completed fiscal year, except in each case with respect to the events or conditions set forth in (i) through (ix) hereof, as would not, individually or in the aggregate, have a Material Adverse Effect.

(dd) Disclosure Controls. The Company and its subsidiaries maintain a system of “disclosure controls and procedures” (as defined in Rule 13a-15(e) of the Exchange Act) that (i) is effective in all material respects to perform the functions for which it was established, and (ii) has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company’s management as appropriate to allow timely decisions regarding required disclosure.

(ee) Accounting Controls. The Company and its subsidiaries maintain systems of “internal control over financial reporting” (as defined in Rule 13a-15(f) of the Exchange Act) that are designed to comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. The
Company and its subsidiaries maintain internal accounting controls which the Company believes is sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management’s general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company is not aware of any material weaknesses in the Company’s internal controls.

(ff) Insurance. The Company and its subsidiaries have insurance covering their respective properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks as the Company reasonably believes are adequate to protect the Company and its subsidiaries and their respective businesses; and neither the Company nor any of its subsidiaries has (i) received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance or (ii) any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business.

(gg) Cybersecurity. (i) Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there has been no security breach or other compromise of or relating to any of the Company’s or any of its subsidiaries’ information technology and computer systems, networks, hardware, software, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them), equipment or technology (collectively, “IT Systems and Data”), except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same, and (y) the Company and its subsidiaries have not been notified of, and have no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to their IT Systems and Data; (ii) the Company and its subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except in the case of this clause (ii), as would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect; and (iii) the Company and its subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices in all material respects.

(hh) No Unlawful Payments. Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, employee, agent, affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries
(i) has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and its subsidiaries have instituted, maintain and enforce, and will continue to maintain and enforce policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(ii) Compliance with Anti-Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental agency (collectively, the “Anti-Money Laundering Laws”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(jj) No Conflicts with Sanctions Laws. Neither the Company nor any of its subsidiaries, nor to the knowledge of the Company, any director, officer, employee, agent, affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries is currently the subject or the target of any sanctions administered or enforced by the U.S. government, (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury (“OFAC”) or the U.S. Department of State and including, without limitation, the designation as a “specially designated national” or “blocked person”), the United Nations Security Council (“UNSC”), the European Union, Her Majesty’s Treasury (“HMT”) or other relevant sanctions authority (collectively, “Sanctions”), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or target of Sanctions, including, without limitation, Crimea, Cuba, Iran, North Korea, Sudan and Syria (each, a “Sanctioned Country”); and the Company will not directly or indirectly use the proceeds of the offering of the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund
or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(kk) **No Restrictions on Subsidiaries.** Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no subsidiary of the Company is currently prohibited, directly or indirectly, under any agreement or other instrument to which it is a party or is subject, from paying any dividends to the Company, from making any other distribution on such subsidiary’s capital stock or similar ownership interest, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary’s properties or assets to the Company or any other subsidiary of the Company.

(ll) **No Broker’s Fees.** Neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against any of them or any Underwriter for a brokerage commission, finder’s fee or like payment in connection with the offering and sale of the Shares.

(mm) **No Registration Rights.** Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, to the extent that any person has the right to require the Company or any of its subsidiaries to register any securities for sale under the Securities Act by reason of the filing of the Registration Statement with the Commission or the issuance and sale of the Shares, those rights have been validly waived as of the date of this Agreement with respect to such filing or issuance and sale of Shares pursuant to this Agreement.

(nn) **No Stabilization.** Neither the Company nor any of its subsidiaries has taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in any stabilization or manipulation of the price of the Shares.

(oo) **Margin Rules.** Neither the issuance, sale and delivery of the Shares nor the application of the proceeds thereof by the Company as described in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(pp) **Forward-Looking Statements.** No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) included in any of the Registration Statement, the Pricing Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.
(qq) **Statistical and Market Data.** Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects.

(rr) **Sarbanes-Oxley Act.** There is and has been no failure on the part of the Company or any of the Company’s directors or officers, in their capacities as such, to comply with any provision of the Sarbanes-Oxley Act of 2002, as amended and the rules and regulations promulgated in connection therewith (the “Sarbanes-Oxley Act”), with which the Company is required to comply, including Section 402 related to loans.

(ss) **Status under the Securities Act.** At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or any offering participant made a *bona fide* offer (within the meaning of Rule 164(b)(2) under the Securities Act) of the Shares and at the date hereof, the Company was not and is not an “ineligible issuer,” as defined in Rule 405 under the Securities Act. The Company has paid the registration fee for this offering pursuant to Rule 456(b)(1) under the Securities Act or will pay such fee within the time period required by such rule (without giving effect to the proviso therein) and in any event prior to the Closing Date.

(tt) **No Ratings.** There are (and prior to the Closing Date, will be) no debt securities or preferred stock issued or guaranteed by the Company or any of its subsidiaries that are rated by a “nationally recognized statistical rating organization”, as such term is defined in Section 3(a)(62) under the Exchange Act.

(uu) **Stamp Taxes.** Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no stamp, registration, documentary, issuance, transfer or other similar taxes or duties are payable by or on behalf of the Underwriters in Bermuda, the United Kingdom or the United States (each, a “Relevant Taxing Jurisdiction”) in connection with (A) the execution, delivery and performance of this Agreement, (B) the creation, issuance and delivery of the Shares in the manner contemplated by this Agreement and the Prospectus, or (C) the sale and delivery by the Underwriters of the Shares to the initial purchasers thereof as contemplated herein and in the Prospectus.

(vv) **No Immunity.** Neither the Company nor any of its subsidiaries or their properties or assets has immunity under Bermuda, U.S. federal or New York state law from any legal action, suit or proceeding, from the giving of any relief in any such legal action, suit or proceeding, from set-off or counterclaim, from the jurisdiction of any Bermuda, U.S. federal or New York state court, from service of process, attachment upon or prior to judgment, or attachment in aid of execution of judgment, or from execution of a judgment, or other legal process or proceeding for the giving of any relief or for the
enforcement of a judgment, in any such court with respect to their respective obligations, liabilities or any other matter under or arising out of or in connection herewith; and, to the extent that the Company or any of its subsidiaries or any of its properties, assets or revenues may have or may hereafter become entitled to any such right of immunity in any such court in which proceedings arising out of, or relating to the transactions contemplated by this Agreement, may at any time be commenced, the Company has, pursuant to Section 16(e) of this Agreement, waived, and it will waive, or will cause its subsidiaries to waive, such right to the extent permitted by law.

(ww) Enforcement of Foreign Judgments. Any final judgment for a fixed or determined sum of money rendered by any U.S. federal or New York state court located in the State of New York having jurisdiction under its own laws in respect of any suit, action or proceeding against the Company based upon this Agreement would be declared enforceable against the Company by the courts of Bermuda, without reconsideration or reexamination of the merits.

(xx) Valid Choice of Law. The choice of laws of the State of New York as the governing law of this Agreement is a valid choice of law under the laws of Bermuda and will be recognised and given effect to in any action brought before a court of competent jurisdiction in Bermuda, subject to the restrictions described under the caption “Enforcement of Civil Liabilities Under United States Federal Securities Laws” in the Registration Statement, the Pricing Disclosure Package and the Prospectus and except for those laws (i) which such court considers to be procedural in nature; (ii) which are revenue or penal laws or (iii) the application of which would be inconsistent with public policy, as such term is interpreted under the laws of Bermuda. The Company has the power to submit, and pursuant to Section 16(c) of this Agreement, has legally, validly, effectively and irrevocably submitted, to the personal jurisdiction of each New York state and United States federal court sitting in the City of New York and has validly and irrevocably waived any objection to the laying of venue of any suit, action or proceeding brought in such court.

(yy) Indemnification and Contribution. The indemnification and contribution provisions set forth in Section 7 hereof do not contravene Bermuda law or public policy.

(zz) Dividends. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no approvals are currently required in any Relevant Taxing Jurisdiction in order for the Company to pay dividends or other distributions declared by the Company to the holders of Shares, and dividends and other distributions declared and payable on the Shares will not be subject to income, withholding or other taxes under the laws and regulations of any Relevant Taxing Jurisdiction.

(aaa) Clinical Data and Regulatory Compliance. The preclinical tests and clinical trials, and other studies (collectively, “studies”) being conducted by or, to the knowledge of the Company, for the Company, or that are described in, or the results of which are referred to in, the Registration Statement, the Pricing Disclosure Package or the Prospectus were and, if still pending, are being conducted in all material respects in
accordance with all applicable laws and regulations, including, without limitation, the Federal Food, Drug and Cosmetic Act and its implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58, and 312, with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures; each description of the results of such studies is accurate and complete in all material respects and fairly presents, in all material respects, the data derived from such studies, and the Company and its subsidiaries have no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Pricing Disclosure Package or the Prospectus; the Company and its subsidiaries have made all such filings and obtained all such Permits as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the “Regulatory Agencies”) for the conduct of its business as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except where the failure to do so would not reasonably be expected to have a Material Adverse Effect; neither the Company nor its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or material modification of any clinical trials currently being conducted or proposed to be conducted by or for the Company, that are described or referred to in the Registration Statement, the Pricing Disclosure Package or the Prospectus; and the Company and its subsidiaries have each operated and currently are in compliance in all material respects with all applicable rules, regulations and policies of the Regulatory Agencies.

(bbb) Compliance with Health Care Laws. The Company’s and its subsidiaries’ business practices have been structured in a manner reasonably designed to comply with the state, federal and foreign health care laws applicable to the respective businesses of the Company and its subsidiaries, and the Company and its subsidiaries are in compliance with all applicable Health Care Laws, except where the failure to do so would not reasonably be expected to have a Material Adverse Effect. For purposes of this Agreement, “Health Care Laws” means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; (ii) all applicable federal, state, local and all applicable foreign health care related fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the U.S. Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the U.S. civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal false claims Law (42 U.S.C. § 1320a-7b(a)), 18 U.S.C. Sections 286 and 287, the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7) and the civil monetary penalties law (42 U.S.C. § 1320a-7a); (iii) HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated pursuant to such statutes; (iv) the Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the Health Care and Education Reconciliation Act (Public Law 111-152); (v) Medicare (Title XVIII of the Social Security Act); (vi) Medicaid (Title XIX of the Social Security Act); and
any and all other applicable health care laws and regulations. Neither the Company nor, to the knowledge of the Company, its subsidiaries has received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Health Care Laws, and, to the Company’s knowledge, no such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened. To the Company’s knowledge, neither the Company nor its subsidiaries have engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other state health care program or federal health care program. Neither the Company nor its subsidiaries is a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any governmental or regulatory authority. Additionally, none of the Company, its subsidiaries or any of their respective employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that would reasonably be expected to result in debarment, suspension, or exclusion.

(c) **Legality.** The legality, validity, enforceability or admissibility into evidence of any of the Registration Statement, the Pricing Disclosure Package, the Prospectus, this Agreement or the Shares in any jurisdiction in which the Company is organized or does business is not dependent upon such document being submitted into, filed or recorded with any court or other authority in any such jurisdiction on or before the date hereof or that any tax, imposition or charge be paid in any such jurisdiction on or in respect of any such document.

(ddd) **Legal Action.** A holder of the Shares and each Underwriter are each entitled to sue as plaintiff in the court of the jurisdiction of formation and domicile of the Company for the enforcement of their respective rights under this Agreement and the Shares and such access to such courts will not be subject to any conditions which are not applicable to residents of such jurisdiction or a company incorporated in such jurisdiction except that plaintiffs not residing in Bermuda may be required to guarantee payment of a possible order for payment of costs or damages at the request of the defendant.

4. **Further Agreements of the Company.** The Company covenants and agrees with each Underwriter that:

(a) **Required Filings.** The Company will file the final Prospectus with the Commission within the time periods specified by Rule 424(h) and Rule 430A, 430B or 430C under the Securities Act, will file any Issuer Free Writing Prospectus to the extent required by Rule 433 under the Securities Act; and the Company will furnish copies of the Prospectus and each Issuer Free Writing Prospectus (to the extent not previously delivered) to the Underwriters in New York City prior to 10:00 A.M., New York City time, on the business day next succeeding the date of this Agreement in such quantities as the Representatives may reasonably request.
(b) **Delivery of Copies.** The Company will deliver, upon written request of the Underwriters and without charge, (i) to the Representatives, two signed copies of the Registration Statement as originally filed and each amendment thereto, in each case including all exhibits and consents filed therewith; and (ii) to each Underwriter (A) a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) and (B) during the Prospectus Delivery Period (as defined below), as many copies of the Prospectus (including all amendments and supplements thereto and each Issuer Free Writing Prospectus) as the Representatives may reasonably request. As used herein, the term “Prospectus Delivery Period” means such period of time after the first date of the public offering of the Shares as in the opinion of counsel for the Underwriters a prospectus relating to the Shares is required by law to be delivered (or required to be delivered but for Rule 172 under the Securities Act) in connection with sales of the Shares by any Underwriter or dealer.

(c) **Amendments or Supplements, Issuer Free Writing Prospectuses.** Before making, preparing, using, authorizing, approving, referring to or filing any Issuer Free Writing Prospectus, and before filing any amendment or supplement to the Registration Statement, the Pricing Disclosure Package or the Prospectus, the Company will furnish to the Representatives and counsel for the Underwriters a copy of the proposed Issuer Free Writing Prospectus, amendment or supplement for review and will not make, prepare, use, authorize, approve, refer to or file any such Issuer Free Writing Prospectus or file any such proposed amendment or supplement to which the Representatives reasonably object in a timely manner.

(d) **Notice to the Representative.** The Company will advise the Representatives promptly, and confirm such advice in writing (which may be by electronic mail), (i) when the Registration Statement has become effective; (ii) when any amendment to the Registration Statement has been filed or becomes effective; (iii) when any supplement to the Pricing Disclosure Package, the Prospectus, any Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication or any amendment to the Prospectus has been filed or distributed; (iv) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or the receipt of any comments from the Commission relating to the Registration Statement or any other request by the Commission for any additional information including, but not limited to, any request for information concerning any Testing-the-Waters Communication; (v) of the issuance by the Commission or any other governmental or regulatory authority of any order suspending the effectiveness of the Registration Statement or preventing or suspending the use of any Preliminary Prospectus, any of the Pricing Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication or the initiation or, to the Company’s knowledge, threatening of any proceeding for that purpose or pursuant to Section 8A of the Securities Act; (vi) of the occurrence of any event or development within the Prospectus Delivery Period as a result of which the Prospectus, any of the Pricing Disclosure Package, any Issuer Free Writing Prospectus or any Written Testing-the-
Waters Communication as then amended or supplemented would include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Prospectus, the Pricing Disclosure Package, any such Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication is delivered to a purchaser, not misleading; and of the receipt by the Company of any notice with respect to any suspension of the qualification of the Shares for offer and sale in any jurisdiction or the initiation or, to the Company’s knowledge, threatening of any proceeding for such purpose; and the Company will use its reasonable best efforts to prevent the issuance of any such order suspending the effectiveness of the Registration Statement, preventing or suspending the use of any Preliminary Prospectus, any of the Pricing Disclosure Package or the Prospectus or any Written Testing-the-Waters Communication or suspending any such qualification of the Shares and, if any such order is issued, the Company will use its reasonable best efforts to obtain as soon as possible the withdrawal thereof.

(e) **Ongoing Compliance.** (1) If during the Prospectus Delivery Period (i) any event or development shall occur or condition shall exist as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Prospectus is delivered to a purchaser, not misleading or (ii) it is necessary to amend or supplement the Prospectus to comply with law, the Company will promptly notify the Underwriters thereof and forthwith prepare and, subject to paragraph (c) above, file with the Commission and furnish to the Underwriters and to such dealers as the Representatives may designate such amendments or supplements to the Prospectus as may be necessary so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances existing when the Prospectus is delivered to a purchaser, be misleading or so that the Prospectus will comply with law and (2) if at any time prior to the Closing Date (i) any event or development shall occur or condition shall exist as a result of which the Pricing Disclosure Package as then amended or supplemented would include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Pricing Disclosure Package is delivered to a purchaser, be misleading or so that the Pricing Disclosure Package will comply with law.

(f) **Blue Sky Compliance.** If required by applicable law, the Company will qualify the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions as the Representatives shall reasonably request and will continue such
qualifications in effect so long as required for distribution of the Shares; provided that the Company shall not be required to (i) qualify as a foreign corporation or other entity or as a dealer in securities in any such jurisdiction where it would not otherwise be required to so qualify, (ii) file any general consent to service of process in any such jurisdiction or (iii) subject itself to taxation in any such jurisdiction if it is not otherwise so subject.

(g) **Earning Statement.** The Company will make generally available to its security holders and the Representatives as soon as practicable an earning statement that satisfies the provisions of Section 11(a) of the Securities Act and Rule 158 of the Commission promulgated thereunder covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the "effective date" (as defined in Rule 158) of the Registration Statement; provided the Company will be deemed to have satisfied such requirement to the extent such information is filed on the Commission’s Electronic Data Gathering, Analysis and Retrieval system or any successor thereto.

(h) **Clear Market.** For a period of 180 days after the date of the Prospectus, the Company will not (i) 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, or file with, or submit to, the Commission a registration statement under the Securities Act relating to, any Common Shares or any securities convertible into or exercisable or exchangeable for Common Shares, or publicly disclose the intention to make any offer, sale, pledge, disposition, submission or filing, (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Common Shares or any such other securities, (iii) make any demand for, or exercise any right with respect to, the registration of any Common Shares or any security convertible into or exercisable or exchangeable for Common Shares or (iv) publicly announce any intention to do any of the foregoing, whether any such transaction described in clause (i), (ii) or (iii) above is to be settled by delivery of Common Shares or such other securities, in cash or otherwise, without the prior written consent of J.P. Morgan and Jefferies, other than (i) the Shares to be sold hereunder, (ii) any Common Shares, options or other rights to receive or purchase Common Shares, or the issuance of Common Shares upon the exercise of options, pursuant to any Company Stock Plan, (iii) the filing of a registration statement on Form S-8 to register Common Shares issuable pursuant to Company Stock Plans, (iv) Common Shares or any securities convertible into, or exercisable or exchangeable for, Common Shares, or the entrance into an agreement to issue Common Shares or any securities convertible into, or exercisable or exchangeable for, Common Shares, in connection with any merger, joint venture, strategic alliances, commercial or other collaborative transaction or the acquisition or license of the business, property, technology or other assets of another individual or entity or the assumption of an employee benefit plan in connection with a merger or acquisition; provided that the aggregate number of Common Shares or any securities convertible into, or exercisable or exchangeable for, Common Shares that the Company may issue or agree to issue pursuant to this clause (iv) shall not exceed 7.5% of the total outstanding share capital of the Company immediately following the issuance of the Shares; and provided, further.
that the recipients thereof provide to the Representatives a signed Lock-Up Agreement. If the Representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up letter described in Section 6(m) hereof for an officer or director of the Company and provide the Company with notice of the impending release or waiver substantially in the form of Exhibit B hereto at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit C hereto through a major news service at least two business days before the effective date of the release or waiver.

(i) **Use of Proceeds.** The Company will apply the net proceeds from the sale of the Shares as described in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus under the heading “Use of proceeds”.

(j) **No Stabilization.** The Company will not take, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in any stabilization or manipulation of the price of the Common Shares.

(k) **Exchange Listing.** The Company will use its reasonable best efforts to list for quotation the Shares on the Nasdaq Market.

(l) **Reports.** For a period of three years from the date of this Agreement, so long as the Shares are outstanding, the Company will furnish to the Representatives, as soon as they are available, copies of all reports or other communications (financial or other) furnished to holders of the Shares, and copies of any reports and financial statements furnished to or filed with the Commission or any national securities exchange or automatic quotation system; provided the Company will be deemed to have furnished such reports and financial statements to the Representatives to the extent they are filed on the Commission’s Electronic Data Gathering, Analysis, and Retrieval system or any successor thereto.

(m) **Record Retention.** The Company will, pursuant to reasonable procedures developed in good faith, retain copies of each Issuer Free Writing Prospectus that is not filed with the Commission in accordance with Rule 433 under the Securities Act.

(n) **Filings.** The Company will file with the Commission such reports as may be required by Rule 463 under the Securities Act.

(o) **Emerging Growth Company.** The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of Shares within the meaning of the Securities Act and (ii) completion of the 180-day restricted period referred to in Section 4(h) hereof.

(p) **Tax Indemnity.** The Company will indemnify and hold harmless the Underwriters against any documentary, stamp, registration, issuance, transfer or similar tax or duty, including any interest and penalties, in connection with (A) the execution,
delivery and performance of this Agreement, (B) the creation, issuance and delivery of the Shares in the manner contemplated by this Agreement and the Prospectus, or (C) the sale and delivery by the Underwriters of the Shares to the initial purchasers thereof as contemplated herein and in the Prospectus. All payments to be made by or on behalf of the Company hereunder shall be made without withholding or deduction for or on account of any present or future taxes, duties or governmental charges whatsoever unless the Company is compelled by law to deduct or withhold such taxes, duties or charges. In that event, except for any net income, capital gains or franchise taxes imposed on the Underwriters by Bermuda or the United States or any political subdivision of taxing authority thereof or therein as a result of any present or former connection (other than any connection resulting from the transactions contemplated by this Agreement) between the Underwriters and the jurisdiction imposing such withholding or deductions, the Company shall pay such additional amounts as may be necessary in order to ensure that the net amounts received after such withholding or deductions shall equal the amounts that would have been received if no withholding or deduction has been made.

5. **Certain Agreements of the Underwriters.** Each Underwriter hereby represents and agrees that:

(a) It has not and will not use, authorize use of, refer to or participate in the planning for use of, any “free writing prospectus”, as defined in Rule 405 under the Securities Act (which term includes use of any written information furnished to the Commission by the Company and not incorporated by reference into the Registration Statement and any press release issued by the Company) other than (i) a free writing prospectus that contains no “issuer information” (as defined in Rule 433(h)(2) under the Securities Act) that was not included (including through incorporation by reference) in the Preliminary Prospectus or a previously filed Issuer Free Writing Prospectus, (ii) any Issuer Free Writing Prospectus listed on Annex A or prepared pursuant to Section 3(c) or Section 4(c) above (including any electronic road show approved in advance by the Company), or (iii) any free writing prospectus prepared by such underwriter and approved by the Company in advance in writing (each such free writing prospectus referred to in clauses (i) or (iii), an “Underwriter Free Writing Prospectus”).

(b) It has not and will not, without the prior written consent of the Company, use any free writing prospectus that contains the final terms of the Shares unless such terms have previously been included in a free writing prospectus filed with the Commission; provided that Underwriters may use a term sheet substantially in the form of Annex C hereto without the consent of the Company; provided further that any Underwriter using such term sheet shall notify the Company, and provide a copy of such term sheet to the Company, prior to, or substantially concurrently with, the first use of such term sheet.

(c) It is not subject to any pending proceeding under Section 8A of the Securities Act with respect to the offering (and will promptly notify the Company if any such proceeding against it is initiated during the Prospectus Delivery Period).
6. **Conditions of Underwriters' Obligations.** The obligation of each Underwriter to purchase the Underwritten Shares on the Closing Date or the Option Shares on the Additional Closing Date, as the case may be, as provided herein is subject to the performance by the Company of its covenants and other obligations hereunder and to the following additional conditions:

(a) **Registration Compliance; No Stop Order.** No order suspending the effectiveness of the Registration Statement shall be in effect, and no proceeding for such purpose or pursuant to Section 8A under the Securities Act shall be pending before or threatened by the Commission; the Prospectus and each Issuer Free Writing Prospectus shall have been timely filed with the Commission under the Securities Act (in the case of an Issuer Free Writing Prospectus, to the extent required by Rule 433 under the Securities Act) and in accordance with Section 4(a) hereof; and all requests by the Commission for additional information shall have been complied with to the reasonable satisfaction of the Representatives.

(b) **Representations and Warranties.** The representations and warranties of the Company contained herein shall be true and correct on the date hereof and on and as of the Closing Date or the Additional Closing Date, as the case may be; and the statements of the Company and its officers made in any certificates delivered pursuant to this Agreement shall be true and correct on and as of the Closing Date or the Additional Closing Date, as the case may be.

(c) **No Material Adverse Change.** No event or condition of a type described in Section 3(h) hereof shall have occurred or shall exist, which event or condition is not described in the Pricing Disclosure Package (excluding any amendment or supplement thereto) and the Prospectus (excluding any amendment or supplement thereto) and the effect of which in the judgment of the Representatives makes it impracticable or inadvisable to proceed with the offering, sale or delivery of the Shares on the Closing Date or the Additional Closing Date, as the case may be, on the terms and in the manner contemplated by this Agreement, the Pricing Disclosure Package and the Prospectus.

(d) **Officer's Certificate.** The Representatives shall have received on and as of the Closing Date or the Additional Closing Date, as the case may be, a certificate of the chief financial officer or chief accounting officer of the Company and one additional senior executive officer of the Company who is satisfactory to the Representatives (i) confirming that such officers have carefully reviewed the Registration Statement, the Pricing Disclosure Package and the Prospectus and, to the knowledge of such officers, the representations set forth in Sections 3(b) and 3(d) hereof are true and correct,

(ii) confirming that the other representations and warranties of the Company in this Agreement are true and correct and that the Company has complied in all material respects with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date or the Additional Closing Date, as the case may be, and (iii) to the effect set forth in paragraphs (a) and (c) above.

(e) **Comfort Letter and CFO Certificate.** (i) On the date of this Agreement and on the Closing Date or the Additional Closing Date, as the case may be, Ernst &
Young LLP shall have furnished to the Representatives, at the request of the Company, letters, dated the respective dates of delivery thereof and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives, containing statements and information of the type customarily included in accountants’ “comfort letters” to underwriters with respect to the financial statements and certain financial information contained in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus.

(ii) On the date of this Agreement and on the Closing Date or the Additional Closing Date, as the case may be, the Company shall have furnished to the Representatives a certificate, dated the respective dates of delivery thereof and addressed to the Underwriters, of its chief financial officer with respect to certain financial data contained in the Pricing Disclosure Package and the Prospectus, in form and substance reasonably satisfactory to the Representatives.

(f) **Opinion and 10b-5 Statement of Counsel for the Company.** Cooley LLP, counsel for the Company, shall have furnished to the Representatives, at the request of the Company, their written opinion and 10b-5 statement, dated the Closing Date or the Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives.

(g) **Opinion of Bermuda Counsel for the Company.** Conyers Dill & Pearman Limited, Bermuda counsel for the Company, shall have furnished to the Representatives, at the request of the Company, their written opinion, dated the Closing Date or the Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives.

(h) **Opinion of Intellectual Property Counsel for the Company.** Sterne, Kessler, Goldstein & Fox P.L.L.C., intellectual property counsel for the Company, shall have furnished to the Representatives, at the request of the Company, their written opinion, dated the Closing Date or the Additional Closing Date, as the case may be, and addressed to the Underwriters, in form and substance reasonably satisfactory to the Representatives.

(i) **Opinion and 10b-5 Statement of Counsel for the Underwriters.** The Representatives shall have received on and as of the Closing Date or the Additional Closing Date, as the case may be, an opinion and 10b-5 statement, addressed to the Underwriters, of Latham & Watkins LLP, counsel for the Underwriters, with respect to such matters as the Representatives may reasonably request, and such counsel shall have received such documents and information as they may reasonably request to enable them to pass upon such matters.

(j) **No Legal Impediment to Issuance and Sale.** No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any federal, state or foreign governmental or regulatory authority that would, as of the Closing Date or the Additional Closing Date, as the case may be, prevent the issuance or sale of the Shares; and no injunction or order of any federal, state or foreign court shall have been issued that would, as of the Closing Date or the Additional Closing Date, as the case may be, prevent the issuance or sale of the Shares.

(k) **Good Standing.** The Representatives shall have received on and as of the Closing Date or the Additional Closing Date, as the case may be, satisfactory evidence of the good standing (where such concept exists) of the Company and its subsidiaries in their respective jurisdictions of organization and their good standing (where such concept exists) in such other jurisdictions as the Representatives may reasonably request, in each case in writing or any standard form of telecommunication from the appropriate governmental authorities of such jurisdictions.
(l) **Exchange Listing.** The Shares to be delivered on the Closing Date or the Additional Closing Date, as the case may be, shall have been approved for listing on the Nasdaq Market, subject to official notice of issuance.

(m) **Lock-up Agreements.** The “lock-up” agreements, each substantially in the form of Exhibit D hereto, between the Representatives and certain stockholders, officers and directors of the Company relating to sales and certain other dispositions of Common Shares or certain other securities, delivered to you on or before the date hereof, shall be full force and effect on the Closing Date or the Additional Closing Date, as the case may be.

(n) **Certification Regarding Beneficial Owners.** The Company will deliver to the Representatives, on the date hereof, a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers, together with copies of identifying documentation, and the Company undertakes to provide such additional supporting documentation as the Representatives may reasonably request in connection with the verification of the foregoing certification.

(o) **Additional Documents.** On or prior to the Closing Date or the Additional Closing Date, as the case may be, the Company shall have furnished to the Representatives such further certificates and documents as the Representatives may reasonably request.

All opinions, letters, certificates and evidence mentioned above or elsewhere in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in form and substance reasonably satisfactory to counsel for the Underwriters.

7. **Indemnification and Contribution.**

   (a) **Indemnification of the Underwriters.** The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors and officers and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any and all losses, claims, damages and liabilities (including, without limitation, reasonable and documented legal fees and other reasonable expenses incurred in connection with any suit, action or proceeding or any claim asserted, as such fees and expenses are incurred), joint or several, that arise out of, or are based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary in order to make the statements therein not misleading, or (ii) any untrue statement or alleged untrue statement of a material fact contained in the Prospectus (or any amendment or supplement thereto), any Preliminary Prospectus, any Issuer Free Writing Prospectus, any “issuer information” filed or required to be filed pursuant to Rule 433(d) under the Securities Act, any Written Testing-the-Waters Communication, any road show as defined in Rule 433(h) under the Securities Act (a “road show”) or any Pricing Disclosure Package.
(including any Pricing Disclosure Package that has subsequently been amended), or caused by any omission or alleged omission to state therein a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading, in each case except insofar as such losses, claims, damages or liabilities arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use therein, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in subsection (b) below.

(b) Indemnification of the Company. Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, its directors, its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the indemnity set forth in paragraph (a) above, but only with respect to any losses, claims, damages or liabilities that arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with any information relating to such Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use in the Registration Statement, the Prospectus (or any amendment or supplement thereto), any Preliminary Prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, any road show or any Pricing Disclosure Package (including any Pricing Disclosure Package that has subsequently been amended), it being understood and agreed upon that the only such information furnished by any Underwriter consists of the following information in the Prospectus furnished on behalf of each Underwriter: the statements set forth in the last paragraph of the cover page regarding delivery of the Shares and, under the heading “Underwriting”, (i) the list of Underwriters and their respective participation in the sale of the Shares, (ii) the sentences related to concession and realallowance and (iii) the paragraphs under “—Price stabilization and short positions.”

(c) Notice and Procedures. If any suit, action, proceeding (including any governmental or regulatory investigation), claim or demand shall be brought or asserted against any person in respect of which indemnification may be sought pursuant to the preceding paragraphs of this Section 9, such person (the “Indemnified Person”) shall promptly notify the person against whom such indemnification may be sought (the “Indemnifying Person”) in writing; provided that the failure to notify the Indemnifying Person shall not relieve it from any liability that it may have under the preceding paragraphs of this Section 9 except to the extent that it has been materially prejudiced (through the forfeiture of substantive rights or defenses) by such failure; and provided further, that the failure to notify the Indemnifying Person shall not relieve it from any liability that it may have to an Indemnified Person otherwise than under the preceding paragraphs of this Section 9. If any such proceeding shall be brought or asserted against an Indemnified Person and it shall have notified the Indemnifying Person thereof, the Indemnifying Person shall retain counsel reasonably satisfactory to the Indemnified Person (who shall not, without the consent of the Indemnified Person, be counsel to the Indemnifying Person) to represent the Indemnified Person and any others entitled to indemnification pursuant to this Section that the Indemnifying Person may designate in such proceeding and shall pay the fees and expenses in such proceeding and shall pay the reasonable and documented fees and expenses
of such counsel related to such proceeding, as incurred. In any such proceeding, any Indemnified Person shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such Indemnified Person unless (i) the Indemnifying Person and the Indemnified Person shall have mutually agreed to the contrary; (ii) the Indemnifying Person has failed within a reasonable time to retain counsel reasonably satisfactory to the Indemnified Person; (iii) the Indemnified Person shall have reasonably concluded that there may be legal defenses available to it that are different from or in addition to those available to the Indemnifying Person; or (iv) the named parties in any such proceeding (including any impleaded parties) include both the Indemnifying Person and the Indemnified Person and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. It is understood and agreed that the Indemnifying Person shall not, in connection with any proceeding or related proceeding in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all Indemnified Persons, and that all such fees and expenses shall be paid or reimbursed as they are incurred. Any such separate firm for any Underwriter, its affiliates, directors and officers and any control persons of such Underwriter shall be designated in writing by J.P. Morgan Securities LLC and any such separate firm for the Company, its directors, its officers who signed the Registration Statement and any control persons of the Company shall be designated in writing by the Company. The Indemnifying Person shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent, the Indemnifying Person agrees to indemnify each Indemnified Person from and against any loss or liability by reason of such settlement. Notwithstanding the foregoing sentence, if at any time an Indemnified Person shall have requested that an Indemnifying Person reimburse the Indemnified Person for fees and expenses of counsel as contemplated by this paragraph, the Indemnifying Person shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by an Indemnifying Person of such request and (ii) the Indemnifying Person shall not have reimbursed the Indemnified Person in accordance with such request prior to the date of such settlement. No Indemnifying Person shall, without the written consent of the Indemnified Person, effect any settlement of any pending or threatened proceeding in respect of which any Indemnified Person is or could have been a party and indemnification could have been sought hereunder by such Indemnified Person, unless such settlement (x) includes an unconditional release of such Indemnified Person, in form and substance reasonably satisfactory to such Indemnified Person, from all liability on claims that are the subject matter of such proceeding and (y) does not include any statement as to or any admission of fault, culpability or a failure to act by or on behalf of any Indemnified Person.

(d) **Contribution.** If the indemnification provided for in paragraphs (a) and (b) above is unavailable to an Indemnified Person or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then each Indemnifying Person under such paragraph, in lieu of indemnifying such Indemnified Person thereunder, shall contribute to the amount paid or payable by such Indemnified Person as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters on the other, from the offering of the Shares or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) but also the relative fault of the
Company, on the one hand, and the Underwriters on the other, in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters on the other, shall be deemed to be in the same respective proportions as the net proceeds (before deducting expenses) received by the Company from the sale of the Shares and the total underwriting discounts and commissions received by the Underwriters in connection therewith, in each case as set forth in the table on the cover of the Prospectus, bear to the aggregate offering price of the Shares. The relative fault of the Company, on the one hand, and the Underwriters on the other, shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties’ relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

(c) Limitation on Liability. The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to paragraph (d) above were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in paragraph (d) above. The amount paid or payable by an Indemnified Person as a result of the losses, claims, damages and liabilities referred to in paragraph (d) above shall be deemed to include, subject to the limitations set forth above, any reasonable and documented legal or other expenses incurred by such Indemnified Person in connection with any such action or claim. Notwithstanding the provisions of paragraphs (d) and (e), in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Shares exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters’ obligations to contribute pursuant to paragraphs (d) and (e) are several in proportion to their respective purchase obligations hereunder and not joint.

(f) Non-Exclusive Remedies. The remedies provided for in this Section 7 paragraphs (a) through (e) are not exclusive and shall not limit any rights or remedies which may otherwise be available to any Indemnified Person at law or in equity.

8. Effectiveness of Agreement. This Agreement shall become effective as of the date first written above.

9. Termination. This Agreement may be terminated in the absolute discretion of the Representatives, by notice to the Company, if after the execution and delivery of this Agreement and on or prior to the Closing Date or, in the case of the Option Shares, prior to the Additional Closing Date (i) trading generally shall have been suspended or materially limited on or by any of the New York Stock Exchange or The Nasdaq Market; (ii) trading of any securities issued or guaranteed by the Company shall have been suspended on any exchange or in any over-the-counter market; (iii) a general moratorium on commercial banking activities shall have been
declared by federal or New York State authorities; or (iv) there shall have occurred any outbreak or escalation of hostilities or any change in financial markets or any calamity or crisis, either within or outside the United States, that, in the judgment of the Representatives, is material and adverse and makes it impracticable or inadvisable to proceed with the offering, sale or delivery of the Shares on the Closing Date or the Additional Closing Date, as the case may be, on the terms and in the manner contemplated by this Agreement, the Pricing Disclosure Package and the Prospectus.

10. **Defaulting Underwriter.**

   (a) If, on the Closing Date or the Additional Closing Date, as the case may be, any Underwriter defaults on its obligation to purchase the Shares that it has agreed to purchase hereunder on such date, the non-defaulting Underwriters may in their discretion arrange for the purchase of such Shares by other persons satisfactory to the Company on the terms contained in this Agreement. If, within 36 hours after any such default by any Underwriter, the non-defaulting Underwriters do not arrange for the purchase of such Shares, then the Company shall be entitled to a further period of 36 hours within which to procure other persons reasonably satisfactory to the non-defaulting Underwriters to purchase such Shares on such terms. If other persons become obligated or agree to purchase the Shares of a defaulting Underwriter, either the non-defaulting Underwriters or the Company may postpone the Closing Date or the Additional Closing Date, as the case may be, for up to five full business days in order to effect any changes that in the opinion of counsel for the Company or counsel for the Underwriters may be necessary in the Registration Statement and the Prospectus or in any other document or arrangement, and the Company agrees to promptly prepare any amendment or supplement to the Registration Statement and the Prospectus that effects any such changes. As used in this Agreement, the term "Underwriter" includes, for all purposes of this Agreement unless the context otherwise requires, any person not listed in Schedule 1 hereto that, pursuant to this Section 10, purchases Shares that a defaulting Underwriter agreed but failed to purchase.

   (b) If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company as provided in paragraph (a) above, the aggregate number of Shares that remain unpurchased on the Closing Date or the Additional Closing Date, as the case may be, does not exceed one-eleventh of the aggregate number of Shares to be purchased on such date, then the Company shall have the right to require each non-defaulting Underwriter to purchase the number of Shares that such Underwriter agreed to purchase hereunder on such date plus such Underwriter’s pro rata share (based on the number of Shares that such Underwriter agreed to purchase on such date) of the Shares of such defaulting Underwriter or Underwriters for which such arrangements have not been made.

   (c) If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company as provided in paragraph (a) above, the aggregate number of Shares that remain unpurchased on the Closing Date or the Additional Closing Date, as the case may be, exceeds one-eleventh of the aggregate amount of Shares to be purchased on such date, or if the Company shall not exercise the right described in paragraph (b) above, then this Agreement or, with respect to any Additional Closing Date, the obligation of the Underwriters to purchase Shares on the Additional
Closing Date, as the case may be, shall terminate without liability on the part of the non-defaulting Underwriters. Any termination of this Agreement pursuant to this Section 10 shall be without liability on the part of the Company, except that the Company will continue to be liable for the payment of expenses as set forth in Section 11 hereof and except that the provisions of Section 7 hereof shall not terminate and shall remain in effect.

(d) Nothing contained herein shall relieve a defaulting Underwriter of any liability it may have to the Company or any non-defaulting Underwriter for damages caused by its default.

11. Payment of Expenses

(a) Whether or not the transactions contemplated by this Agreement are consummated or this Agreement is terminated, the Company will pay or cause to be paid all costs and expenses incident to the performance of its obligations hereunder including without limitation, (i) the costs incident to the authorization, issuance, sale, preparation and delivery of the Shares; (ii) the costs incident to the preparation, printing and filing under the Securities Act of the Registration Statement, the Preliminary Prospectus, any Issuer Free Writing Prospectus, any Pricing Disclosure Package and the Prospectus (including all exhibits, amendments and supplements thereto) and the distribution thereof; (iii) the fees and expenses of the Company’s counsel and independent accountants; (iv) the fees and expenses incurred in connection with the registration or qualification and determination of eligibility for investment of the Shares under the laws of such jurisdictions as the Representatives may designate and the preparation, printing and distribution of a Blue Sky Memorandum (including the related fees and expenses of counsel for the Underwriters in an aggregate amount not to exceed $10,000); (v) the cost of preparing share certificates; (vi) the costs and charges of any transfer agent and any registrar; (vii) all expenses and application fees incurred in connection with any filing with, and clearance of the offering by, FINRA (including the reasonable fees and expenses of counsel for the Underwriters related to such filings) in an aggregate amount not to exceed $25,000; (viii) the transportation and other expenses incurred by or on behalf of Company representatives in connection with presentations to prospective purchasers of the Common Shares and 50% of the cost of any aircraft chartered in connection with the road show with the remaining 50% of the cost of such aircraft to be paid by the Underwriters; and (ix) all expenses and application fees related to the listing of the Shares on the Nasdaq Market.

(b) If (i) this Agreement is terminated pursuant to Section 9, (ii) the Company for any reason fails to tender the Shares for delivery to the Underwriters (other than by reason of a default by any Underwriter) or (iii) the Underwriters decline to purchase the Shares for any reason permitted under this Agreement, the Company agrees to reimburse the Underwriters for all documented out-of-pocket costs and expenses (including the fees and expenses of their counsel) reasonably incurred by the Underwriters in connection with this Agreement and the offering contemplated hereby; provided that, in the event any such termination is effected after the Closing Date but prior to any settlement date for the Option Shares, the Company will only reimburse the Underwriters for all documented out-of-pocket costs and expenses (including the fees and expenses of their counsel) reasonably incurred by the Underwriters after the Closing Date in connection with the proposed purchase of such Option Shares. For the avoidance of doubt, it is understood that the Company will not pay or reimburse any costs, fees or expenses incurred by any Underwriter that defaults on its obligation to purchase Shares hereunder.
12. **Persons Entitled to Benefit of Agreement.** This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers and directors and any controlling persons referred to herein, and the affiliates of each Underwriter referred to in Section 7 hereof. Nothing in this Agreement is intended or shall be construed to give any other person any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision contained herein. No purchaser of Shares from any Underwriter shall be deemed to be a successor merely by reason of such purchase.

13. **Survival.** The respective indemnities, rights of contribution, representations, warranties and agreements of the Company and the Underwriters contained in this Agreement or made by or on behalf of the Company or the Underwriters pursuant to this Agreement or any certificate delivered pursuant hereto shall survive the delivery of and payment for the Shares and shall remain in full force and effect, regardless of any termination of this Agreement or any investigation made by or on behalf of the Company or the Underwriters or the directors, officers, controlling persons or affiliates referred to in Section 7 hereof.

14. **Certain Defined Terms.** For purposes of this Agreement, (a) except where otherwise expressly provided, the term “affiliate” has the meaning set forth in Rule 405 under the Securities Act; (b) the term “business day” means any day other than a day on which banks are permitted or required to be closed in New York City; (c) the term “subsidiary” has the meaning set forth in Rule 405 under the Securities Act.

15. **Compliance with USA Patriot Act.** In accordance with the requirements of the USA Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)), the Underwriters are required to obtain, verify and record information that identifies their respective clients, including the Company, which information may include the name and address of their respective clients, as well as other information that will allow the Underwriters to properly identify their respective clients.

16. **Miscellaneous.**

   (a) **Notices.** All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted and confirmed by any standard form of telecommunication. Notices to the Underwriters shall be given to the Representatives c/o J.P. Morgan Securities LLC, 383 Madison Avenue, New York, New York 10179 (fax: (212) 622-8358); Attention: Equity Syndicate Desk, c/o Jefferies LLC, 520 Madison Avenue, New York, New York 10022 (fax: (646) 619-4437) and c/o Cowen at 599 Lexington Avenue, New York, New York 10022, Attention: General Counsel (facsimile: (646) 562-1124); Attention: General Counsel. Notices to the Company shall be given to it at Urovant Sciences Ltd., c/o Urovant Sciences, Inc., 5151 California Avenue, Suite #250, Irvine, California; Attention: General Counsel with a copy (which shall not constitute notice) to Cooley LLP, 3175 Hanover Street, Palo Alto, California 94304, Attention Frank F. Rahmani.

   (b) **Governing Law.** This Agreement and any claim, controversy or dispute arising under or related to this Agreement shall be governed by and construed in accordance with the laws of the State of New York.
(c) Submission to Jurisdiction. The Company hereby submits to the exclusive jurisdiction of the U.S. federal and New York state courts in the Borough of Manhattan in The City of New York in any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. The Company waives any objection which it may now or hereafter have to the laying of venue of any such suit or proceeding in such courts. The Company agrees that final judgment in any such suit, action or proceeding brought in such court shall be conclusive and binding upon the Company and may be enforced in any court to the jurisdiction of which Company is subject by a suit upon such judgment. The Company irrevocably appoints [●], located at [●], New York, New York [●], as its authorized agent in the Borough of Manhattan in The City of New York upon which process may be served in any such suit or proceeding, and agrees that service of process upon such authorized agent, and written notice of such service to the Company by the person serving the same to the address provided in this Section 16, shall be deemed in every respect effective service of process upon the Company in any such suit or proceeding. The Company hereby represents and warrants that such authorized agent has accepted such appointment and has agreed to act as such authorized agent for service of process. The Company further agree to take any and all action as may be necessary to maintain such designation and appointment of such authorized agent in full force and effect for a period of seven years from the date of this Agreement.

(d) Waiver of Immunity. To the extent that either party has or hereafter may acquire any immunity (sovereign or otherwise) from jurisdiction of any court of (i) Bermuda, or any political subdivision thereof, (ii) the United States or the State of New York, (iii) any jurisdiction in which it owns or leases property or assets or from any legal process (whether through service of notice, attachment prior to judgment, attachment in aid of execution, execution, set-off or otherwise) with respect to themselves or their respective property and assets or this Agreement, such party hereby irrevocably waives such immunity in respect of its obligations under this Agreement to the fullest extent permitted by applicable law.

(e) Waiver of Jury Trial. Each of the parties hereto hereby waives any right to trial by jury in any suit or proceeding arising out of or relating to this Agreement.

(g) Counterparts. This Agreement may be signed in counterparts (which may include counterparts delivered by any standard form of telecommunication), each of which shall be an original and all of which together shall constitute one and the same instrument.

(h) Amendments or Waivers. No amendment or waiver of any provision of this Agreement, nor any consent or approval to any departure therefrom, shall in any event be effective unless the same shall be in writing and signed by the parties hereto.

(i) Headings. The headings herein are included for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.
If the foregoing is in accordance with your understanding, please indicate your acceptance of this Agreement by signing in the space provided below.

Very truly yours,

UROVANT SCIENCES LTD.

By: ________________________________
   Name: Keith A. Katkin
   Title: Principal Executive Officer

Accepted: As of the date first written above

J.P. MORGAN SECURITIES LLC
JEFFERIES LLC
COWEN AND COMPANY, LLC

For themselves and on behalf of the several Underwriters listed in Schedule 1 hereto.

J.P. MORGAN SECURITIES LLC
By: ________________________________
   Authorized Signatory

JEFFERIES LLC
By: ________________________________
   Authorized Signatory

COWEN AND COMPANY, LLC
By: ________________________________
   Authorized Signatory
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Total


a. Pricing Disclosure Package

[●]
Annex B

Written Testing-the-Waters Communications

[●]
Urovant Sciences Ltd.

Pricing Information

Number of Underwritten Shares: [●]
Price per Share to the public: $[●]
Number of Optional Shares: [●]
In reliance on Section 5(d) of the Securities Act of 1933, as amended (the “Act”), Urovant Sciences Ltd. (the “Issuer”) hereby authorizes J.P. Morgan Securities LLC (“J.P. Morgan”) and its affiliates and their respective employees, Jefferies LLC and its affiliates and their respective employees and Cowen and Company, LLC and its affiliates and their respective employees, to engage on behalf of the Issuer in oral and written communications with potential investors that are “qualified institutional buyers”, as defined in Rule 144A under the Act, or institutions that are “accredited investors”, as defined in Regulation D under the Act, to determine whether such investors might have an interest in the Issuer’s contemplated initial public offering (“Testing-the-Waters Communications”). A “Written Testing-the-Waters Communication” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Act.

The Issuer represents that it is an “emerging growth company” as defined in Section 2(a)(19) of the Act (“Emerging Growth Company”) and agrees to promptly notify J.P. Morgan, Jefferies LLC and Cowen and Company, LLC in writing if the Issuer hereafter ceases to be an Emerging Growth Company while this authorization is in effect. If at any time following the distribution of any Written Testing-the-Waters Communication there occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Issuer will promptly notify J.P. Morgan, Jefferies LLC and Cowen and Company, LLC will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

Nothing in this authorization is intended to limit or otherwise affect the ability of J.P. Morgan and its affiliates and their respective employees, Jefferies LLC and its affiliates and their respective employees and Cowen and Company, LLC and its affiliates and their respective employees to engage in communications in which they could otherwise lawfully engage in the absence of this authorization, including, without limitation, any written communication containing only one or more of the statements specified under Rule 134(a) under the Act. This authorization shall remain in effect until the Issuer has provided to J.P. Morgan, Jefferies LLC and Cowen and Company, LLC a written notice revoking this authorization. All notices as described herein shall be sent by email to the attention of Mike Gaito at mike.gaito@jpmorgan.com, with copies to Katja Lange at katja.lange@jpmorgan.com, Kevin Sheridan at ksheridan@jefferies.com and Michael Brinkman at mbrinkman@jefferies.com and Mariel Healy at mhealy@cowen.com and Julianne Llanes at julianne.llanes@cowen.com.
[Form of Waiver of Lock-up]

J.P. MORGAN SECURITIES LLC
JEFFERIES LLC

Urovant Sciences Ltd.

Public Offering of Common Shares

Dear Mr./Ms. [Name]:

This letter is being delivered to you in connection with the offering by Urovant Sciences Ltd. (the “Company”) of ______ shares of common shares, $0.00001 par value (the “Common Shares”), of the Company and the lock-up letter dated ________, 20__ (the “Lock-up Letter”), executed by you in connection with such offering, and your request for a [waiver] [release] dated ________, 20__ , with respect to ________ shares of Common Shares (the “Shares”).

J.P. Morgan Securities LLC and Jefferies LLC hereby agree to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Shares, effective ________, 20__, provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Yours very truly,

[Signature of J.P. Morgan Securities LLC Representative]
[Name of J.P. Morgan Securities LLC Representative]

[Signature of Jefferies LLC Representative]
[Name of Jefferies LLC Representative]

cc: Company
Urovant Sciences Ltd. [Date]

Urovant Sciences Ltd. (“Company”) announced today that J.P. Morgan Securities LLC and Jefferies LLC, the lead book-running managers in the Company’s recent public sale of [common shares], are [waiving] [releasing] a lock-up restriction with respect to [common shares] of the Company held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on ______________, 20__, and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.
FORM OF LOCK-UP AGREEMENT

J.P. MORGAN SECURITIES LLC
JEFFERIES LLC

As Representatives of
the several Underwriters listed in
Schedule 1 to the Underwriting
Agreement referred to below

c/o J.P. Morgan Securities LLC
383 Madison Avenue
New York, NY 10179

Jefferies LLC
520 Madison Avenue
New York, NY 10022

Re:  Urovant Sciences Ltd. — Initial Public Offering

Ladies and Gentlemen:

The undersigned understands that you, as Representatives of the several Underwriters, propose to enter into an underwriting agreement (the “Underwriting Agreement”) with Urovant Sciences Ltd., a company incorporated and organized under the laws of Bermuda (the “Company”), providing for the public offering (the “Public Offering”) by the several Underwriters named in Schedule 1 to the Underwriting Agreement (the “Underwriters”), of the Company’s common shares, $0.00001 par value (the “Common Shares”). Capitalized terms used herein and not otherwise defined shall have the meanings set forth in the Underwriting Agreement.

Annex A sets forth definitions for capitalized terms used in this Letter Agreement (as defined below) that are not defined in the body of this Letter Agreement. Those definitions are part of this Letter Agreement.

In consideration of the Underwriters’ agreement to purchase and make the Public Offering of the Common Shares, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the undersigned hereby agrees that, without the prior written consent of J.P. Morgan Securities LLC and Jefferies LLC, the undersigned will not (and will use reasonable best efforts to cause any Family Member not to), during the period beginning on the date of this letter agreement (this “Letter Agreement”) and ending 180 days after the date of the prospectus relating to the Public Offering (the “Prospectus”) (such period, the “Restricted Period”), (1) 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 Common Shares or any securities convertible into or exercisable or exchangeable for Common Shares (including without limitation, Common Shares or such other securities which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a share option or warrant), or publicly disclose the intention to make any offer, sale, pledge or disposition, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Common Shares or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Shares or such other securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any shares of Common Shares or any security convertible into or exercisable or exchangeable for Common Shares or (4) publicly announce any intention to do any of the foregoing, in each case other than:

(i) transactions consisting of Common Shares or other securities acquired in open market transactions after the completion of the Public Offering, provided that no public disclosure or filing under Section 16(a) of the Exchange Act will be required or will be voluntarily made during the Restricted Period in connection with subsequent sales of Common Shares or other securities acquired in such open market transactions during the Restricted Period;

(ii) transfers of Common Shares or any security convertible into or exercisable or exchangeable for Common Shares as a bona fide gift or charitable contribution;

(iii) distributions of Common Shares or any security convertible into or exercisable or exchangeable for Common Shares to (a) limited partners, members, stockholders or holders of similar equity interests in the undersigned or (b) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate (as defined in Rule 405 promulgated under the Securities Act) of the undersigned, or to any investment fund or other entity controlled or managed by the undersigned or affiliates of the undersigned;

(iv) transfers of Common Shares or any security convertible into or exercisable or exchangeable for Common Shares by will or intestacy or to any Family Member or to a trust whose beneficiaries consist exclusively of one or more of the undersigned and/or a Family Member;

(v) transfers of Common Shares or any security convertible into or exercisable or exchangeable for Common Shares pursuant to a domestic order or negotiated divorce settlement;

(vi) the exercise of a stock option granted under a stock incentive plan described in the Prospectus by the undersigned, and the receipt by the undersigned from the Company of Common Shares upon such exercise, insofar as such option is outstanding as of the date of the Prospectus, provided that the underlying
Common Shares received as a result of such option exercise shall continue to be subject to the restrictions on transfer set forth in this Letter Agreement and provided, further that, if required, any public report or filing under Section 16 of the Exchange Act shall clearly indicate in the footnotes thereto that the filing relates to the exercise of a stock option, that no Common Shares were sold by the reporting person and that Common Shares received upon exercise of the stock option are subject to this Letter Agreement with the underwriters of the Public Offering;

(vii) the disposition of Common Shares to the Company, or the withholding of Common Shares by the Company, in a transaction exempt from Section 16(b) of the Exchange Act solely in connection with the payment of taxes due with respect to the vesting of restricted stock granted under a stock incentive plan or pursuant to a contractual employment arrangement described in the Prospectus, insofar as such restricted stock is outstanding as of the date of the Prospectus, provided that no public disclosure or filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the Restricted Period;

(viii) transfers to the Company in connection with the repurchase of Common Shares in connection with the termination of the undersigned’s employment with the Company pursuant to contractual agreements with the Company as in effect as of the date of the Prospectus, provided that no public disclosure or filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the Restricted Period;

(ix) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Common Shares, provided that (a) such plan does not provide for the transfer of Common Shares during the Restricted Period and (b) the entry into such plan is not publicly disclosed, including in any filings under the Exchange Act, during the Restricted Period; or

(x) pursuant to a bona fide third party tender offer for all outstanding Common Shares of the Company, merger, consolidation or other similar transaction approved by the Company’s Board of Directors and made to all holders of the Company’s securities involving a change of control of the Company (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of Common Shares or other such securities in connection with such transaction, or vote any Common Shares or other such securities in favor of any such transaction), provided that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such securities held by the undersigned shall remain subject to the provisions of this Letter Agreement;
provided however, in the case of any transfer or distribution pursuant to clause (ii), (iii), (iv) and (v), it shall be a condition to such transfer that:

- each donee, transferee or distributee executes and delivers to the Representatives an agreement in form and substance satisfactory to the Representatives stating that such donee, transferee or distributee is receiving and holding such Common Shares or any securities convertible into or exercisable or exchangeable for Common Shares subject to the provisions of this Letter Agreement and agrees not to (1) 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 Common Shares or any securities convertible into or exercisable or exchangeable for Common Shares (including without limitation, Common Shares or such other securities which may be deemed to be beneficially owned by such donee, transferee or distributee in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a share option or warrant), or publicly disclose the intention to make any offer, sale, pledge or disposition (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Common Shares or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Shares or such other securities, in cash or otherwise, (3) make any demand for, or exercise any right with respect to, the registration of any shares of Common Shares or any security convertible into or exercisable or exchangeable for Common Shares or (4) publicly announce any intention to do any of the foregoing, except in accordance with this Letter Agreement (as if such donee, transferee or distributee had been an original signatory hereto), and

- prior to the expiration of the Restricted Period, no public disclosure or filing under the Exchange Act by any party to the transfer (donor, donee, transferee, distributor or distributee) shall be required, or made voluntarily (other than any such disclosure required to be made by applicable law or regulation, including, without limitation, one or more filings on Form 4, Form 5, Schedule 13G or Schedule 13D, in each case, in accordance with applicable law and made after the expiration of the Restricted Period).

If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any Company-directed Common Shares the undersigned may purchase in the Public Offering.

If the undersigned is an officer or director of the Company, (i) J.P. Morgan Securities LLC and Jefferies LLC agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Shares, J.P. Morgan Securities LLC and Jefferies LLC will notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by J.P. Morgan Securities LLC and Jefferies LLC hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this letter to the extent and for the duration that such terms remain in effect at the time of the transfer.
In furtherance of the foregoing, the Company, and any duly appointed transfer agent for the registration or transfer of the securities described herein, are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this Letter Agreement.

The undersigned hereby waives any and all notice requirements and rights with respect to the registration of Common Shares pursuant to any agreement, understanding or anything otherwise setting forth the terms of any security of the Company held by the undersigned, including any registration rights agreement to which the undersigned and the Company may be party; provided that such waiver shall apply only to the proposed Public Offering, and any other action taken by the Company in connection with the proposed Public Offering.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Letter Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

The undersigned understands that, if (i) the Company notifies the Representatives in writing prior to the execution of the Underwriting Agreement that it does not intend to proceed with the Public Offering, (ii) the Underwriting Agreement does not become effective by October 31, 2018, or (iii) if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Shares to be sold thereunder, this Letter Agreement shall automatically, and without any action on the part of any other party, terminate and be of no further force and effect, and the undersigned shall be released from all obligations under this Letter Agreement. The undersigned understands that the Underwriters are entering into the Underwriting Agreement and proceeding with the Public Offering in reliance upon this Letter Agreement.
This Letter Agreement and any claim, controversy or dispute arising under or related to this Letter Agreement shall be governed by and construed in accordance with the laws of the State of New York.

Very Truly Yours,

[insert officer, director or shareholder]

By:
Name:
Title:
For purposes of this Letter Agreement to which this Annex A is attached and of which it is made a part:


“Family Member” shall mean the spouse of the undersigned, an immediate family member of the undersigned or an immediate family member of the undersigned’s spouse, in each case living in the undersigned’s household or whose principal residence is the undersigned’s household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or otherwise). “Immediate family member” as used above shall have the meaning set forth in Rule 16a-1(e) under the Exchange Act.

“Securities Act” shall mean the Securities Act of 1933, as amended.

Capitalized terms not defined in this Annex A shall have the meanings given to them in the body of this lock-up agreement.
LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the “Agreement”) is entered into as of August 24, 2018 (the “Effective Date”), by and between ION CHANNEL INNOVATIONS, LLC, a limited liability company organized under the laws of the State of New York and having an address of 23 Agnes Circle, Ardsley, NY 10502, U.S. (“Licensor”), and UROVANT SCIENCES, GMBH, a company organized under the laws of Switzerland and having an address of Viaduktstrasse 8, 4051 Basel, Switzerland (“Licensee”). Licensor and Licensee may be referred to herein individually as a “Party” or collectively as the “Parties”.

RECITALS

WHEREAS, Licensor is an early stage biotechnology company dedicated to improving the quality of life of millions of people with specific smooth muscle based urologic disorders through treatment with its plasmid-based gene therapy, and Licensor owns or controls certain patents, know-how and data relating to such gene therapy; and

WHEREAS, Licensee desires to obtain from Licensor, and Licensor desires to grant to Licensee, an exclusive worldwide license to develop, manufacture and commercialize Licensor’s gene therapy product, all subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Licensor and Licensee hereby agree as follows:

ARTICLE 1
DEFINITIONS

“Accounting Standards” shall mean internationally recognized accounting principles (including IFRS, US GAAP, and the like), in each case, as generally and consistently applied by the applicable Selling Entity.

“Affiliate” means:

(i) with respect to the Licensee, any entity or any other person that controls, is controlled by, or is under common control with, the Licensee, but excluding Roivant Sciences Ltd., a company organized under the laws of Bermuda (“Roivant”), and any entity or any other person controlled by, or under common control with, Roivant other than through the intermediary of Urovant Sciences Ltd.,

(ii) with respect to Licensor, any entity or other person that controls, is controlled by, or is under common control with, Licensor; and

(iii) with respect to any Third Party, any entity or other person that controls, is controlled by, or is under common control with, such Third Party.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
“Applicable Laws” means the applicable provisions of any and all national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, permits (including MAAs) of or from any court, arbitrator, Regulatory Authority or Governmental Authority having jurisdiction over or related to the subject item.

“Auditor” has the meaning set forth in Section 7.9 (Audit Dispute).

“Business Day” means a day other than a Saturday, Sunday or a bank or other public holiday in Basel, Switzerland; or New York, New York.

“Calendar Year” means each respective period of twelve (12) consecutive months ending on December 31.

“cGMP” means the then-current standards for Good Manufacturing Practices, as defined in FDA rules and regulations or as defined in another Regulatory Authority’s rules and regulations, that apply to the manufacture of Gene Therapy or Licensed Product, including (a) the United States regulations set forth in Title 21 of the United States Code of Federal Regulations Parts 11, and 820 and the corresponding regulation of any other applicable Regulatory Authority, (b) the International Organization for Standardization (ISO) 13485, and (c) all additional Regulatory Authority documents that correspond to, replace, amend, modify, supplant, or complement any of the foregoing.

“Claims” means all Third Party demands, claims, suits, actions, investigations proceedings and liabilities (whether criminal or civil, in contract, tort or otherwise) for losses, damages, fees, costs (including reasonable attorneys’ fees), and other expenses of any nature.

“CMC” means chemistry, manufacturing, and controls.

“CMO” means a Third Party contract manufacturing organization.

“Combination Product” means any Licensed Product comprising a Gene Therapy and at least one other active compound or ingredient, that is formulated together (i.e., a fixed dose combination), mixed together or packaged together and sold for a single price.

“Commercialization” means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering Licensed Products to customers) of Licensed Products in or outside of the Territory, including: (a) sales force efforts, detailing, advertising, medical education, planning, marketing, sales force training, and sales and distribution; and (b) scientific and medical affairs. For clarity, Commercialization does not include any Development activities, whether conducted before or after Regulatory Approval. “Commercialize”, “Commercialized”, and “Commercializing” have correlative meanings.

“Commercially Reasonable Efforts” means, with respect to a Party’s obligations under this Agreement relating to Gene Therapies and Licensed Products, those efforts and resources that

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are consistent with the exercise of customary scientific and business practices, as applied by such Party for development, regulatory, manufacturing and commercialization activities conducted with respect to products at a similar stage of development or commercialization and having similar commercial potential, taking into [***]. The Parties hereby agree that the level of effort may be different for different markets and may change over time, reflecting changes in the status of the aforementioned attributes and potential of the Licensed Product(s).

“Confidential Information” of a Party means all Know-How, materials, and other proprietary scientific, marketing, financial, or commercial information that is: (a) disclosed by or on behalf of such Party or any of its Affiliates or otherwise made available to the other Party or any of its Affiliates, whether made available orally, in writing, or in electronic form; or (b) learned by the other Party pursuant to this Agreement. The existence and terms of this Agreement are the Confidential Information of both Parties. All information disclosed by Licensor under the Confidentiality Agreement that relates to any Gene Therapy or Licensed Product or the transaction under this Agreement is deemed the Confidential Information of Licensor under this Agreement, and all information disclosed by Roivant Sciences, Inc. under the Confidentiality Agreement that relates to any Gene Therapy or Licensed Product or the transaction under this Agreement is deemed the Confidential Information of Licensee under this Agreement. Notwithstanding the foregoing to the contrary, during the Term, Licensor Know-How that is solely related to a Gene Therapy or a Licensed Product will be deemed to be the Confidential Know-How of Licensee.

“Confidentiality Agreement” means mutual nondisclosure agreement that is between Licensor and Roivant Sciences, Inc. and that is dated August 12, 2018.

“Consulting Agreement” means the consulting agreement that is between Urovant Sciences, Inc. and Dr. Arnold Melman and that is dated as of August 24, 2018.

“Control” or “Controlled” means, with respect to any Know-How, materials, Patents or other intellectual property rights, the legal authority or right (whether by ownership, license or otherwise but without taking into account any rights granted by one Party to the other Party pursuant to this Agreement) of a Party to grant access, a license or a sublicense of or under such Know-How, materials, Patents or other intellectual property rights to the other Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

“Cover” means, with respect to a claim of a Patent related to a Gene Therapy or Licensed Product, that such claim would be infringed, absent a license, by the manufacture, use, offer for sale, sale or importation of such Gene Therapy or Licensed Product (considering claims of patent applications to be issued as then pending). “Covered” has a correlative meaning.

“Data” means any and all scientific, technical and test data pertaining to the Gene Therapies or Licensed Products, including research data, clinical pharmacology data, CMC data (including analytical and quality control data and stability data), pre-clinical data, clinical data or submissions made in association with an IND or MAA with respect to any Gene Therapy or Licensed Product, in each case that is Controlled by a Party.

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“Develop” means to develop (including clinical, non-clinical and CMC development), analyze, test and conduct preclinical, clinical and all other regulatory trials for a Gene Therapy or a Licensed Product, including all post-approval clinical trials, as well as all related regulatory activities and any and all activities pertaining to new Indications, pharmacokinetic studies and all related activities including work on new formulations, new methods of treatment and CMC activities including new manufacturing methods. “Developing” and “Development” have correlative meanings.

“Disclosing Party” has the meaning set forth in Section 11.1(a) (Duty of Confidence).

“Dollar” means United States dollars and “$” shall be interpreted accordingly.

“EMA” means the European Medicines Agency or any successor agency thereto.

“European Union” or “EU” means the economic, scientific and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto.

“Excluded Claim” has the meaning set forth in Section 13.9(g) (Dispute Resolution).

“FDA” means the U.S. Food and Drug Administration or any successor agency thereto.

“Field” means the treatment, prevention and diagnosis of any and all human and animal diseases, disorders and conditions.

“First Commercial Sale” means, on a Licensed Product-by-Licensed Product and country-by-country basis, the first sale by or on behalf of Licensee or any of its Affiliates to a Third Party for end use or consumption of a Licensed Product that is Covered by a Valid Claim of a Licensor Patent in a given country in the Territory after Regulatory Approval has been granted with respect to such Licensed Product in such country. A First Commercial Sale will not include any Licensed Product: (a) supplied for use in clinical trials, for research or for other non-commercial uses, or as part of a compassionate use program (or other program for providing Licensed Product before it has received Regulatory Approval in a country); or (b) not Covered by a Valid Claim of a Licensor Patent in a given country in the Territory after Regulatory Approval has been granted with respect to such Licensed Product in such country.

“Fiscal Quarter” means each of the following three (3)-month periods during each Fiscal Year: January 1 through March 31; April 1 through June 30; July 1 through September 30; and October 1 through December 31; provided, that the first Fiscal Quarter shall commence on the Effective Date and end on September 30, 2018.

“Fiscal Year” means the period from April 1 of a Calendar Year through March 31 of the following Calendar Year.

“Gene Therapy” means: (a) any gene therapy that: (i) has as a primary mechanism of action the expression of the Target; or (ii) is Covered by any Licensor Patent or disclosed in any

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expired Patent that was owned by the Licensor and that relates to the Target; and (b) all preparations, formulations and compositions of such gene therapy.

“Governmental Authority” means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

“IND” means any investigational new drug application, clinical trial application, clinical trial exemption or similar or equivalent application or submission for approval to conduct human clinical investigation filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

“Indemnified Party” has the meaning set forth in Section 10.3 (Indemnification Procedure).

“Indemnifying Party” has the meaning set forth in Section 10.3 (Indemnification Procedure).

“Indication” means a separate and distinct disease, disorder, illness or health condition for which a separate Regulatory Approval may be filed.

“Initiation” means, with respect to a clinical trial, the enrollment of the first patient in such clinical trial.

“Invention” means any process, method, composition, composition of matter, article of manufacture, discovery or finding, patentable or otherwise, that is made, generated, conceived or otherwise invented as a result of a Party exercising its rights or carrying out its obligations under this Agreement, whether directly or via its Affiliates, agents or independent contractors, including all rights, title and interest in and to the intellectual property rights therein.

“JAMS Rules” has the meaning set forth in Section 13.9(b) (Dispute Resolution).

“Joint Inventions” has the meaning set forth in Section 8.1(b) (Ownership of Inventions).

“Joint Patents” has the meaning set forth in Section 8.1(b) (Ownership of Inventions).

“Know-How” means any information, including discoveries, improvements, modifications, processes, methods, techniques, protocols, formulas, Data, inventions, know-how, trade secrets and results, patentable or otherwise, including physical, chemical, biological, toxicological, pharmacological, safety, and pre-clinical and clinical data, dosage regimens, control assays, and product specifications, but excluding any Patents.

“Knowledge” means, when used in connection with Licensor or Licensee, with respect to any matter in question, the actual knowledge of, in the case of Licensor, the Chief Commercial Officer of Urovant Sciences, Inc., and in the case of Licensee, Licensee’s founders, employees, officers or members, in each case, following reasonable inquiry as to such matter.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
“Licensed Product” means any product containing a Gene Therapy as an active ingredient, alone or in combination with one or more other molecules or agents in any dosage form or formulation.

“Licensee Data” has the meaning set forth in Section 8.1(a) (Data).

“Licensee Indemnitee” has the meaning set forth in Section 10.1 (Indemnification by Licensor).

“Licensee Patents” means all Patents that: (a) Licensee or its Affiliates Control as of the Effective Date or during the Term; and (b) that are necessary or reasonably useful for the Development, manufacture or Commercialization of any Gene Therapy or Licensed Product in the Field in the Territory, excluding the Licensor Patents and the Joint Patents.

“Licensor Indemnitee” has the meaning set forth in Section 10.2 (Indemnification by Licensee).

“Licensor Know-How” means all Know-How that: (a) Licensor or its Affiliates Control as of the Effective Date or during the Term; and (b) is necessary or reasonably useful for the Development, manufacture or Commercialization of any Licensed Product or any gene therapy having as a primary mechanism of action the expression of the Target (including the Gene Therapy) in the Field in the Territory, including Licensor’s Sole Inventions and Licensor’s interest in Joint Inventions.

“Licensor Manufacturing Know-How” has the meaning set forth in Section 5.3(a) (Manufacturing Technology Transfer).

“Licensor Patents” means all Patents in the Territory that: (a) Licensor or its Affiliates Control as of the Effective Date or during the Term; and (b) are necessary or reasonably useful for the Development, manufacture or Commercialization of any Licensed Product or any gene therapy having as a primary mechanism of action the expression of the Target (including the Gene Therapy) in the Field in the Territory; (y) any Patents covering modifications, combinations, technological advances or improvements developed or acquired by Licensor during the Term; and (z) any Patents prepared or filed by Licensee that claim Licensor Know-How after the Effective Date. The Licensor Patents existing as of the Effective Date are listed on Exhibit A.

“Licensor Technology” means the Licensor Know-How and the Licensor Patents.

“MAA” means an application to the appropriate Regulatory Authority for approval to market for commercial sale a Licensed Product (but excluding Pricing Approval) in any particular country, including: (a) a new drug application submitted to the FDA pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b) (an “NDA”); (b) a biologics license application submitted to the FDA pursuant to the Public Health Service Act, 42 U.S.C. § 262 (a “BLA”), or (c) an application for authorization to market and/or sell a drug product submitted to a Regulatory Authority in a country other than the U.S., in each case ((a), (b) or (c)), including all amendments and supplements thereto.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
“Major Market” means each of the United States, the United Kingdom, France, Germany, Italy, Spain, and Japan.

“Manufacturing Transfer Period” has the meaning set forth in Section 5.3(a) (Manufacturing Technology Transfer).

“Net Sales” means the gross amount received, for the sale of a Licensed Product during the applicable Royalty Term, by a Selling Entity to a Third Party after deducting, if not previously deducted, from the amount received: [***].

“Patents” means: (a) all patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications; (b) any renewals, divisions, continuations continued prosecution applications, continuations-in-part, or requests for continued examination of any of such patents, certificates of invention and patent applications, any and all patents or certificates of invention issuing thereon, and any and all reissuances, reexaminations, divisions, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing; and (c) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

“Phase 3 Clinical Trial” means a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or any amended or successor regulations) or any equivalent regulations in other countries in the Territory, regardless of where such clinical trial is conducted.

“PMDA” means Japan’s Pharmaceuticals and Medical Devices Agency or any successor entity thereto.

“Pricing Approval” means such governmental approval, agreement, determination or decision establishing prices for a Licensed Product that can be charged or reimbursed in a regulatory jurisdiction where the applicable Governmental Authorities approve or determine the price or reimbursement of pharmaceutical products and where such approval or determination is reasonably necessary for the commercial sale of such Licensed Product in such jurisdiction.

“Product Infringement” has the meaning set forth in Section 8.4(a) (Notice).

“Public Official or Entity” means any: (a) officer or employee of a Governmental Authority or of a public international organization, or any person acting in an official capacity for or on behalf of such person; (b) officer, employee or person acting in an official capacity on behalf of a political party; (c) candidate for political office; (d) officer or employee of a government-owned or government-controlled entity or company, including public stock companies in which the majority shareholders are government-owned or government-controlled entities or companies, regardless of the officer’s or employee’s rank or title; (e) uncompensated honorary officials who have influence in the award of business; (f) members of royal families; (g) any entity hired to review or accept bids for a Government Authority; (h) officials, whether elected, appointed or under a contract, permanent or temporary, who hold a legislative, administrative, or judicial position of any kind in a country or territory; (i) person who performs public functions in any

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branch of the national, local, or municipal governments of a country or territory or who exercises a public function for any public agency or public enterprise of such country or territory; (j) executive, officer, agent or employee acting in a business (even if privately owned) providing a service to the general public; or (k) immediate family members of any of the persons listed above. An immediate family member is a parent, spouse, significant other, child, or sibling.

“Receiving Party” has the meaning set forth in Section 11.1(a) (Duty of Confidence).

“Regulatory Approval” means all approvals, including Pricing Approvals and MAAs, that are necessary for the commercial sale of a Licensed Product in a given country or regulatory jurisdiction.

“Regulatory Authority” means any applicable Governmental Authority responsible for granting Regulatory Approvals for Licensed Product, including the FDA, the EMA, the PMDA, and any corresponding national or regional regulatory authorities.

“Regulatory Documentation” means all applications, filings, submissions, approvals, licenses, registrations, permits, notifications and authorizations (or waivers), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), all reports and documentation in connection with studies and tests (including study reports and study protocols, and copies of all interim study analysis), and all Data contained in any of the foregoing, with respect to the testing, Development, manufacture or Commercialization of any Licensed Product, including any IND, NDA, MAA, Regulatory Approval, manufacturing data and drug master files.

“Regulatory Exclusivity” means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a pharmaceutical product other than a Patent, including orphan drug exclusivity, new chemical entity exclusivity, biologics exclusivity, new clinical data exclusivity, pediatric exclusivity, or rights similar thereto in other countries or regulatory jurisdictions.

“Remedial Action” has the meaning set forth in Section 4.4 (Remedial Actions).

“Royalty Term” has the meaning set forth in Section 7.3(b) (Royalty Term).

“SEC” has the meaning set forth in Section 11.7(a) (Disclosure to the SEC).

“Selling Entity” means Licensee, its Affiliates and Sublicensees.

“Sole Inventions” has the meaning set forth in Section 8.1(b) (Ownership of Inventions).

“Sublicense” means a license or sublicense to Develop, make, use, import, promote, offer for sale or sell any Gene Therapy or any Licensed Product.

“Sublicensee” means a Third Party to whom Licensee or its Affiliates has granted a Sublicense in accordance with the terms of this Agreement.

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“Target” means the voltage-gated potassium channels (for any species and either as a peptide or full protein) known as Maxi-K channels or BK channels. Maxi-K channels or BK channels are encoded by the KCNMA1 gene, also known as, for example, slo1, Kca1.1, SLO, hSlo, BKCA Alpha Subunit, BKTM, or PKNKD3.

“Tax” or “Taxes” means any (a) all federal, provincial, territorial, state, municipal, local, foreign or other taxes, imposts, rates, levies, assessments and other charges in the nature of a tax (and all interest and penalties thereon and additions thereto imposed by any Governmental Authority), including all income, excise, franchise, gains, capital, real property, goods and services, transfer, value added, gross receipts, windfall profits, severance, ad valorem, personal property, production, sales, use, license, stamp, documentary stamp, mortgage recording, employment, payroll, social security, unemployment, disability, escheat, estimated or withholding taxes, and all customs and import duties, together with all interest, penalties and additions thereto imposed with respect to such amounts, in each case whether disputed or not; (b) any liability for the payment of any amounts of the type described in clause (a) as a result of being or having been a member of an affiliated, consolidated, combined or unitary group; and (c) any liability for the payment of any amounts as a result of being party to any tax sharing agreement or arrangement or as a result of any express or implied obligation to indemnify any other person with respect to the payment of any amounts of the type described in clause (a) or (b).

“Term” has the meaning set forth in Section 12.1 (Term).

“Territory” means worldwide.

“Third Party” means any entity other than Licensor or Licensee or an Affiliate of Licensor or Licensee.

“Transfer Plan” has the meaning set forth in Section 2.3 (Initial Transfer of Know-How and Materials).

“Transfer Tax” has the meaning set forth in Section 7.7(c) (Transfer Tax).

“United States” or “U.S.” means the United States of America, including its territories and possessions.

“Valid Claim” means a claim of an issued and unexpired Patent that has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is not appealable or has not been appealed within the time allowed for appeal, and that has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

ARTICLE 2
LICENSE GRANTS

2.1 Licenses to Licensee. Licensor hereby grants to Licensee an exclusive (even as to Licensor), royalty-bearing license, with the right to grant Sublicenses including through multiple tiers in accordance with Section 2.2 (Sublicense Rights), under the Licensor Technology to research, Develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise Commercialize Licensed Products in the Field in the Territory.

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2.2 Sublicense Rights. Licensee may grant Sublicenses of the licenses granted in Section 2.1 (Licenses to Licensee) through multiple tiers to Affiliates of Licensee or to any Third Parties without the prior written consent of Licensor. Each Sublicense granted hereunder, if any, whether to an Affiliate or Sublicensee, shall be in writing and shall incorporate terms and conditions sufficient to enable Licensee to comply with this Agreement. Licensee shall notify Licensor in writing promptly after entering into each sublicense of the licenses granted in Section 2.1 (Licenses to Licensee).

2.3 Initial Transfer of Know-How and Materials. Within thirty (30) days after the Effective Date, the Parties shall agree on a plan for the transfer of Licensor Know-How (including the Data therein) and certain tangible materials that are Controlled by Licensor as of the Effective Date to Licensee (including all inventory of Licensed Product (e.g., approximately 385 vials of Gene Therapy) and related samples (e.g., vials of sucrose), in each case that exist as of the Effective Date, “Existing Inventory”), which plan shall be incorporated by reference herein (the “Transfer Plan”). As soon as practical and pursuant to the Transfer Plan, Licensor shall commence disclosing and making available to Licensee the Licensor Know-How and materials listed in the Transfer Plan, according to the timeline set forth in the Transfer Plan, and Licensor shall complete such transfer no later than [***] after the effective date of the Transfer Plan, except that Licensee may take possession of the Existing Inventory at Licensee’s discretion prior to the establishment of the Transfer Plan. The Parties shall cooperate with each other in good faith to enable a smooth transfer of the Licensor Know-How to Licensee. Upon Licensee’s reasonable request, Licensor shall provide reasonable technical assistance (including making appropriate employees available to Licensee at reasonable times, places, and frequency and facilitating Licensee’s contact to the respective research laboratories, CMOs and CROs), and upon reasonable prior notice, for the purpose of assisting Licensee to understand and use the Licensor Know-How in connection with Licensee’s Development of Licensed Products. If (a) one or both Parties become aware of Licensor Know-How that was Controlled by Licensor as of the Effective Date but was not transferred to Licensee; or (b) one or both Parties become aware of Licensor Know-How that first came within the Control of Licensor after the Effective Date; then, in each case of (a) and (b), Licensor shall promptly upon identifying any such Licensor Know-How disclose and transfer such Licensor Know-How to Licensee, and Licensor shall provide reasonable technical assistance, including making appropriate employees available to Licensee at reasonable times, places, and frequency, and upon reasonable prior notice, for the purpose of assisting Licensee to understand and use such Licensor Know-How in connection with Licensee’s Development of Licensed Products.

2.4 Provisions for Insolvency.

(a) Section 365(n) of the Bankruptcy Code. The licenses granted pursuant to Sections 2.1 (Licenses to Licensee) are, for all purposes of Section 365(n) of Title 11 of the United States Code, as amended (the “Bankruptcy Code”), licenses of rights to “intellectual property” as defined in the Bankruptcy Code. Upon the occurrence of any Insolvency Event with respect to Licensor, the Parties agree that Licensee, as licensee of such licenses under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code with respect

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to such licenses. Without limiting the generality of the foregoing, Licensor and Licensee intend and agree that any sale of Licensor’s assets under Section 363 of the Bankruptcy Code shall be subject to Licensee’s rights under Section 365(n) of the Bankruptcy Code, that Licensee cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser “free and clear” of Licensee’s rights under this Agreement and Section 365(n) of the Bankruptcy Code without the express, contemporaneous consent of Licensee. Further, each Party agrees and acknowledges that all payments by Licensee to Licensor hereunder, other than the royalty payments pursuant to Section 7.3 (Royalty Payments), do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. The Licensor shall, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all intellectual property licensed pursuant to this Agreement. The Licensor and Licensee acknowledge and agree that “embodiments” of intellectual property within the meaning of Section 365(n) include laboratory notebooks, cell lines, vectors, reagents, assays, product samples and inventory, research studies and data, Regulatory Documentation and Regulatory Approvals. If (i) a case under the Bankruptcy Code is commenced by or against a Licensor, (ii) this Agreement is rejected as provided in the Bankruptcy Code, and (iii) the Licensee elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, Licensor (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall:

(i) provide to the Licensee all such intellectual property (including all embodiments thereof) held by Licensor and such successors and assigns, or otherwise available to them, immediately upon the Licensee’s written request. Whenever Licensor or any of its successors or assigns provides to the Licensee any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 2.4 (Provisions for Insolvency), the Licensee shall have the right to perform Licensor’s obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by the Licensee shall release Licensor from liability resulting from rejection of the license or the failure to perform such obligations; and

(ii) not interfere with the Licensee’s rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Bankruptcy Code.

(b) Cumulative Remedies. All rights, powers and remedies of the Licensee provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to Licensor. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n):

(i) the right of access to any intellectual property (including all embodiments thereof) of Licensor, or any Third Party with whom Licensor contracts to perform an obligation of Licensor under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import or export of Licensed Products; and

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(ii) the right to contract directly with any Third Party to complete the contracted work.

2.5 Exclusivity. During the Term and for [***] thereafter, Licensor shall not conduct, itself or through an Affiliate or Third Party, and shall not enable a Third Party to conduct, any pre-clinical or clinical development, manufacture, promotion, or commercialization of any gene therapy, biologic, compound or other therapeutic, regardless of modality, that has as a primary mechanism of action of either the: (a) expression of the Target; or (b) the direct or indirect inhibition or other direct or indirect modulation of the Target. Each Party recognizes that the restrictions contained in this Section 2.5 (Exclusivity) are properly required for the adequate protection of the Parties’ rights hereunder, and agree that if any provision in this Section 2.5 (Exclusivity) is determined by any court to be unenforceable by reason of its extending for too great a period of time or over too great a geographic area, or by reason of its being too extensive in any other respect, such restrictions shall be interpreted to extend only for the longest period of time and over the greatest geographic area, and to otherwise have the broadest application as shall be enforceable.

ARTICLE 3
DEVELOPMENT

3.1 General. Licensee shall be solely responsible for the Development of Gene Therapies and Licensed Products in the Field in the Territory, including the performance of preclinical and clinical studies of any Gene Therapy or Licensed Product in the Field and, subject to Section 5.2, the manufacture and supply of Gene Therapies and Licensed Products for use in such Development work. Licensee shall provide Licensor with periodic updates of its pre-clinical and clinical Development plans, progress, and results for Gene Therapies and Licensed Products. As between the Parties, Licensee shall be solely responsible for the cost for the Development of Gene Therapies and Licensed Products in the Field in the Territory.

3.2 Development Diligence. Licensee, directly or indirectly through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to Develop and to seek Regulatory Approval for at least one Licensed Product in the Field according to a development plan prepared by Licensee in its sole discretion within [***] after the Effective Date, and updated thereafter by Licensee in its sole discretion on an annual basis as reasonably necessary in connection with the Development and Regulatory Approval of the Licensed Product (“Development Plan”).

3.3 Development Records. Licensee shall use Commercially Reasonable Efforts to maintain reasonably complete, current and accurate records of all Development activities conducted by or on behalf of Licensee, its Affiliates and Sublicensees for any Gene Therapy and Licensed Product in the Field, and all data and other information resulting from such activities. Such records shall properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes.

3.4 Compliance. Licensee agrees that, in performing its obligations under this Agreement, (a) it shall comply with all Applicable Laws, and (b) it shall not employ or engage any person who has been debarred or disqualified by any Regulatory Authority, or, to its Knowledge, is the subject of debarment or disqualification proceedings by a Regulatory Authority.

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3.5 Subcontractor. Licensee may engage subcontractors for the performance of its obligations under the Agreement and shall cause the subcontractors engaged by it to be bound by written obligations of confidentiality and non-use of Licensor’s Confidential Information and invention assignment consistent with those contained herein, and Licensee shall remain primarily responsible for the performance of such subcontractors.

ARTICLE 4
REGULATORY

4.1 Regulatory Responsibilities. Licensee shall be responsible for all regulatory activities necessary to obtain and maintain Regulatory Approval of Gene Therapies and Licensed Products in the Field in the Territory. Licensee shall keep Licensor informed of material regulatory developments related to Gene Therapies and Licensed Products in the Field in the Territory.

4.2 Regulatory Documentation. Promptly following the Effective Date (but in no event later than ten (10) days thereafter), Licensor shall and hereby does assign to Licensee all Regulatory Documentation and Regulatory Approvals related to any Gene Therapy or Licensed Product, and Licensor shall promptly take all actions reasonably requested by Licensee to effect and evidence such assignment. Licensee shall prepare and submit all Regulatory Documentation for Gene Therapies and Licensed Products in the Field in the Territory and shall own all Regulatory Documentation for Gene Therapies and Licensed Products in the Field in the Territory. Upon reasonable advance request by Licensee, Licensor shall provide Licensee with, or provide Licensee access to, all raw data underlying or referenced in, any Regulatory Documentation, to the extent not provided as part of the transfer contemplated under Section 2.3 (Initial Transfer of Know-How and Materials); provided, however, that if Licensor is not able under Applicable Laws to provide access to Licensee to such raw data, and if such data is required or requested by any Regulatory Authority, Licensor shall provide such raw data directly to such Regulatory Authority on Licensee’s behalf upon request of Licensee.

4.3 Rights of Reference. Licensor hereby grants Licensee the right to use and reference all Regulatory Documentation (including data contained therein) and Regulatory Approvals for the Gene Therapies and Licensed Products or the platform used to develop the Gene Therapies submitted by or on behalf of Licensor, its Affiliates, or sublicensees.

4.4 Remedial Actions. Each Party shall notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that a Licensed Product may be subject to any recall, corrective action, or other regulatory action with respect to the Licensed Product taken by virtue of Applicable Laws (a "Remedial Action"). The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action.

ARTICLE 5
MANUFACTURING

5.1 Manufacturing Responsibilities. Licensee shall be solely responsible for all preclinical, clinical, and commercial manufacture and supply of Gene Therapies and Licensed Products.
5.2 Manufacturing Technology Transfer. In order to enable Licensee or its CMO to manufacture Gene Therapies and Licensed Products, Licensor shall perform or facilitate technology transfer to Licensee or its CMO as set forth below:

(a) During a mutually agreed time period of at least **[***]** (the “Manufacturing Transfer Period”), Licensor shall make available and transfer to Licensee, at Licensor’s sole cost, copies of the Licensor Know-How and any tangible materials that are necessary or useful in the manufacture of Gene Therapies or Licensed Products and as of such date are being used by Licensor to manufacture Gene Therapies and Licensed Products (the “Licensor Manufacturing Know-How”) solely for Licensee or its CMO to manufacture or have manufactured Gene Therapies or Licensed Products in accordance with the terms and conditions of this Agreement.

(b) During the Manufacturing Transfer Period, upon Licensee’s request and at Licensor’s sole cost, Licensor shall make available to Licensee, its Affiliates or contract manufacturers a reasonable number of appropriately trained personnel to provide, on a mutually convenient timetable, technical assistance (both on site and otherwise) in the transfer and demonstration of the Licensor Manufacturing Know-How that is necessary to manufacture Gene Therapies and Licensed Products. After the Manufacturing Transfer Period, if requested by Licensee, Licensor shall use reasonable efforts to provide additional technical assistance in the transfer of Licensor Manufacturing Know-How to Licensee.

ARTICLE 6
COMMERCIALIZATION

6.1 General. Licensee shall be responsible for all aspects of the Commercialization of the Licensed Products in the Field in the Territory, including:
(a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of the Licensed Products and obtaining and maintaining Pricing Approvals; (c) marketing, medical affairs, and promotion; (d) formulary access arrangements, including agreements with third party payers and pharmacy benefit managers; (e) advertising and promotional material and activities (f) storage, warehousing and distribution activities and any permits required in connection therewith; (g) booking sales and distribution and performance of related services; (h) handling all aspects of order processing, invoicing and collection, inventory and receivables; (i) providing customer support, including handling medical queries, and performing other related functions; and (j) conforming its practices and procedures to Applicable Law relating to the marketing, detailing and promotion of Licensed Products in the Field in the Territory. As between the Parties, Licensee shall be solely responsible for the costs and expenses of Commercialization of the Licensed Products in the Field in the Territory.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
ARTICLE 7
FINANCIAL PROVISIONS

7.1 Upfront Payment. Licensee shall make a one-time, upfront payment of Two Hundred Fifty Thousand Dollars ($250,000) to Licensor within [***] after receipt of: (a) an invoice issued by Licensor on or promptly after the Effective Date; and (b) notarized signatures of the patent assignment documents between Licensor and the inventors of the Licensor Patents.

7.2 Milestone Payments.

(a) Development and Regulatory Milestone Payments.

(i) Within [***] after the first achievement of each milestone event below by or on behalf of Licensee or any of its Affiliates or Sublicensees, Licensee shall notify Licensor of the achievement of such milestone event. Licensor shall invoice Licensee for the applicable milestone payment corresponding to such milestone event as shown below. Licensee shall remit payment to Licensor within [***] of the receipt of such invoice. For clarity, if a milestone event described in [***] is achieved by or on behalf of Licensee or any of its Affiliates or Sublicensees, then Licensee’s failure to notify Licensor of such achievement would not remove Licensee’s obligation to make the applicable milestone payment.

<table>
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<th>Milestone Event</th>
<th>Milestone Payments (in Dollars)</th>
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(ii) [***]. The maximum amount payable by Licensee under Section 7.2(a)(i) (Development and Regulatory Milestone Payments) is Thirty-Five Million Dollars ($35,000,000).

(b) Sales Milestone Payments.

(i) Subject to Section 7.2(b)(ii) (Sales Milestone Payments), within [***] after the end of the first Fiscal Year in which annual Net Sales of all Licensed Products in the Field in the Territory first reach any threshold indicated in the milestone events listed below, Licensee shall notify Licensor of the achievement of such milestone event. Licensor shall invoice Licensee for the corresponding milestone payment set forth below. Licensee shall remit payment to Licensor within [***] of the receipt of such invoice.

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<tr>
<th>Annual Net Sales Milestone Events</th>
<th>Milestone Payments (in Dollars)</th>
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(ii) [***]. The maximum amount payable by Licensee under Section 7.2(b)(i) (Sales Milestone Payments) is Sixty-Million Dollars ($60,000,000).

7.3 Royalty Payments.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
(a) **Royalty Rate.** Subject to the terms and conditions of this Agreement, Licensee shall make royalty payments to Licensor on the Net Sales of Licensed Products sold in the Territory during the applicable Royalty Term, as calculated by multiplying the applicable royalty rate set forth below by the corresponding amount of Net Sales of all Licensed Products sold in the Territory in the applicable Fiscal Year.

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<tr>
<th>Net Sales of Licensed Products in the Territory</th>
<th>Royalty Rate</th>
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(b) **Royalty Term.** Royalties shall be paid on a Licensed Product-by-Licensed Product and country-by-country basis from the First Commercial Sale of such Licensed Product in such country in the Territory until the expiration of the last-to-expire Valid Claim of the Licensor Patents that Cover the manufacture, use, or sale of such Licensed Product (or the Gene Therapy therein) in such country in the Territory (the “**Royalty Term**” for such Licensed Product and country). Notwithstanding anything to the contrary in this Agreement, no royalty will be owed on the Net Sales of a Licensed Product that is not Covered by a Valid Claim of a Licensor Patent in a given country in the Territory where such Net Sales occurred.

(c) **Royalty Adjustment.** Royalties due pursuant to this Section 7.3 (**Royalty Payments**) are subject to adjustment on a country-by-country, Licensed Product-by-Licensed Product, and Fiscal Quarter-by-Fiscal Quarter basis as a result of the events set forth below (such adjustments to be prorated for the then-current Fiscal Quarter in which the reduction becomes applicable).

   (i) **Royalty Adjustment for Third Party License Payments.** If Licensee, its Affiliates, or Sublicensees, in their reasonable judgment and as part of an arms’ length transaction, is required or determines it is reasonably useful to make any payments to a Third Party for a license under any Patent to make, have made, use, offer for sale, sell or import any Licensed Product in the Field in any country in the Territory, then the amount of royalties payable under Section 7.3(a) (**Royalty Rate**) shall be reduced by [***] of the amount of such payments to such Third Party on account of the sale of the Licensed Products in such country in such Fiscal Quarter, and any payments in excess of such [***] reduction will be carried forward and used as reductions for any subsequent Fiscal Quarter.

7.4 **Payment; Reports.** Within (a) [***] after the end of each Fiscal Quarter (other than the last Fiscal Quarter of a Fiscal Year) and (b) [***] after the end of the last Fiscal Quarter of a Fiscal Year, commencing with the First Commercial Sale of any Licensed Product is made anywhere in the Territory (whichever is earlier), Licensee shall provide Licensor with a report that contains the following information for the applicable Fiscal Quarter, on a Licensed Product-by-Licensed Product and country-by-country basis: (i) Net Sales in the Territory; (ii) a calculation of the royalty payment due on Net Sales in the Territory; and (iii) the exchange rates used. Licensor shall invoice Licensee for the corresponding royalty payment. Licensee shall remit payment to Licensor within [***] of the receipt of such invoice.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
7.5 Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in Dollars. When conversion of payments from any currency other than Dollars is required, such conversion shall be at the exchange rate published by The Wall Street Journal, Eastern U.S. Edition, on the last day of the Fiscal Quarter in which the applicable sales were made. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Licensor, unless otherwise specified in writing by Licensor.

7.6 Late Payments. If any undisputed payment due is not paid by the due date, Licensor may charge interest on any outstanding amount of such payment, accruing as of the original due date, at an annual rate equal to the rate of prime (as reported in The Wall Street Journal, Eastern U.S. Edition) plus [***]. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

7.7 Taxes.

(a) Taxes on Income. Notwithstanding anything else in this Section 7.7 (Taxes), each Party shall solely bear and pay all Taxes imposed on such Party’s net income or gain (in each case, however denominated) arising directly or indirectly from the activities of the Parties under this Agreement.

(b) Tax Cooperation. The Parties shall use Commercially Reasonable Efforts to cooperate with one another and shall use Commercially Reasonable Efforts to avoid or reduce, to the extent permitted by Applicable Laws, tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Licensee to Licensor under this Agreement. If withholding Taxes are imposed on any such payment, the liability for such Taxes shall be the sole responsibility of Licensor, and Licensee shall (i) deduct or withhold such Taxes from the payment made to Licensor, (ii) timely pay such Taxes to the proper taxing authority, and (iii) send proof of payment to Licensor within thirty (30) days following such payment. To the extent that amounts are so withheld and paid to the proper taxing authority, such amounts shall be treated for all purposes of this Agreement as having been paid to the persons with respect to whom such amounts were withheld. Each Party shall comply with (or provide the other Party with) any certification, identification or other reporting requirements that may be reasonably necessary in order for Licensee to not withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with commercially reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of Licensor as the Party bearing the cost of such withholding Tax under this Section 7.7(b) (Tax Cooperation).

(c) Transfer Tax. Subject to Section 7.7(a) (Taxes on Income), Licensee, on the one hand, and Licensor, on the other hand, shall each bear and pay [***] of any transfer, stamp, value added, sales, use, or similar Taxes or obligations (“Transfer Tax”) imposed on amounts payable by Licensee to Licensor in connection with this Agreement. Each party shall cooperate with the other to file any Tax returns (as required to be filed under Applicable Law) with respect to such Transfer Taxes.

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
7.8 Financial Records and Audit. Licensee shall (and shall ensure that its Affiliates and Sublicensees will) maintain complete and accurate records in sufficient detail to permit Licensor to confirm the accuracy of any royalty payments and other amounts payable under this Agreement and to verify the achievement of milestone events under this Agreement. Upon at least thirty (30) days’ prior notice, such records shall be open for examination, during regular business hours, for a period of five (5) Fiscal Years from the end of the Fiscal Year to which such records pertain, and not more often than once each Fiscal Year, by an independent certified public accountant selected by Licensor and reasonably acceptable to Licensee, for the sole purpose of verifying for Licensor the accuracy of the financial reports furnished by Licensee under this Agreement or of any payments made, or required to be made, by Licensee to Licensor pursuant to this Agreement. The independent certified public accountant shall disclose to Licensor only whether the audited reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Licensor. No record may be audited more than once. Licensor shall bear the full cost of such audit unless such audit reveals an underpayment by Licensee of more than [***] of the amount actually due for any Fiscal Year being audited, in which case Licensee shall reimburse Licensor for the reasonable costs for such audit. Licensee shall pay to Licensor any underpayment discovered by such audit within thirty (30) days after the accountant’s report, plus interest (as set forth in Section 7.6 (Late Payments)) from the original due date. If the audit reveals an overpayment by Licensee, then Licensee may take a credit for such overpayment against any future payments due to Licensor.

7.9 Audit Dispute. If Licensee disputes the results of any audit conducted pursuant to Section 7.8 (Financial Records and Audit), the Parties shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party’s certified public accountants or to such other person as the Parties shall mutually agree (the “Auditor”). The decision of the Auditor shall be final and the costs of such procedure as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. If the Auditor determines that there has been an underpayment by Licensee, Licensee shall pay to Licensor the underpayment within thirty (30) days after the Auditor’s decision, plus interest (as set forth in Section 7.6 (Late Payments)) from the original due date. If the Auditor determines that there has been an overpayment by Licensee, then Licensee may take a credit for such overpayment against any future payments due to Licensor.

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 Ownership.

(a) Data. All Data generated in connection with any Development, regulatory, manufacturing or Commercialization activities with respect to any Gene Therapy or any Licensed Product conducted by or on behalf of Licensee or its Affiliates or Sublicensees (the “Licensee Data”) shall be the sole and exclusive property of Licensee or of its Affiliates or Sublicensees, as applicable.

(b) Ownership of Inventions. Inventorship of Inventions shall be determined by application of U.S. patent laws pertaining to inventorship. Ownership of all Inventions shall

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be based on inventorship, as determined in accordance with the rules of inventorship under United States patent laws. Each Party shall solely own any Inventions made solely by its or its Affiliates’ employees, agents or independent contractors (“Sole Inventions”). Licensee shall own any Inventions that are made jointly by employees, agents or independent contractors of one Party or its Affiliates together with employees, agents or independent contractors of the other Party or its Affiliates (“Joint Inventions”). All Patents claiming Joint Inventions shall be referred to herein as “Joint Patents” and shall be owned by Licensee. Licensor agrees to assign and hereby assigns all right, title, and interest in any Joint Inventions and Joint Patents to Licensee.

(c) Disclosure of Inventions. Licensor shall promptly disclose to Licensee all Sole Inventions of Licensor that are related to Gene Therapies or Licensed Products and all Joint Inventions, including any invention disclosures or other similar documents submitted to Licensor by its employees, agents or independent contractors describing such Inventions, and shall promptly respond to reasonable requests from Licensee for additional information relating to such Inventions.

8.2 Patent Prosecution and Maintenance.

(a) Licensee Patents. Licensee shall have the sole right, but not the obligation, to prepare, file, prosecute (including any interferences, reissue proceedings, derivation proceedings, reexaminations, oppositions, revocations, inter partes review proceedings and post-grant review proceedings before the United States Patent and Trademark Office and the relevant local equivalent thereof, and applications for patent term extensions, supplementary protection certificates or equivalents thereof) and maintain (“Prosecute and Maintain”) all Licensee Patents at its sole cost and expense and by counsel of its own choice.

(b) Licensor Patents and Joint Patents.

(i) Licensee shall have the first right, but not the obligation, to Prosecute and Maintain all Licensor Patents and Joint Patents, at its sole cost and expense and by counsel selected by Licensee. Licensee shall reasonably consult with Licensor and keep Licensor reasonably informed of the status of such Patents, and shall provide Licensor with all material correspondence received from any patent authority in connection therewith at Licensor’s reasonable request. In addition, at Licensor’s reasonable request, Licensee shall provide Licensor with drafts of all proposed material filings and correspondence to any patent authority with respect to such Patents for Licensor’s review and comment prior to the submission of such proposed filings and correspondence. Licensee shall confer with Licensor and consider in good faith Licensor’s comments prior to submitting such filings and correspondence, provided that Licensor provides such comments within [***] of receiving the draft filings and correspondence from Licensee. To aid Licensee in prosecution of such Patents, Licensor will provide information, execute and deliver documents, and cooperate with Licensee and do other acts as Licensee may reasonably request.

(ii) If Licensee desires to abandon or cease to Prosecute and Maintain any Licensor Patent or Joint Patent, Licensee shall provide reasonable prior written notice to Licensor of such intention (which notice shall, to the extent possible, be given no later than [***] prior to the last deadline for any action that must be taken with respect to any such Patent in the relevant patent office). In such case, upon Licensor’s written election provided no later than [***]
after such notice from Licensee, Licensor may Prosecute and Maintain such Patent at Licensor’s sole cost and expense. If Licensor does not provide such election within [***] after such notice from Licensee, Licensee may, in its sole discretion, continue Prosecute and Maintain such Patent or discontinue to Prosecute and Maintain such Patent. Any Patent that is abandoned under this Section 8.2(b)(ii) will no longer be subject to the license granted in Section 2.1.

(iii) Within [***] after the Effective Date, Licensor shall deliver to Licensee copies of all patent prosecution files relating to Licensor Patents in the Territory.

8.3 Cooperation of the Parties. If either Licensor or Licensee becomes aware of any challenges by any Third Parties to the validity of any of any Licensor Patent, Licensee Patent, or Joint Patent, it will notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, by such Third Party. Each Party agrees to cooperate fully in the preparation, filing, prosecution, and maintenance of Patents under Section 8.2 (Patent Prosecution and Maintenance), at its own cost. Such cooperation includes: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as enable the other Party to apply for and to prosecute patent applications in any country as permitted by Section 8.2 (Patent Prosecution and Maintenance); and (b) promptly informing the other Party of any matters coming to such Party’s attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

8.4 Infringement by Third Parties.

(a) Notice. If either Licensor or Licensee becomes aware of any infringement or threatened infringement by a Third Party of any Licensor Patent, Licensee Patent, or Joint Patent, which infringing activity involves the using, making, importing, offering for sale or selling of a Licensed Product, or the submission to a Party or a Regulatory Authority of an application for a product referencing a Licensed Product, or any declaratory judgment, inter partes review, post-grant review, derivation proceeding or equivalent action challenging any Licensor Patent, Licensee Patent, or Joint Patent in connection with any such infringement (each, a “Product Infringement”), it will notify the other Party in writing to that effect. Any such notice shall include evidence to support an allegation of infringement or threatened infringement, or declaratory judgment or equivalent action, by such Third Party.

(b) Licensor Patents and Joint Patents.

(i) Subject to this Section 8.4(b) (Licensor Patents), Licensee shall have the first right, as between Licensor and Licensee, but not the obligation, to bring an appropriate suit or take other action against any person or entity engaged in, or to defend against, a Product Infringement of any Licensor Patents or Joint Patents, and entirely under its own direction and control, including the right to select counsel of its own choice and the unfettered right to settle such action. Licensor may, at its own expense, be represented in any such action, and Licensee and its counsel will reasonably cooperate with Licensor and its counsel in strategizing, preparing, and prosecuting any such action or proceeding. If Licensee fails to bring an action or proceeding with respect to such Product Infringement of any Licensor Patent or Joint Patent within (A) [***] following the notice of alleged infringement or declaratory judgment or

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(B) [***] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Licensor shall have the right, but not the obligation, to bring and control any such action at its own expense and by counsel of its own choice, and Licensee may, at its own expense, be represented in any such action by counsel of its own choice.

(ii) Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding with respect to Licensor Patents shall be used first to reimburse the Parties’ documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining compensatory damages relating to Licensed Products (including lost sales or lost profits with respect to Licensed Products) shall be retained by the Party that brought and controlled such action or proceeding, and in the case that Licensee brought and controlled such action or proceeding, such remaining compensatory damages shall be deemed to be Net Sales subject to royalty payments to Licensor in accordance with the royalty provisions of Section 7.3 (Royalty Payments), and any punitive damages shall be equally shared by the Parties.

(c) Licensee Patents. Licensee shall have the sole right, as between Licensor and Licensee, but not the obligation, to bring an appropriate suit or take other action against any person or entity engaged in, or to defend against, a Product Infringement of any Licensee Patents at its own expense and by counsel of its own choice. Any recovery or damages realized as a result of such action or proceeding by Licensee with respect to Licensee Patents in the Territory shall be used first to reimburse Licensee’s documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining compensatory damages relating to Licensed Products (including lost sales or lost profits with respect to Licensed Products) shall be retained by Licensee, and any punitive damages shall be retained by Licensee.

(d) Biosimilars. Licensee shall be responsible for determining the strategy with respect to certifications, notices and patent enforcement procedures regarding Licensor Patents Covering any Gene Therapy or Licensed Product under the U.S. Food, Drug & Cosmetics Act and the Biologics Price Competition and Innovation Act of 2009 (the “BPCIA”). Licensor hereby authorizes Licensee to: (i) provide in any BLA or in connection with the BPCIA, a list of Licensor Patents as required under the BPCIA; (ii) except as otherwise expressly provided in this Agreement, exercise any rights exercisable by Licensee as an exclusive licensee under the BPCIA; and (iii) exercise any rights that may be exercisable by Licensee as reference product sponsor under the BPCIA, including: (A) engaging in the Patent resolution provisions of the BPCIA with regard to Licensor Patents Covering any Gene Therapy or Licensed Product; and (B) determining which Patents will be the subject of an immediate Patent infringement action under 42 U.S.C. § 262(l)(6) of the BPCIA.

(e) Cooperation. In the event a Party brings an action in accordance with, or needs to enforce its rights under, this Section 8.4 (Infringement by Third Parties), the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party to such action.

(f) Other Infringement. Licensor shall have the sole right, but not the obligation, to bring and control, at its own cost and expense, any legal action in connection with any infringement of any Licensor Patent that is not a Product Infringement. Licensee shall have

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the sole right, but not the obligation, to bring and control, at its own cost and expense, any legal action in connection with any infringement of any Licensee Patent or Joint Patent that is not a Product Infringement.

8.5 Infringement of Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the manufacture, Development, or Commercialization of any Gene Therapy or Licensed Product infringes or may infringe the intellectual property rights of a Third Party. If a Third Party asserts that any of its Patents or other rights are infringed by the manufacture, Commercialization or Development by Licensee or its Affiliates of any Licensed Product, Licensee shall have the right, but not the obligation, to defend against any such assertions at its sole cost and expense. If Licensee elects not to defend against such Third Party claims within [***] of learning of same, Licensor shall have the right, but not the obligation, to defend against such an action. In any event, the other Party shall cooperate fully and shall provide full access to documents, information and witnesses as reasonably requested by the Party defending such action. The Party defending the action will reimburse all reasonable, out-of-pocket costs incurred in connection with such requested cooperation. Notwithstanding the foregoing, the Parties’ rights and obligations under this Section 8.5 (Infringement by Third Parties), including payment obligations, will be subject to the terms of ARTICLE 10 (Indemnification).

8.6 Consent for Settlement. The Licensor shall not unilaterally enter into any settlement or compromise of any action or proceeding under this ARTICLE 8 (Intellectual Property) that would in any manner alter, diminish, or be in derogation of the Licensee’s rights under this Agreement without the prior written consent of Licensee and at Licensee’s sole discretion.

8.7 Patent Marking. Licensee shall mark and ensure that its Affiliates mark all patented Licensed Products they sell or distribute pursuant to this Agreement in accordance with the applicable patent statutes or regulations in the country or countries of manufacture and sale thereof.

8.8 Patent Extensions. Licensee shall have sole decision-making authority regarding, and Licensor shall cooperate with Licensee in obtaining, patent term restoration, supplemental protection certificates or their equivalents, and patent term extensions with respect to the Licensor Patents, Licensee Patents, and Joint Patents in any country in the Territory where applicable. Licensee shall file for such extensions at Licensee’s sole cost and expense.

8.9 Trademarks. Licensee shall own and be responsible for all trademarks, trade names, branding or logos related to Licensed Products in the Field in the Territory. Licensee shall be responsible for selecting, registering, prosecuting, defending, and maintaining all such marks at Licensee’s sole cost and expense.

8.10 Relevant Third Party Rights. If either Party identifies any Patent, or other intellectual property, that is Controlled by a Third Party in any country in the Territory and that may be commercially necessary in connection with the Development, manufacture or Commercialization of a Licensed Product hereunder, then, such Party will promptly notify the other Party. Following receipt of such notice, on Licensee’s request, the Parties shall meet and

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discuss whether Licensee or Licensor should obtain one or more licenses with respect to such rights or take other appropriate measures in view of such Third Party rights, such as whether the Parties should obtain an opinion relating to such Third Party intellectual property rights, or take alternative approaches to avoid using such Third Party intellectual property rights. As between the Parties, Licensee shall have the right, but not the obligation, to negotiate and obtain a license or other rights from such Third Party to such Third Party Right as necessary or desirable to Develop or Commercialize Licensed Products in such country. Notwithstanding the foregoing, if Licensee negotiates and obtains any such license from a Third Party, Licensee shall be entitled to offset payments made on account of such license to the extent set forth in Section 7.3(c)(i) (Royalty Adjustment for Third Party License Payments).

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the Effective Date: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action; (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, subject to bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally and equitable principles, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and (d) it has the right to grant the licenses granted by it under this Agreement.

9.2 Mutual Covenants.

(a) Employees, Consultants and Contractors. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants and contractors who perform Development, manufacturing or Commercialization activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign Inventions in a manner consistent with the provisions of this Agreement.

(b) Debarment. Each Party represents, warrants and covenants to the other Party that it is not debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act, as may be amended, or comparable laws in any country or jurisdiction other than the U.S., and it does not, and will not during the Term, employ or use the services of any person who is debarred or disqualified, in connection with activities relating to any Gene Therapy or Licensed Product. If either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, including the Party itself or its Affiliates, that directly or indirectly relate to activities contemplated by this Agreement, such Party shall immediately notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

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(c) Compliance. Each Party covenants as follows:

(i) In the performance of its obligations under this Agreement, such Party shall comply and shall cause its and its Affiliates’ employees and contractors to comply with all Applicable Laws, including all anti-corruption and anti-bribery laws and regulations, economic, trade and financial sanctions, and trade embargoes.

(ii) Such Party and its and its Affiliates’ employees and contractors shall not, in connection with the performance of their respective obligations under this Agreement, directly or indirectly through Third Parties, pay, promise or offer to pay, or authorize the payment of, any money or give any promise or offer to give, or authorize the giving of anything of value to a Public Official or Entity or other person for purpose of obtaining or retaining business for or with, or directing business to, any person, including either Party (and each Party represents and warrants that as of the Effective Date, such Party, and to its Knowledge, its and its Affiliates’ employees and contractors, have not directly or indirectly promised, offered or provided any corrupt payment, gratuity, emolument, bribe, kickback, illicit gift or hospitality or other illegal or unethical benefit to a Public Official or Entity or any other person in connection with the performance of such Party’s obligations under this Agreement, and each Party covenants that it and its Affiliates’ employees and contractors shall not, directly or indirectly, engage in any of the foregoing).

(iii) Neither Party, nor any of its directors, officers, employees or subcontractors, or, to its Knowledge, agents, is subject to economic, trade and financial sanctions under Applicable Law. Licensor will not directly or indirectly use the proceeds of the transactions contemplated hereby, or lend, contribute or otherwise make available such proceeds, to any individual or entity otherwise subject to such sanctions.

(iv) Each Party may suspend or terminate this Agreement in its entirety where there is a credible finding, after a reasonable investigation, that the other Party, in connection with performance of such other Party’s obligations under this Agreement, has violated any anti-corruption or anti-bribery laws or regulations, economic, trade or financial sanctions, or trade embargoes, in each case under Applicable Law.

9.3 Additional Licensor Representations, Warranties and Covenants. Licensor represents, warrants and covenants, as applicable, to Licensee that, as of the Effective Date:

(a) Licensor is the sole and exclusive owner of all right, title and interest in Licensor Technology, and Licensor has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Licensor Technology in a manner that is inconsistent with the exclusive license granted to Licensee under Section 2.1 (Licenses to Licensee);

(b) all issued Patents listed on Exhibit A: (i) are: (A) to Licensor’s Knowledge, subsisting and are not invalid or unenforceable, in whole or in part; (B) free of any encumbrance, lien or claim of ownership by any Third Party; and (ii) have been prosecuted, filed and maintained in accordance with Applicable Law and all applicable fees have been paid on or before the due date for payment. With respect to any pending applications listed on Exhibit A, 

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such applications are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law and Licensor and its Affiliates have presented all relevant references, documents, and information of which it or the inventors are aware to the relevant patent examiner at the relevant patent office;

(c) true, complete and correct copies of the file wrappers and other documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of the Patents listed on Exhibit A have been provided or made available to Licensee prior to the Effective Date;

(d) to Licensor's Knowledge, (i) each person who has or has had any rights in or to any Patents listed on Exhibit A or any Licensor Know-How, has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Patents listed on Exhibit A and Licensor Know-How to Licensor, and (ii) no current officer, employee, agent, or consultant of Licensor or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of the Patents listed on Exhibit A or other intellectual property or proprietary Know-How of Licensor or such Affiliate or of any employment contract relating to the relationship of any such person with Licensor;

(e) Licensor has not received any notice from a Third Party that the Development of any Gene Therapy or Licensed Product conducted by Licensor prior to the Effective Date has infringed any Patents of any Third Party or misappropriated any other intellectual property of any Third Party and is not aware of any imminent or likely threat from a Third Party of such infringement or misappropriation;

(f) Licensor has not received any notice from a Third Party challenging the inventorship or ownership of any Licensed Technology

(g) Licensor has not, and will not during the Term, grant any right (including any option or license) to any Third Party under the Licensor Technology that would conflict with the rights granted to Licensee hereunder;

(h) to Licensor's Knowledge, no Third Party is infringing or misappropriating any of the Licensor Technology;

(i) no claim or action has been brought or, to Licensor's Knowledge, threatened in writing by any Third Party alleging that the Licensor Patents are invalid or unenforceable, and no Licensor Patent is the subject of any interference, derivation, opposition, cancellation or other protest proceeding;

(j) the patents and patent applications listed on Exhibit A constitute all existing Licensor Patents relating to the development and commercialization of the Licensed Products;

(k) to Licensor's Knowledge, there is no Know-How necessary for the Development and manufacture of the Gene Therapies or Licensed Products that, in any case, is Controlled (mutatis mutandis) by any Third Party;

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(l) neither Licensor nor its Affiliates has granted any Third Party any rights of reference or use with respect to any Regulatory Documentation;

(m) to Licensor’s Knowledge, there are no circumstances currently existing that would reasonably be expected to lead to, any loss of or refusal to renew any Regulatory Approval or result in an investigation, corrective action or enforcement action by any other Regulatory Authority with respect to any Gene Therapy or Licensed Product;

(n) to Licensor’s Knowledge, except for adverse events reported in the documents provided by Licensor to Licensee, no information exists that indicates the existence of any material side effect or adverse effect, resulting from, or alleged to result from any Gene Therapy or Licensed Product;

(o) to Licensor’s Knowledge, it has provided Licensee with true, accurate and complete information, reports and data concerning all scientific studies and human clinical trials relating to Gene Therapies and Licensed Products; and

(p) to Licensor’s Knowledge, all animal studies and other non-clinical tests conducted by Licensor or its Affiliates relating to any Gene Therapy or Licensed Product were conducted by or on behalf of Licensor or its Affiliates in all material respects in accordance with Applicable Law and its or their standard operating procedures for the conduct of animal or non-clinical studies at the time such tests were conducted.

9.4 No Other Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF PATENTS, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

ARTICLE 10
INDEMNIFICATION

10.1 Indemnification by Licensor. Licensor shall indemnify and hold Licensee, its Affiliates and Sublicensees, and their respective officers, directors, agents and employees (“Licensee Indemnitees”) harmless from and against any Claims to the extent arising or resulting from:

(a) the research, development (both pre-clinical and clinical), manufacture, promotion, or commercialization of any Gene Therapy or Licensed Product by or on behalf of Licensor, its Affiliates, or its licensees prior to the Effective Date;

(b) the supply by Licensor of any Gene Therapy or Licensed Product pursuant to Section 5.2 (Supply of Clinical Product) that fails to meet cGMP or the applicable specifications of such Gene Therapy or Licensed Product;

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10.2 Indemnification by Licensee. Licensee shall indemnify and hold Licensor, its Affiliates, and their respective officers, directors, agents and employees ("Licensor Indemnitees") harmless from and against any Claims to the extent arising or resulting from:

(a) the research, development (both pre-clinical and clinical), manufacture, promotion, or commercialization of any Gene Therapy or Licensed Product by or on behalf of Licensee, its Affiliates, or Sublicensees on or after the Effective Date;

(b) the gross negligence or willful misconduct of any Licensee Indemnitees;

(c) any material breach of any of the warranties or representations made by Licensee to Licensor under this Agreement; or

(d) any material breach by Licensee of its covenants pursuant to this Agreement;

in each case, except to the extent such Claims result from Section 10.1(a)–(e) (Indemnification by Licensor). The foregoing obligation shall not apply to the extent that the Licensee Indemnitees fail to comply with the procedures set forth in Section 10.3 (Indemnification Procedure) and Licensor’s defense of the relevant Claims is prejudiced by such failure.

10.3 Indemnification Procedure. If either Party is seeking to enforce its rights under Sections 10.1 (Indemnification by Licensor) or 10.2 (Indemnification by Licensee) (the “Indemnified Party”), such Indemnified Party shall inform the other Party (the “Indemnifying Party”) of the Claim giving rise to the obligation to indemnify pursuant to such section as soon as reasonably practicable after receiving notice of the Claim, but not later than [***] after receiving notice of the Claim. The Indemnifying Party may assume the defense of any such Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party’s insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party’s cost and expense. The Indemnified Party may participate, at its own expense and with counsel of its choice, in the defense of any Claim or suit that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without such Party’s written

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consent, which consent shall not be unreasonably conditioned, withheld, or delayed. If the Parties cannot agree as to the application of Section 10.1 (Indemnification by Licensor) or Section 10.2 (Indemnification by Licensee) as to any Claim, pending resolution of the dispute pursuant to Section 13.9 (Dispute Resolution), the Parties may conduct separate defenses of such Claim, with each Party retaining the right to Claim indemnification from the other Party in accordance with Section 10.1 (Indemnification by Licensor) or Section 10.2 (Indemnification by Licensee) upon resolution of the underlying Claim.

10.4 Mitigation of Loss. Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and actions as are reasonably necessary or as the Indemnifying Party may reasonably require in order to mitigate any Claims (or potential losses or damages) under this ARTICLE 10 (Indemnification). Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

10.5 Special, Indirect and Other Losses. EXCEPT IN THE EVENT OF LICENSOR’S BREACH OF SECTION 2.5 (EXCLUSIVITY) OR A PARTY’S BREACH OF ARTICLE 11 (CONFIDENTIALITY), NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that this Section 10.5 (Special, Indirect and Other Losses) shall not be construed to limit either Party’s indemnification obligations under Section 10.1 (Indemnification by Licensor) or Section 10.2 (Indemnification by Licensee), as applicable.

10.6 Insurance. Each Party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with sound business practice and reasonable in light of its obligations under this Agreement during the Term. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

ARTICLE 11
CONFIDENTIALITY; PUBLICATION

11.1 Duty of Confidence. Subject to the other provisions of this ARTICLE 11 (Confidentiality; Publication):

(a) all Confidential Information disclosed by a Party (the “Disclosing Party”) or its Affiliates under this Agreement will be maintained in confidence and otherwise safeguarded by the recipient Party (the “Receiving Party”) and its Affiliates using at least the same standard of care as the Receiving Party uses to protect its own proprietary or Confidential Information (but in no event less than reasonable care);

(b) the Receiving Party may only use any such Confidential Information for the purposes of performing its obligations or exercising its rights under this Agreement; and

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the Receiving Party may disclose Confidential Information of the Disclosing Party only to: (i) the Receiving Party’s Affiliates and, in the case of Licensee as the Receiving Party, its Sublicensees; and (ii) employees, directors, agents, contractors, consultants and advisers of the Receiving Party and its Affiliates and, in the case of Licensee as the Receiving Party, Sublicensees, in each case to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such persons are bound to maintain the confidentiality, and not to make any unauthorized use, of the Confidential Information in a manner consistent with this ARTICLE 11 (Confidentiality; Publication).

11.2 Exceptions. The foregoing obligations as to particular Confidential Information of a Disclosing Party shall not apply to the extent that the Receiving Party can demonstrate by competent evidence that such Confidential Information:

(a) is known by the Receiving Party at the time of its receipt, and not through a prior disclosure by the Disclosing Party, as shown by contemporaneous written documents of the Receiving Party;

(b) is in the public domain by use or publication before its receipt from the Disclosing Party, or thereafter enters the public domain through no fault of, or breach of this Agreement by, the Receiving Party;

(c) is subsequently disclosed to the Receiving Party on a non-confidential basis by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the Disclosing Party; or

(d) is developed by the Receiving Party independently and without use of or reference to any Confidential Information disclosed to it by or on behalf of the Disclosing Party, as shown by contemporaneous written documents of the Receiving Party.

11.3 Authorized Disclosures. Notwithstanding the obligations set forth in Section 11.1 (Duty of Confidence), the Receiving Party may disclose Confidential Information of the Disclosing Party and the terms of this Agreement to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting of Patents as permitted by this Agreement;

(b) enforcing the Receiving Party’s rights under this Agreement or performing the Receiving Party’s obligations under this Agreement;

(c) in Regulatory Documentation for Licensed Products that such Party has the right to file under this Agreement;

(d) prosecuting or defending litigation as permitted by this Agreement;

(e) to the Receiving Party’s directors, Affiliates, actual or potential Sublicensees (in the case of Licensee), commercial partners, independent contractors, consultants, attorneys, independent accountants or financial advisors who, in each case, have a need to know

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such Confidential Information in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, provided that, in each case, that any such person agrees to be bound by terms of confidentiality and non-use (or, in the case of the Receiving Party’s attorneys and independent accountants, such person is obligated by applicable professional or ethical obligations) at least as restrictive as those set forth in this ARTICLE 11 (Confidentiality; Publication);

(f) to actual or potential investors, investment bankers, lenders, other financing sources or acquirors (and attorneys and independent accountants thereof) in connection with potential investment, acquisition, collaboration, merger, public offering, due diligence or similar investigations by such Third Parties or in confidential financing documents, provided that, in each case, that any such Third Party agrees to be bound by terms of confidentiality and non-use (or, in the case of the Receiving Party’s attorneys and independent accountants, such Third Party is obligated by applicable professional or ethical obligations) that are no less stringent than those contained in this Agreement (except to the extent that a shorter confidentiality period is customary in the industry); and

(g) such disclosure is required by court order, judicial or administrative process or Applicable Law, provided that in such event the Receiving Party shall promptly inform the Disclosing Party of such required disclosure and provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed as required by court order, judicial or administrative process or Applicable Law shall remain otherwise subject to the confidentiality and non-use provisions of this ARTICLE 11 (Confidentiality; Publication), and the Receiving Party shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information.

11.4 **Publication.** Licensor shall not publish nor otherwise publicly disclose any data or results regarding any Gene Therapy or Licensed Product without the prior written consent of Licensee. Licensor does not have any data, results, or publications currently under review that may be published or otherwise publicly disclosed after the Effective Date. After the Effective Date, Licensee may freely publish and give presentations on its Development and Commercialization of the Gene Therapies or Licensed Products.

11.5 **Publicity; Use of Names.** No disclosure of the existence, or the terms, of this Agreement may be made by either Party or its Affiliates, and neither Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as set forth in Section 11.7 (**Disclosure to the SEC**) or as otherwise may be required by law. Notwithstanding the above, each Party and its Affiliates may disclose on its website and in its promotional materials that the other Party is a development partner of such Party for the Licensed Products and may use the other Party’s name and logo in conjunction with such disclosure.

11.6 **Prior Confidentiality Agreement.** As of the Effective Date, the terms of this ARTICLE 11 (**Confidentiality; Publication**) shall supersede any prior non-disclosure, secrecy or confidentiality agreement between the Parties (or their Affiliates) relating to the subject of this

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
Agreement, including the Confidentiality Agreement. Any information disclosed pursuant to any such prior agreement shall be deemed Confidential Information for purposes of this Agreement.

11.7 Disclosure to the SEC.

(a) A Party may disclose this Agreement and its terms, and material developments or material information generated under this Agreement, in securities filings (including any Form S-1, amended Form S-1, or subsequent quarterly or annual filings) with the U.S. Securities and Exchange Commission (“SEC”) (or equivalent foreign agency) to the extent required by Applicable Law after complying with the procedure set forth in this Section 11.7 (Disclosure to the SEC). In such event, the Party seeking to make such disclosure will prepare a draft confidential treatment request and a redacted version of this Agreement to request confidential treatment for this Agreement, which redacted version will be provided to the other Party. The Party seeking such disclosure shall exercise Commercially Reasonable Efforts to obtain confidential treatment of this Agreement from the SEC as represented by such redacted version provided to the other Party.

(b) Further, each Party acknowledges that the other Party may be legally required, or may be required by the listing rules of any exchange on which the other Party’s or its Affiliate’s securities are traded, to make public disclosures (including in filings with the SEC or other agency) of certain material developments or material information generated under this Agreement and agrees that each Party may make such disclosures as required by law or such listing rules, provided that the Party seeking such disclosure shall provide the other Party with a copy of the proposed text of such disclosure sufficiently in advance of the scheduled release to afford such other Party a reasonable opportunity to review and comment thereon.

11.8 Press Release.

(a) The Licensee may issue a press release or make a public announcement concerning the material terms of this Agreement or the Development or Commercialization of the Licensed Product under this Agreement, such as the achievement of Regulatory Approvals of the Licensed Product, at Licensee’s sole discretion and without needing to obtain the consent of the Licensor. If the Licensor desires to issue a press release or make a public announcement concerning the material terms of this Agreement or the Development or Commercialization of the Licensed Product under this Agreement, such as the achievement of Regulatory Approvals of the Licensed Product, Licensor shall provide the Licensee with the proposed text of such announcement for prior review and approval by the Licensee.

(b) The Parties agree that after a public disclosure has been made or a press release or other public announcement has been issued in compliance with this Agreement, each Party may make subsequent public disclosures or issue press releases or other public announcements disclosing the same content without having to obtain the other Party’s prior consent and approval.

11.9 Reporting of Financial Information. From and after the Effective Date, to the extent required by the SEC in connection with Licensee or an Affiliate of Licensee registering securities in a public offering, Licensor shall (a) cooperate with Licensee or its Affiliates and their

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respective accountants and auditors by providing access to information, books, and records related to the Licensed Products as Licensee may reasonably request in connection with the preparation by Licensee or its Affiliates of historical and pro forma financial statements related to the Licensed Products as may be required to be included in any filing made by Licensee or any of its Affiliates under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder, including Regulation S-X and (b) without limiting the foregoing, shall provide Licensee with such information as is required for Licensee or its Affiliates to prepare audited “carve out” financial statements related to the Licensed Products, for the two (2) Fiscal Years prior to the Effective Date (or such shorter period as agreed to by Licensee) and information requested by Licensee and reasonably necessary to prepare any applicable pro forma financial information required to be filed by Licensee with the SEC. Such cooperation shall include, as applicable, (i) the signing of management representation letters to the extent required in connection with any such audit performed by Licensee’s auditors, (ii) providing Licensee or its Affiliates and their respective accountants and auditors with access to management representation letters provided by Licensor to Licensee’s accountants and auditors, and (iii) causing Licensor’s accountants, auditors, and counsel to cooperate with Licensee or its Affiliates and its accountants, auditors, and counsel in connection with the preparation and audit of any financial information to be provided under this Section 11.9 (Reporting of Financial Information). If Licensor is required to provide Licensee with the audited financial statements contemplated hereunder, the selection of an external audit firm will be at the discretion of Licensor. Such financial statements shall be derived from Licensor’s historical financial statements, and accurately present in all material respects the financial position of the Licensed Products as of the dates thereof. Licensor hereby consents to the inclusion or incorporation by reference of any financial statements provided to Licensee under this Section 11.9 (Reporting of Financial Information) in any filing by Licensee or its Affiliates with the SEC and, upon request thereof of Licensee, agrees to request that any auditor of Licensor that audits any financial statements provided to Licensee or its Affiliates under this Section 11.9 (Reporting of Financial Information) consent to the inclusion or incorporation by reference of its audit opinion with respect to such financial statements in any filing by Licensee or its Affiliates with the SEC.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. Unless earlier terminated as permitted by this Agreement, the term of this Agreement commences upon the Effective Date and continues in full force and effect, on a Licensed Product-by-Licensed Product basis, until the expiration of the Royalty Term for such Licensed Product in the Territory (the “Term”). Upon the expiration (but not early termination) of the Term for such Licensed Product, the licenses granted to Licensee shall continue in effect, as non-exclusive, fully paid-up, royalty-free, transferable, perpetual and irrevocable, with the right to grant Sublicenses through multiple tiers, with respect to such Licensed Product in the Field in the Territory.

12.2 Termination.

(a) Termination by Licensee for Convenience. At any time, Licensee may terminate this Agreement, at its sole discretion and for any reason or no reason, in its entirety or on a Licensed Product-by-Licensed Product basis, by providing written notice of termination to
Licensor, which notice includes an effective date of termination at least (i) ninety (90) days after the date of the notice if the notice is given before the Regulatory Approval of any Licensed Product; or (ii) one hundred eighty (180) days after the date of the notice if the notice is given after the Regulatory Approval of any Licensed Product.

(b) Termination for Cause. If either Party believes that the other is in material breach of its obligations hereunder, then the non-breaching Party may deliver notice of such breach to the other Party. The allegedly breaching Party shall have ninety (90) days to cure such breach from the receipt of the notice; provided, that if such breach is capable of being cured but cannot be cured within such ninety (90)-day period, the breaching Party may cure such breach during an additional period as is reasonable in the circumstances by initiating actions to cure such breach during such ninety (90)-day period and using Commercially Reasonable Efforts to pursue such actions. If the allegedly breaching Party fails to cure that breach within the applicable period set forth above, then the Party originally delivering the notice of breach may terminate this Agreement on written notice of termination. Any right to terminate this Agreement under this Section 13.2(b) (Termination for Cause) shall be stayed and the applicable cure period tolled if, during such cure period, the Party alleged to have been in material breach shall have initiated dispute resolution in accordance with Section 13.9 (Dispute Resolution) with respect to the alleged breach, which stay and tolling shall continue until such dispute has been resolved in accordance with Section 13.9 (Dispute Resolution). If a Party is determined to be in material breach of this Agreement, the other Party may terminate this Agreement if the breaching Party fails to cure the breach within thirty (30) days after the conclusion of the dispute resolution procedure (and such termination shall then be effective upon written notification from the notifying Party to the breaching Party).

(c) Termination for Bankruptcy. This Agreement may be terminated at any time during the Term by either Party upon the other Party’s filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

12.3 Effect of Termination. Upon termination of this Agreement by: (a) Licensee pursuant to Section 12.2(a) (Termination by Licensee for Convenience); (b) either Party pursuant to Section 12.2(b) (Termination for Cause); or (c) either Party pursuant to Section 12.2(c) (Termination for Bankruptcy), the following consequences shall apply (either to the Agreement in its entirety, or on a Licensed Product-by-Licensed Product bases, as applicable) and shall be effective as of the effective date of such termination:

(i) Licensee’s licenses under Section 2.1 (Licenses to Licensee) shall terminate;

(ii) Licensee shall return to Licensor or destroy, at Licensor’s election, all Confidential Information of Licensor, including all copies thereof and all materials, substances and compositions delivered or provided by Licensor to Licensee; provided, however, that Licensee may keep one copy of such Confidential Information in its legal files solely for the purpose of enabling it to comply with the provisions of this Agreement, and Licensee shall not be required to

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remove such Confidential Information from its back-up or archive electronic records, including its electronic laboratory notebook and laboratory information management systems; and

(iii) Licensor shall be solely responsible for all future Development, manufacture and Commercialization of Gene Therapies and Licensed Products in the Field, at its sole cost and expense.

12.4 Alternative to Termination. Without limiting any other remedy that may be available to Licensee hereunder, if Licensee has the right under Section 12.2(b) (Termination for Cause) to terminate this Agreement, but elects by written notice to Licensor to not exercise such right and continue this Agreement, this Agreement shall continue in full force and effect, except that all milestone and royalty payment obligations under this Agreement from Licensee to Licensor shall be reduced by [***] to the extent such obligations accrue following the date of Licensee’s notice of its right to terminate under Section 12.2(b) (Termination for Cause).

12.5 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement. In addition, the provisions of Articles 1, 10, 11 and 13, and Sections 2.5, 7.8, 7.9, 8.1(b), 8.1(c), 12.1, 12.3, 12.5 and 12.6 hereof shall survive the expiration or termination of this Agreement.

12.6 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies will remain available except as agreed to otherwise herein.

ARTICLE 13
GENERAL PROVISIONS

13.1 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California (U.S.), without reference to any rules of conflict of laws.

13.2 Assignment.

(a) Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably conditioned, withheld, or delayed); provided, however, that either Party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other Party’s consent: (i) in connection with the transfer or sale of all or substantially all of the business or assets of such Party to which this Agreement relates to a Third Party, whether by merger, consolidation, divesture, restructure, sale of stock, sale of assets or otherwise; provided that in the event of any such transaction (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) and

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its Affiliates existing prior to the transaction shall not be included in the technology licensed hereunder (a “Sale Transaction”); or (ii) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate. The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties, and the name of a Party appearing herein will be deemed to include the name of such Party’s successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Section 13.2 (Assignment) shall be null and void.

(b) In the event of: (i) a Sale Transaction by a Party; or (ii) the acquisition by a Party of all or substantially all of the business of a Third Party (together with any entities that were Affiliates of such Third Party immediately prior to such acquisition, an “Acquiree”), whether by merger, consolidation, divestiture, restructure, sale of stock, sale of assets or otherwise (an “Acquisition”), intellectual property rights of the acquiring party in a Sales Transaction or the Acquiree, if other than one of the Parties to this Agreement (together with any entities that were Affiliates of such Acquiree, as applicable), in each case existing prior to such transaction shall not be included in the intellectual property rights (including Patents or Know-How) licensed hereunder or otherwise subject to this Agreement.

13.3 Entire Agreement; Modification. This Agreement and the Consulting Agreement are both a final expression of the Parties’ agreement and a complete and exclusive statement with respect to all of its terms. This Agreement and the Consulting Agreement supersede all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein, including the Confidentiality Agreement and for clarity, the confidential and proprietary information exchanged thereunder shall be treated as Confidential Information under this Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

13.4 Relationship Between the Parties. The Parties’ relationship with one another, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party. Neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

13.5 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

13.6 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war,

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acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any Governmental Authority or unavailability of materials related to the manufacture of Gene Therapies or Licensed Products. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations in spite of the ongoing circumstances.

13.7 Severability If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provisions adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provisions with valid, legal and enforceable provisions which, insofar as practical, implement the purposes of this Agreement.

13.8 Notices Any notice to be given under this Agreement must be in writing and delivered either (a) in person, (b) by air mail (postage prepaid) requiring return receipt, (c) by overnight courier, or (d) by e-mail with delivery and return receipts requested and confirmation of delivery thereafter, to the Party to be notified at its address(es) given below, or at any address such Party may designate by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (i) the date of actual receipt; (ii) if air mailed, five (5) days after the date of postmark; (iii) if delivered by overnight courier, the next day the overnight courier regularly makes deliveries or (iv) if sent by e-mail, the date of confirmation of receipt.

If to Licensor:
Ion Channel Innovations, LLC
23 Agnes Circle,
Ardsley, NY 10502
U.S.
Attention: Directing Member

With a copy to:
one llp
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660
Attention: Anthony Kuhlmann, Ph.D.
Email: [***]

If to Licensee:
Urovant Sciences GmbH
Viaduktstrasse 8
4051 Basel, Switzerland
Attention: Head of Global Transactions
Email: [***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
With a copy to:
Urovant Sciences, Inc.
5151 California Avenue, Suite 250
Irvine, CA 92617
Attention: General Counsel
Email: [***]

13.9 Dispute Resolution

(a) Subject to Section 13.9(h) (Dispute Resolution), the Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. Subject to Section 13.9(h) (Dispute Resolution), in the event the Parties cannot resolve such dispute, controversy or claim within a period of thirty (30) days, then the matter shall be referred to designated senior executives of the Parties for resolution by the sending of a Notice of Dispute(s) for Executive Resolution. The designated senior executives shall endeavor to meet in person within ten (10) days following transmittal of the Notice of Dispute(s) for Executive Resolution. The initial designated senior executives shall be the Chief Commercial Officer of Urovant Sciences, Inc., and the Directing Member of Licensor (or the duly appointed successor). Each Party shall be entitled to name substitute senior executives upon written notice to the other Party.

(b) Subject to Section 13.9(h) (Dispute Resolution), if, after going through the procedure set forth in Section 13.9(a) (Dispute Resolution), the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an Excluded Claim (defined in Section 13.9(g) (Dispute Resolution)) shall be finally resolved by binding arbitration administered by JAMS pursuant to JAMS’ Streamlined Arbitration Rules and Procedures then in effect (the “JAMS Rules”).

(c) The arbitration shall be conducted by a panel of three (3) neutral arbitrators, each of whom shall have significant legal or business experience in the pharmaceutical industry, and none of whom shall be a current or former employee or director, or a current significant shareholder, of either Party or any of their respective Affiliates or any Sublicensee: within thirty (30) days after initiation of arbitration, each Party shall select one (1) person to act as arbitrator and the two (2) Party-selected arbitrators shall select a third (3rd) arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third (3rd) arbitrator, the third (3rd) arbitrator shall be appointed by JAMS. The seat of arbitration shall be New York, New York, the law governing the arbitration shall be the law of the State of New York (U.S.), and all proceedings and communications shall be in English. Within thirty (30) days after selection of the third arbitrator, the arbitrators shall conduct the Preliminary Conference (as defined in the JAMS Rules). In addressing any of the subjects within the scope of the Preliminary Conference, the arbitrators shall take into account both the desirability of making discovery efficient and cost-effective and the needs of the Parties for an understanding of any legitimate issue raised in the arbitration. The award rendered by the arbitrators shall be final,

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction.

(d) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. The arbitrators’ authority to award punitive or any other type of damages not measured by a Party’s compensatory damages shall be subject to the limitation set forth in Section 10.5 (Special, Indirect and Other Losses). Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ fees and any administrative fees of arbitration.

(e) Except to the extent necessary to confirm or enforce an award or as may be required by law, neither Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of the other Party. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable California statute of limitations.

(f) The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

(g) As used in this Section 13.9 (Dispute Resolution), the term “Excluded Claim” means a dispute, controversy or claim that concerns (i) the construction, scope, validity, enforceability, inventorship or infringement of a patent, patent application, trademark or copyright; or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

(h) Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violation of Patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Sections 13.9(b) (Dispute Resolution) and 13.9(c) (Dispute Resolution).

13.10 Performance by Affiliates. Each Party may perform its obligations and exercise any rights hereunder (directly or indirectly) through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party’s obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.

13.11 Headings. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

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13.12 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

13.13 Business Day Requirements. If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission shall be deemed to require such notice or action or omission to be taken on the next occurring Business Day.

13.14 English Language. This Agreement has been prepared in the English language, and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

13.15 Interpretation. All references in this Agreement to the singular include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article include all Sections, subsections and paragraphs in such Article, and references to any Section include all subsections and paragraphs in such Section. The word “including” and similar words mean “including without limitation”. The words “herein,” “hereof” and “hereunder” and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision. The word “or” is used in the conjunctive sense (i.e., “and/or”), unless the context clearly requires otherwise. All references to days in this Agreement mean calendar days, unless otherwise specified. Except as otherwise specified herein, references to a person or entity are also to its permitted successors and assigns.

13.16 Further Assurances. Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

13.17 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.
IN WITNESS WHEREOF, the Parties hereto have caused this LICENSE AGREEMENT to be executed and entered into by their duly authorized representatives as of the Effective Date.

ION CHANNEL INNOVATIONS, LLC

By: /s/ Arnold Melman, M.D.
Name: Arnold Melman, M.D.
Title: Directing Member

UROVANT SCIENCES, GMBH

By: /s/ Sascha Bucher
Name: Sascha Bucher
Title: Head of Global Transactions

SIGNATURE PAGE TO LICENSE AGREEMENT

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
Exhibit A  Licensor Patents as of the Effective Date

• [***]

[***] = CERTAIN CONFIDENTIAL INFORMATION OMITTED
THIS INDEMNITY AGREEMENT (the “Agreement”) is made and entered into as of [date], 20[20] between Urovant Science Ltd., an exempted limited company registered in Bermuda (the “Company”), and [Name] (“Indemnitee”).

RECITALS

A. Highly competent persons have become more reluctant to serve companies as directors or officers or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

B. Although furnishing of insurance to protect persons serving a company and its subsidiaries from certain liabilities has been a customary and widespread practice among Bermuda companies and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to companies or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Bye-laws of the Company permit indemnification of the officers, directors and certain other persons of the Company in accordance with Bermuda law;

C. The uncertainties relating to such liability insurance and to indemnification have increased the difficulty of attracting and retaining such persons;

D. The Board has determined that the increased difficulty in attracting and retaining such persons would be detrimental to the best interests of the Company’s shareholders, and that the Company should act to assure such persons that there will be increased certainty of protection in the future;

E. It is reasonable, prudent, and necessary for the Company to contractually obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

F. This Agreement is a supplement to and in furtherance of the Company’s amended and restated Bye-laws (the “Bye-laws”) and any resolutions adopted pursuant to such indemnification, and will not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee; and

H. Indemnitee may have certain rights to indemnification and insurance provided by other entities or organizations which Indemnitee and such other entities and organizations intend to be secondary to the primary obligation of the Company to indemnify Indemnitee as provided in this Agreement, with the Company’s acknowledgment and agreement to the foregoing being a material condition to Indemnitee’s willingness to serve on the Board.

I. This Agreement supersedes and replaces in its entirety any previous indemnification agreement entered into between the Company and the Indemnitee.
NOW, THEREFORE, in consideration of Indemnitee’s agreement to serve as an officer or a director from and after the date first written above, the parties agree as follows:

1. **Indemnity of Indemnitee.** The Company agrees to hold harmless and indemnify Indemnitee to the fullest extent permitted by law, as such may be amended from time to time in accordance with the terms of this Agreement. In furtherance of this indemnification, and without limiting the generality of such indemnification:

   (a) **Proceedings Other Than Proceedings by or in the Right of the Company.** Indemnitee will be entitled to the rights of indemnification provided in this Section 1(a) if, by reason of his or her Corporate Status, the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding other than a Proceeding by or in the right of the Company. Pursuant to this Section 1(a), Indemnitee will be indemnified against all Expenses, judgments, penalties, fines, and amounts paid in settlement actually and reasonably incurred by him or her, or on his or her behalf, in connection with such Proceeding or any claim, issue, or matter. This indemnification is provided if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and with respect to any criminal Proceeding, had no reasonable cause to believe the Indemnitee’s conduct was fraudulent or dishonest to the extent prohibited by the Companies Act of 1981 of Bermuda, as amended.

   (b) **Proceedings by or in the Right of the Company.** Indemnitee will be entitled to the rights of indemnification provided in this Section 1(b) if, by reason of his or her Corporate Status, the Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding brought by or in the right of the Company. Pursuant to this Section 1(b), Indemnitee will be indemnified against all Expenses actually and reasonably incurred by the Indemnitee, or on the Indemnitee’s behalf, in connection with such Proceeding if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Company. Indemnification will not be provided against such Expenses if made in respect of any claim, issue, or matter in such Proceeding as to which Indemnitee will have been adjudged to be liable to the Company unless and to the extent that a court of competent jurisdiction will determine that such indemnification may be made.

   (c) **Indemnification for Expenses of a Party Who is Wholly or Partly Successful.** Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his or her Corporate Status, a party to and is successful, on the merits or otherwise, in any Proceeding, he or she will be indemnified to the maximum extent permitted by law against all Expenses actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company will indemnify Indemnitee against all Expenses actually and reasonably incurred by him or her or on his or her behalf in connection with each successfully resolved claim, issue, or matter. For purposes of this Section, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, will be deemed to be a successful result as to such claim, issue, or matter.

2. **Additional Indemnity.** In addition to, and without regard to any limitations on, the indemnification provided for in Section 1, the Company agrees to indemnify and hold Indemnitee harmless against all Expenses, judgments, penalties, fines, and amounts paid in settlement actually and reasonably incurred by him or her or on his or her behalf if, by reason of his or her Corporate Status, he or she is, or is threatened to be made, a party to or participant in any Proceeding (including a Proceeding by or in the right of the Company), including, without limitation, any and all liability arising out of the negligence or active or passive wrongdoing of Indemnitee. The only limitation that will exist on the Company’s obligations pursuant to this Agreement will be that the Company will not be obligated to make any payment to Indemnitee that is finally determined (under the procedures, and subject to the presumptions, in Sections 6 and 7) to be unlawful.

2.
3. **Contribution.**

   (a) Whether or not the indemnification provided in Sections 1 and 2 is available, in respect of any threatened, pending, or completed action, suit, or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit, or proceeding), the Company will pay, in the first instance, the entire amount of any judgment or settlement of such action, suit, or proceeding without requiring Indemnitee to contribute to such payment, and the Company waives and relinquishes any right of contribution it may have against Indemnitee. The Company will not enter into any settlement of any action, suit, or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit, or proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee. The Company will not settle any action or claim in a manner that would impose any penalty or admission of guilt or liability on Indemnitee without Indemnitee’s written consent.

   (b) Without diminishing or impairing the obligations of the Company in the preceding subparagraph, if Indemnitee elects or is required to pay all or any portion of any judgment or settlement in any threatened, pending, or completed action, suit, or proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such action, suit, or proceeding), the Company will contribute to the amount of Expenses, judgments, fines, and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the Company and all officers, directors, or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such action, suit, or proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction from which such action, suit or proceeding arose.

   To the extent necessary to conform to law, the proportion determined on the basis of relative benefit may be further adjusted by reference to the relative fault of the Company and all officers, directors, or employees of the Company other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the events that resulted in such expenses, judgments, fines, or settlement amounts, as well as any other equitable considerations which the applicable law may require to be considered. The relative fault of the Company and all officers, directors, or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such action, suit or proceeding), on the one hand, and Indemnitee, on the other hand, will be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary, and the degree to which their respective conduct is active or passive.

   (c) The Company agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be brought by the Company’s officers, directors, or employees, other than Indemnitee, who may be jointly liable with Indemnitee.

   (d) To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, will contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding to reflect: (i) the relative benefits received by the Company and Indemnitee as a result of the events and transactions giving cause to such Proceeding; and (ii) the relative fault of the Company (and its directors, officers, employees, and agents) and Indemnitee in connection with such events and transactions.
4. **Indemnification for Expenses of a Witness.** Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of his or her Corporate Status, a witness, or is made (or asked) to respond to discovery requests, in any Proceeding to which Indemnitee is not a party, he or she will be indemnified against all Expenses actually and reasonably incurred by him or her or on his or her behalf in connection therewith.

5. **Advancement of Expenses.** Notwithstanding any other provision of this Agreement, the Company will advance all Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding by reason of Indemnitee’s Corporate Status within 30 days after the receipt by the Company of a statement from Indemnitee requesting such advance or advances, whether prior to or after final disposition of such Proceeding. Such statement will reasonably evidence the Expenses incurred by Indemnitee and will include or be preceded or accompanied by a written undertaking by or on behalf of Indemnitee to repay any Expenses advanced if it is ultimately determined that Indemnitee is not entitled to be indemnified against such Expenses. Any advances and undertakings to repay pursuant to this Section 5 will be unsecured and interest free.

6. **Procedures and Presumptions for Determination of Entitlement to Indemnification.** It is the intent of this Agreement to secure for Indemnitee rights of indemnity that are as favorable as may be permitted under Bermuda law. Accordingly, the parties agree that the following procedures and presumptions will apply in the event of any question as to whether Indemnitee is entitled to indemnification under this Agreement:

   (a) To obtain indemnification under this Agreement, Indemnitee will submit to the Company a written request with such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification. The Secretary of the Company will, promptly on receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification. Notwithstanding the foregoing, any failure of Indemnitee to provide such request to the Company, or to provide such a request in a timely fashion, will not relieve the Company of any liability that it may have to Indemnitee unless, and to the extent that, such failure actually and materially prejudices the interests of the Company.

   (b) On written request by Indemnitee for indemnification pursuant to the first sentence of Section 6(a), Indemnitee’s entitlement to indemnification will be determined in the specific case:

      (i) by one of the following three methods, which will be at the election of the Board:

         (i) by a majority vote of the Disinterested Directors, even though less than a quorum;

         (ii) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum; or

         (iv) if so directed by the Board, by the shareholders of the Company; or

   (c) In making a determination with respect to entitlement to indemnification under this Agreement, the person or persons or entity making such determination will presume that Indemnitee is entitled to indemnification under this Agreement. Anyone seeking to overcome this presumption will
have the burden of proof and the burden of persuasion by clear and convincing evidence. Neither the failure of the Company (including its Board) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including its Board) that Indemnitee has not met such applicable standard of conduct, will be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(d) Indemnitee will be deemed to have acted in good faith if Indemnitee’s action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Enterprise. In addition, the knowledge and actions, or failure to act, of any director, officer, agent, or employee of the Enterprise will not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement. Whether or not the foregoing provisions of this Section 6(e) are satisfied, it will in any event be presumed that Indemnitee has at all times acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Company. Anyone seeking to overcome this presumption will have the burden of proof and the burden of persuasion by clear and convincing evidence.

(e) If the person, persons, or entity empowered or selected under Section 6 to determine whether Indemnitee is entitled to indemnification has not made a determination within 60 days after receipt by the Company of the request, the requisite determination of entitlement to indemnification will be deemed to have been made, and Indemnitee will be entitled to such indemnification absent (i) a misstatement by Indemnitee of a material fact or an omission of a material fact necessary to make Indemnitee’s statement not materially misleading in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law. Such 60-day period may be extended for a reasonable time, not to exceed an additional 30 days, if the person, persons, or entity making such determination with respect to entitlement to indemnification in good faith requires such additional time to obtain or evaluate documentation or information relating thereto. The provisions of this Section 6(f) will not apply if the determination of entitlement to indemnification is to be made by the shareholders pursuant to Section 6(b) and if (A) within 15 days after receipt by the Company of the request for such determination, the Board or the Disinterested Directors, if appropriate, resolve to submit such determination to the shareholders for their consideration at an annual meeting to be held within 75 days after such receipt, and such determination is made at that annual meeting, or (B) a special meeting of shareholder is called within 15 days after such receipt for the purpose of making such determination, such meeting is held for such purpose within 60 days after having been so called and such determination is made at that special meeting.

(f) Indemnitee will cooperate with the person, persons, or entity making such determination with respect to Indemnitee’s entitlement to indemnification, including providing such person, persons, or entity on reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any member of the Board, or shareholder of the Company will act reasonably and in good faith in making a determination regarding the Indemnitee’s entitlement to indemnification under this Agreement. Any costs or expenses (including attorneys’ fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons, or entity making such determination will be borne by the Company (irrespective of the determination as to Indemnitee’s entitlement to indemnification), and the Company indemnifies and agrees to hold Indemnitee harmless therefrom.

5.
The Company acknowledges that a settlement or other disposition short of final judgment may be successful if it permits a party to avoid expense, delay, distraction, disruption, and uncertainty. In the event that any action, claim, or proceeding to which Indemnitee is a party is resolved in any manner other than by adverse judgment against Indemnitee (including, without limitation, settlement of such action, claim or proceeding with or without payment of money or other consideration) it will be presumed that Indemnitee has been successful on the merits or otherwise in such action, suit, or proceeding. Anyone seeking to overcome this presumption will have the burden of proof and the burden of persuasion by clear and convincing evidence.

The termination of any Proceeding or of any claim, issue, or matter in any Proceeding, by judgment, order, settlement or conviction, or on a plea of nolo contendere or its equivalent, will not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his or her conduct was unlawful.

7. Remedies of Indemnitee.

(a) In the event that (i) a determination is made pursuant to Section 6 that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 5, (iii) subject to the limitations set forth herein, no determination of entitlement to indemnification is made pursuant to Section 6(b) within 90 days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to this Agreement within 10 days after receipt by the Company of a written request for such payment, or (v) payment of indemnification is not made within 10 days after a determination has been made that Indemnitee is entitled to indemnification or such determination is deemed to have been made pursuant to Section 6, Indemnitee will be entitled to an adjudication in an appropriate court in Bermuda or in any other court of competent jurisdiction, of Indemnitee’s entitlement to such indemnification. Indemnitee will commence such proceeding seeking an adjudication within one year following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 7(a). The Company will not oppose Indemnitee’s right to seek any such adjudication.

(b) In the event that a determination has been made pursuant to Section 6(b) that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this Section 7 will be conducted in all respects as a de novo trial on the merits, and Indemnitee will not be prejudiced by reason of the adverse determination under Section 6(b).

(c) If a determination has been made pursuant to Section 6(b) that Indemnitee is entitled to indemnification, the Company will be bound by such determination in any judicial proceeding commenced pursuant to this Section 7, absent (i) a misstatement by Indemnitee of a material fact or an omission of a material fact necessary to make Indemnitee’s misstatement not materially misleading in connection with the application for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) In the event that Indemnitee, pursuant to this Section 7, seeks a judicial adjudication of his or her rights under, or to recover damages for breach of, this Agreement, or to recover under any directors’ and officers’ liability insurance policies maintained by the Company, the Company will pay on his or her behalf, in advance, any and all expenses (of the types described in the definition of Expenses) actually and reasonably incurred by him or her in such judicial adjudication, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of expenses, or insurance recovery.

6.
The Company will be precluded from asserting in any judicial proceeding commenced pursuant to this Section 7 that the procedures and presumptions of this Agreement are not valid, binding, and enforceable, and will stipulate in any such court that the Company is bound by all the provisions of this Agreement. The Company will indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, will (within 10 days after receipt by the Company of a written request therefore) advance, to the extent not prohibited by law, such expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors’ and officers’ liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of Expenses, or insurance recovery, as the case may be.

Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification under this Agreement will be required to be made prior to the final disposition of the Proceeding.

8. Non-Exclusivity; Survival of Rights; Insurance; Primacy of Indemnification; Subrogation.

(a) The rights of indemnification as provided by this Agreement will not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Bye-laws, any agreement, a vote of shareholders, a resolution of Board, or otherwise. No amendment, alteration, or repeal of this Agreement or of any provision of this Agreement will limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his or her Corporate Status prior to such amendment, alteration, or repeal. To the extent that a change in applicable law, whether by statute or judicial decision, permits greater indemnification than would be afforded currently under the Bye-laws, and this Agreement, it is the intent of the parties of this Agreement that Indemnitee will enjoy all greater benefits so afforded by such change. No right or remedy in this Agreement conferred is intended to be exclusive of any other right or remedy, and every other right and remedy given under this Agreement or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy under this Agreement, or otherwise, will not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan, or other enterprise that such person serves at the request of the Company, the Company will procure such insurance policy or policies under which the Indemnitee will be covered in accordance with its or their terms to the maximum extent of the coverage available for any director, officer, employee, agent, or fiduciary under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms of this Agreement, the Company has director and officer liability insurance in effect, the Company will give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures in the respective policies. The Company will thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of such policies.

(c) The Company acknowledges that Indemnitee has or may have in the future certain rights to indemnification, advancement of expenses, or insurance provided by other entities or
organizations (collectively, the “Secondary Indemnitors”). The Company agrees that (i) it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Secondary Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary), (ii) it will be required to advance the full amount of expenses incurred by Indemnitee and will be liable for the full amount of all Expenses, judgments, penalties, fines, and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement, the Company’s Bye-laws (or any other agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Secondary Indemnitors, and (iii) it irrevocably waives, relinquishes, and releases the Secondary Indemnitors from any and all claims against the Secondary Indemnitors for contribution, subrogation, or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Secondary Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company will affect the foregoing and the Secondary Indemnitors will have a right of contribution and be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Secondary Indemnitors are express third party beneficiaries of the terms of this Section 8(c).

(d) Except as provided in Section 8(c), in the event of any payment under this Agreement, the Company will be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee (other than against the Secondary Indemnitors), who will execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(e) Except as provided in Section 8(c), the Company will not be liable under this Agreement to make any payment of amounts otherwise indemnifiable under this Agreement if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement, or otherwise.

(f) Except as provided in Section 8(c), the Company’s obligation to indemnify or advance Expenses under this Agreement to Indemnitee who is or was serving at the request of the Company as a director, officer, employee, or agent of any other corporation, partnership, joint venture, trust, employee benefit plan, or other enterprise will be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan, or other enterprise.

9. Exceptions to Right of Indemnification. Notwithstanding any provision in this Agreement, the Company will not be obligated under this Agreement to make any indemnity in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision, provided that the foregoing will not affect the rights of Indemnitee or the Secondary Indemnitors in Section 8(c);

(b) for an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of shares of the Company;

(c) in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees, or other indemnitees, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law;
(d) with respect to remuneration paid to Indemnitee if it is determined by final judgment or other final adjudication that such remuneration was in violation of law;

(e) a final judgment or other final adjudication is made that Indemnitee’s conduct was fraudulent or dishonest (but only to the extent of such specific determination);

(f) in connection with any claim for reimbursement or any recovery policy of the Company by Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by Indemnitee from the sale of shares of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act or Section 954 of the Dodd-Frank Act, or the payment to the Company of profits arising from the purchase and sale by Indemnitee of shares or securities in violation of Section 306 of the Sarbanes-Oxley Act), if Indemnitee is held liable therefor (including pursuant to any settlement); or

(g) on account of conduct that is established by a final judgment as constituting a breach of Indemnitee’s duty of loyalty to the Company or resulting in any personal profit or advantage to which Indemnitee is not legally entitled.

For purposes of this Section 9, a final judgment or other adjudication may be reached in either the underlying proceeding or action in connection with which indemnification is sought or a separate proceeding or action to establish rights and liabilities under this Agreement.

Any provision herein to the contrary notwithstanding, the Company will not be obligated pursuant to the terms of this Agreement to indemnify Indemnitee or otherwise act in violation of any undertaking appearing in and required by the rules and regulations promulgated under the Securities Act, or in any registration statement filed with the SEC under the Securities Act. Indemnitee acknowledges that paragraph (h) of Item 512 of Regulation S-K promulgated under the Securities Act currently generally requires the Company to undertake, in connection with any registration statement filed under the Securities Act, to submit the issue of the enforceability of Indemnitee’s rights under this Agreement in connection with any liability under the Securities Act on public policy grounds to a court of appropriate jurisdiction and to be governed by any final adjudication of such issue. Indemnitee specifically agrees that any such undertaking will supersede the provisions of this Agreement and to be bound by any such undertaking.

10. Duration of Agreement. All agreements and obligations of the Company contained herein will continue during the period Indemnitee is an officer or director of the Company (or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise) and will continue thereafter so long as Indemnitee will be subject to any Proceeding (or any proceeding commenced under Section 7) by reason of his or her Corporate Status, whether or not he or she is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement. This Agreement will be binding on and inure to the benefit of and be enforceable by the parties of this Agreement and their respective successors (including any direct or indirect successor by purchase, merger, consolidation, or otherwise to all or substantially all of the business or assets of the Company), assigns, spouses, heirs, executors, and personal and legal representatives.
11. Security. To the extent requested by Indemnitee and approved by the Board, the Company may at any time and from time to time provide security to Indemnitee for the Company’s obligations under this Agreement through an irrevocable bank line of credit, funded trust, or other collateral. Any such security, once provided to Indemnitee, may not be revoked or released without the prior written consent of the Indemnitee.

12. Enforcement. (a) The Company expressly confirms and agrees that it has entered into this Agreement and assumes the obligations imposed on it to induce Indemnitee to serve as an officer or director of the Company, and the Company acknowledges that Indemnitee is relying on this Agreement in serving as an officer or director of the Company.

(b) Other than as provided in this Agreement, this Agreement constitutes the entire agreement between the parties with respect to this subject matter and supersedes all prior agreements and understandings, oral, written and implied, between the parties with respect to this subject matter.

13. Definitions. For purposes of this Agreement:

(a) “Beneficial Owner” has the meaning given to such term in Rule 13d-3 under the Exchange Act; provided that Beneficial Owner will exclude any Person otherwise becoming a Beneficial Owner by reason of the shareholders of the Company approving a merger of the Company with another entity.

(b) “Board” means the Board of Directors of the Company.

(c) “Change in Control” means the earliest to occur after the date of this Agreement of any of the following events:

   (i) Acquisition of Securities by Third Party. Any Person is or becomes the Beneficial Owner (as defined above), directly or indirectly, of shares of the Company representing twenty five percent (25%) or more of the combined voting power of the Company’s then outstanding shares;

   (ii) Change in Board. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in clause (i), (iii) or (iv) of this definition of Change in Control) whose election by the Board or nomination for election by the Company’s shareholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority of the members of the Board;

   (iii) Corporate Transactions. The effective date of a merger, amalgamation or consolidation of the Company with any other entity, other than a merger, amalgamation or consolidation which would result in the voting shares of the Company outstanding immediately prior to such merger, amalgamation or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 51% of the combined voting power of the voting shares of the surviving or amalgamated entity outstanding immediately after such merger, amalgamation or consolidation and with the power to elect a majority of the Board or other governing body of such surviving or amalgamated entity;
(iv) **Liquidation.** The approval by the shareholders of the Company of a complete liquidation and winding-up of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company’s assets; and

(v) **Other Events.** There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act, whether or not the Company is then subject to such reporting requirement.

(d) “**Corporate Status**” describes the status of a person who is or was a director, officer, employee, agent or fiduciary of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that such person is or was serving at the express written request of the Company.

(e) “**Disinterested Director**” means a non-executive director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(f) “**Dodd-Frank Act**” means the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

(g) “**Enterprise**” means the Company and any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise that Indemnitee is or was serving at the express written request of the Company as a director, officer, employee, agent or fiduciary.


(i) “**Expenses**” includes all documented and reasonable attorneys’ fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, participating, or being or preparing to be a witness in a Proceeding, or responding to, or objecting to, a request to provide discovery in any Proceeding. Expenses also will include Expenses incurred in connection with any appeal resulting from any Proceeding and any federal, state, local, or foreign taxes imposed on the Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, including without limitation the premium, security for, and other costs relating to any cost bond, supersede as bond, or other appeal bond or its equivalent. Expenses will not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(j) “**Person**” for purposes of the definition of Beneficial Owner and Change in Control set forth above, will have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided that Person will exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of shares of the Company.

(k) “**Proceeding**” includes any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought by or in the right of the Company or otherwise and whether civil, criminal, administrative or investigative, in which Indemnitee was, is or will be involved as a party or otherwise, by reason of the fact that Indemnitee is or was an officer or director of the Company, by reason of any action taken by him or her or of any inaction on his or her part while

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acting as an officer or director of the Company, or by reason of the fact that he or she is or was serving at the request of the Company as a director, officer, employee, agent or fiduciary of another corporation, partnership, joint venture, trust or other Enterprise; in each case whether or not he or she is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification can be provided under this Agreement; including one pending on or before the date of this Agreement, but excluding one initiated by an Indemnitee pursuant to Section 7 of this Agreement to enforce his or her rights under this Agreement.

(l) “Sarbanes-Oxley Act” will mean the Sarbanes-Oxley Act of 2002, as amended.

(m) “SEC” will mean the Securities and Exchange Commission.

(n) “Securities Act” will mean the Securities Act of 1933, as amended.

14. **Severability.** The invalidity or unenforceability of any provision hereof will in no way affect the validity or enforceability of any other provision. Without limiting the generality of the foregoing, this Agreement is intended to confer upon Indemnitee indemnification rights to the fullest extent permitted by applicable laws. In the event any provision hereof conflicts with any applicable law, such provision will be deemed modified, consistent with the aforementioned intent, to the extent necessary to resolve such conflict.

15. **Modification and Waiver.** No supplement, modification, termination or amendment of this Agreement will be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement will be deemed or will constitute a waiver of any other provisions hereof (whether or not similar) nor will such waiver constitute a continuing waiver.

16. **Notice By Indemnitee.** Indemnitee agrees promptly to notify the Company in writing upon being served with or otherwise receiving any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification covered under this Agreement. The failure to so notify the Company will not relieve the Company of any obligation which it may have to Indemnitee under this Agreement or otherwise unless and only to the extent that such failure or delay materially prejudices the Company.

17. **Notices.** All notices and other communications given or made pursuant to this Agreement will be in writing and will be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, and if not so confirmed, then on the next business day, (c) 5 days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications will be sent:

(a) To Indemnitee at the address on the books and records of the Company.

(b) To the Company at:
Urovant Sciences, Inc.
Attention: General Counsel
5151 California Avenue, Suite 250
Irvine, California 92617

or to such other address as may have been furnished to Indemnitee by the Company or to the Company by Indemnitee, as the case may be.

12.
18. **Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same Agreement. This Agreement may also be executed and delivered by facsimile signature, electronic mail (including .pdf or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, e.g., [www.docusign.com](http://www.docusign.com)) or other transmission method and in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument and be deemed to have been duly and validly delivered and be valid and effective for all purposes.

19. **Headings.** The headings of the paragraphs of this Agreement are inserted for convenience only and will not be deemed to constitute part of this Agreement or to affect the construction thereof.

20. **Governing Law and Consent to Jurisdiction.** This Agreement, and all rights, remedies, liabilities, powers and duties of the parties of this Agreement, shall be governed by and construed in accordance with the laws of Bermuda without regard to its principles of conflicts of laws.

[Signature page follows.]
IN WITNESS WHEREOF, the parties hereto have entered into this Agreement effective as of the date first above written.

UROVANT SCIENCES LTD.

By:

Name: ____________________________
Title: ____________________________

INDEMNITEE

Signature of Indemnitee

Print or Type Name of Indemnitee

[Signature page to Urovant Sciences, Inc. Indemnity Agreement]
This Employment Agreement (this “Agreement”) is entered into as of September 14, 2017, by and between Keith Katkin (the “Executive”) and Urovant Sciences, Inc. (the “Company”).

RECATLALS

A. The Company desires the association and services of the Executive and his skills, abilities, background and knowledge, and is willing to engage the Executive’s services on the terms and conditions set forth in this Agreement.

B. The Executive desires to be in the employ of the Company, and is willing to accept such employment on the terms and conditions set forth in this Agreement.

C. This Agreement supersedes any and all prior and contemporaneous oral or written employment agreements or arrangements between the Executive and the Company or any predecessor thereof.

AGREEMENT

In consideration of the foregoing, the parties agree as follows:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position; Duties. Subject to the terms and conditions of this Agreement, the Executive shall hold the position of President and Chief Executive Officer of the Company. In this position, the Executive will have the duties and authorities normally associated with a chief executive officer of a company. The Executive will report to, and be subject to the direction of, the Board of Directors of the Company (the “Board”). The Executive shall devote the Executive’s full business energies, interest, abilities and productive time to the proper and efficient performance of the Executive’s duties under this Agreement; provided, however, that the Executive may devote reasonable periods of time to (a) serving on the board of directors of other corporations subject to the prior approval of the Board, and (b) engaging in charitable or community service activities, so long as none of the foregoing additional activities materially interfere with the Executive’s duties under this Agreement.

1.2 Service to Affiliates. It is understood and agreed that the Executive’s duties may include providing services to or for the benefit of the Company’s affiliates, including, but not limited to, Urovant Sciences, Ltd. (the “Parent”), provided, that the Executive agrees that he will not provide any services from within the United States for the Parent or any affiliate or subsidiary of the Parent that is organized in a jurisdiction outside the United States. In addition, at such time as when the Parent files a registration statement registering an offering of securities under the Securities Act of 1933, the Executive shall become the Principal Executive Officer of the Parent solely for the requirements of the Parent being a registrant with the Securities and Exchange Commission. The Executive will also serve as a member of the Parent’s board of directors (the “Parent Board”) and as a member of the board of directors of Urovant Sciences GmbH, an affiliate
of the Company. The Executive will not become an employee of the Parent, and the Executive’s activities as a Principal Executive Officer of the Parent shall be strictly ministerial and shall not involve conducting any of the Parent’s business activities from within the United States, including day-to-day management or other operational activities of the Parent.

1.3 Location of Employment. The Executive’s principal location of employment shall be the Company’s principal base of operations, which is currently expected to be in Orange County, California, or within fifty (50) miles thereof. The Executive understands that his duties may require periodic business travel, including, for the avoidance of doubt, his required part-time presence in New York, New York during the initial ramp up period of employment that is expected to continue for approximately three (3) months from the Start Date.

1.4 Policies and Procedures. The employment relationship between the parties shall be governed by this Agreement and by the written employment policies and practices established by the Company and/or its Board, to the extent provided to the Executive in advance of the application thereof to the Executive. In the event that the terms of this Agreement differ from or are in conflict with the Company’s policies or practices, this Agreement shall govern and control.

1.5 Exclusive Employment; Agreement not to Participate in Company’s Competitors. Subject to Section 1.1 and 1.2 above, except with the prior written consent of the Board, the Executive will not during his employment with the Company undertake or engage in any other employment, occupation or business enterprise. During the Executive’s employment, the Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by the Executive to be adverse or antagonistic to the Company, its business, or prospects, financial or otherwise, or in any company, person, or entity that is, directly or indirectly, in competition with the business of the Company. Ownership by the Executive in professionally managed funds over which the Executive does not have control or discretion in investment decisions, or, an investment of less than two percent (2%) of the outstanding shares of capital stock of any corporation with one or more classes of its capital stock listed on a national securities exchange or publicly traded on a national securities exchange or in the over-the-counter market shall not constitute a breach of this Section.

1.6 Start Date. The Executive’s employment with the Company shall commence on September 21, 2017 (the “Start Date”).

2. AT-WILL EMPLOYMENT.

The Executive’s employment relationship with the Company is, and shall at all times remain, at-will. This means that either the Executive or the Company may terminate the employment relationship at any time, for any reason or for no reason, with or without Cause (as defined below) or advance notice; provided, however, however, the Executive must provide the Company at least three (3) months’ advance written notice of the Executive’s intention to resign from employment (except for a resignation for Good Reason, in which case such procedure shall be governed by the terms set forth in the definition of Good Reason) and the Company shall provide the Executive written notice in the event of a termination of the Executive’s employment by the Company without Cause.
3. COMPENSATION AND BENEFITS.

3.1 Salary. The Company shall pay the Executive a base salary at the annualized rate of $300,000.00 (the “Base Salary”), less payroll deductions and all required withholdings, payable in regular periodic payments in accordance with the Company’s normal payroll practices. The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day year. The Base Salary shall be subject to periodic review and may be adjusted from time to time in the Board’s discretion in consultation with the Executive and in consideration of peer compensation data, to the extent available, including other affiliates of RSL.

3.2 Annual Performance Bonus. Each fiscal year, the Executive will be eligible to earn an annual discretionary cash bonus (the “Annual Performance Bonus”) with a target bonus opportunity equal to 150% of the Executive’s Base Salary, based on the Board’s assessment of the Executive’s individual performance and overall Company performance. In order to earn and receive the Annual Performance Bonus, the Executive must remain employed by the Company through and including the last day of the applicable fiscal year, which will be on March 31st of the year following the year for which the Annual Performance Bonus relates. The Annual Performance Bonus, if any, will be paid no later than thirty (30) days following the end of the Company’s fiscal year or by April 30th. The Annual Performance Bonus payable, if any, shall be prorated if the Company’s review or assessment of the Executive’s performance covers a period that is less than a full fiscal year. The foregoing to the contrary notwithstanding, with respect to fiscal year 2017, ending on March 31, 2018, the Executive shall be eligible to receive a guaranteed Annual Performance Bonus of $300,000, provided the Executive remains employed by the Company through March 31, 2018. The determination of whether the Executive has earned a bonus and the amount thereof shall be determined by the Board (and/or a committee thereof) in its sole discretion. The Board (and/or a committee thereof) reserves the right to modify the bonus criteria from year to year.

3.3 Equity.

(a) On the Start Date, subject to the terms of the Parent’s 2017 Equity Incentive Plan (the “Plan”) and approval of the grant by the Parent Board, the Executive will be granted an option to purchase 3,750,000 shares of Parent common stock (the “Time-Vesting Options”), which shall vest and become exercisable in accordance with this Section 3.3(a). In addition, on the Start Date, the Executive will be granted an additional option to purchase up to 750,000 shares of Parent common stock (the “Anti-Dilution Options”, and together with the Time-Vesting Options, the “Option Awards”), which shall only be eligible to vest and become exercisable under the circumstances set forth below under Section 3.3(c). The Time Vesting Options will represent 5% of the basic Parent common shares outstanding as of the Start Date. Both the Time-Vesting Options and the Anti-Dilution Options under each Option Award will have an exercise price equal to the fair market value of the common stock on the grant date and will, subject to Section 3.3(c) below, be subject to a 4-year vesting period, with (i) twenty-five percent (25%) of each Option Award vesting on the one-year anniversary of the Start Date and (ii) the balance of the Option Awards vesting in a series of twelve (12) successive equal quarterly installments measured from the first anniversary of the Start Date, provided the Executive is employed by the Company on each such vesting date. The Option Awards will be governed by the Plan and other documents issued in connection with the grants and will expire and cease to be
exercisable on the ten (10) year anniversary of the Start Date. Upon a Change of Control (as defined in the Plan), any unvested portion of the Option Awards (except the portion of the Anti-Dilution Options that have not satisfied the dilution performance condition set forth in Section 3.3(c)) shall immediately vest in full.

(b) The Executive shall also receive a grant of 66,845 restricted stock units in Roivant Sciences Ltd. ("RSL"), an affiliate of the Company (the “RSL Grant”). The RSL Grant will be subject to the terms of the Roivant Sciences Ltd. 2015 Restricted Stock Unit Plan (the “RSL RSU Plan”) and the applicable award agreement. The terms of the RSL Grant shall be identical to the terms of grants made to RSL and Roivant Sciences Inc. senior management team members participating in the RSL RSU Plan. The RSL Grant is subject to approval by the board of directors of RSL.

c) The Time-Vesting Options shall vest and become exercisable in accordance with the conditions set forth in Section 3(a). Until such point that the Company cumulatively raises an aggregate of two hundred million ($200,000,000) in capital (including capital contributions from RSL or otherwise), the Anti-Dilution Options shall, at such times as new common shares of the Parent should be issued (subject further to the time-vesting conditions set forth in Section 3(a) above), become vested in a portion of the Anti-Dilution Options equal to five percent (5%) of the total Parent common shares issued and outstanding in excess of 75,000,000 Parent common shares (excluding any common shares that become issued and outstanding through the exercise or vesting of outstanding equity awards after the date hereof). For the avoidance of doubt, the portion of the Anti-Dilution Options which have not satisfied their performance-vesting dilution condition at such time when the Parent has raised an aggregate of $200 million from any source shall be forfeited. In the event that Parent issues more than an aggregate of 15,000,000 shares of common stock (excluding any common shares that become issued and outstanding through the exercise or vesting of outstanding equity awards after the date hereof) (the “Share Cap”) before the Parent has raised an aggregate of $200 million from any source, then the Executive shall receive one or more additional option grants ("Anti-Dilution Grants") equal to five (5%) of the excess amount over the Share Cap. Any such additional Anti-Dilution Grants will have an exercise price equal to the fair market value of the Parent common shares at the time of grant and have vesting terms, measured from the grant date rather than the Start Date, that are similar to the Time-Vesting Options. The Anti-Dilution Grants will be governed by the Plan and other documents issued in connection with the grants.

Example #1: If the Parent issues 1,000,000 shares in excess of 75,000,000 common shares for consideration not to exceed $200 million of proceeds on the sixth (6th) month anniversary of the Start Date, then five percent (5%) of such 1,000,000 shares (or 50,000 shares) will be eligible for vesting in accordance with Section 3.3(a). Accordingly, 12,500 of these “performance vested” common shares will vest on the one (1) year anniversary of the Start Date, with the remaining 37,500 shares vesting quarterly over the next three (3) years, subject to the Executive’s continued employment on each vesting date.

Example #2: If the Parent issues 3,000,000 shares of common stock in excess of 75,000,000 for consideration not to exceed $200 million of proceeds on the two (2) year anniversary of the Start Date, then five percent (5%) of such 3,000,000 shares (or 150,000 shares) will be eligible for vesting in accordance with Section 3.3(a). Accordingly, 75,000 of these “performance vested” shares will vest on the one (1) year anniversary of the Start Date, with the remaining 75,000 shares vesting quarterly over the next three (3) years, subject to the Executive’s continued employment on each vesting date.
common shares will be immediately vested and exercisable on the two (2) year anniversary of the Start Date, with the remaining 75,000 shares vesting quarterly over the next two (2) years, subject to the Executive’s continued employment on each vesting date.

(d) In addition to the Option Awards and the Anti-Dilution Grants described in Section 3(c), the Executive shall also be eligible to receive semi-annual grants on each six (6)-month anniversary of the Start Date until such time the Parent has raised an aggregate of $200 million from any source (the “Equity Award Anti-Dilution Grants”). The Equity Award Anti-Dilution Grants shall each cover a number of shares equal to five percent (5%) of the net positive number of Parent common shares underlying equity awards that were granted to individuals (other than the Executive) in the prior six (6)-month period less any such equity awards that were forfeited during such six (6)-month period, provided that the cumulative net number of Parent common shares underlying equity grants issued since the Start Date (excluding the Option Awards and the Anti-Dilution Grants) compared to the number of such equity awards forfeited is positive at the time of measurement. The Equity Award Anti-Dilution Grants will have an exercise price equal to the fair market value of Parent common stock on the applicable grant date and will be subject to a 4-year vesting period, with (i) twenty-five percent (25%) of each Equity Award Anti-Dilution Grant vesting on the one-year anniversary of the grant date thereof and (ii) the balance of each Equity Award Anti-Dilution Grant vesting on the one-year anniversary of the grant date thereof and (ii) the balance of each Equity Award Anti-Dilution Grant vesting on the one-year anniversary of the grant date thereof.

3.4 Benefits and Insurance. The Executive shall, in accordance with Company policy and the terms of the applicable plan documents, be eligible to participate in benefits under any benefit plan or arrangement that may be in effect from time to time and made available to similarly situated Company executives (including, but not limited to, being named as an officer for purposes of the Company’s Directors & Officers insurance policy). The Company reserves the right to modify, add or eliminate benefits from time to time. The Executive shall be entitled to vacation each year, in addition to sick leave and observed holidays in accordance with the policies and practices of the Company. Vacation may be taken at such times and intervals as the Executive shall determine, subject to the business needs of the Company.

3.5 Attorney’s Fees. The Executive shall be reimbursed by the Company for the reasonable attorney’s fees incurred by the Executive in negotiating this Agreement, up to twenty five thousand dollars ($25,000), upon the Company’s receipt of such appropriate documentation thereof as the Company may require.
3.6 Expense Reimbursements. The Company will reimburse the Executive for all reasonable business expenses that the Executive incurs in conducting his duties hereunder, pursuant to the Company’s usual expense reimbursement policies. Reimbursement will be made as soon as practicable following receipt from the Executive of reasonable documentation supporting said expenses.

4. PROPRIETARY INFORMATION OBLIGATIONS.

As a condition of employment, the Executive agrees to execute and abide by the Company’s Employee Non-Disclosure and Inventions Assignment Agreement (“NDI”).

5. TERMINATION OF EMPLOYMENT.

5.1 Termination Without Cause Or Resignation For Good Reason. If the Executive’s employment with the Company is terminated without Cause or the Executive resigns for Good Reason (as defined below), then the Company shall pay the Executive any earned but unpaid Base Salary and unused vacation accrued (if applicable) through the date of termination, at the rates then in effect, less standard deductions and withholdings. In addition, if the Executive furnishes to the Company an executed waiver and release of claims in the form attached hereto as Exhibit A (the “Release”) and if the Executive allows the Release to become effective in accordance with its terms, then the Executive shall receive the following benefits:

(a) The Company shall pay the Executive severance in an amount equal to one times (1x) the sum of the (i) Executive’s then current Base Salary and (ii) the Executive’s target Annual Performance Bonus opportunity in respect of the calendar year in which the termination of employment occurs. Said amount shall be paid to the Executive in a single lump sum within five (5) days following the Release becoming effective and irrevocable and will be subject to required withholding. Notwithstanding the foregoing, if such severance amounts are being paid upon a termination under this Section 5.1 within twenty-four (24) months following the consummation of a Change of Control, the multiplier set forth in this Section 5.1(a) shall be two times (2x), rather than one times (1x).

(b) If the Executive is eligible for and timely elects COBRA continuation coverage under the federal COBRA law or applicable state law (collectively, “COBRA”), the Company will reimburse COBRA premiums for the first thirty-six (36) months of COBRA coverage; provided, however, that if the Executive ceases to be eligible for COBRA under applicable law or becomes eligible to enroll in the group health insurance plan of another employer, the Executive shall immediately notify the Company and the Company’s obligation to provide the COBRA premium benefits shall immediately cease. Further, notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law, then in lieu of paying COBRA premiums on the Executive’s behalf, the Company will pay the Executive on a monthly basis a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding.
The Option Awards, including the Anti-Dilution Options, but only to the extent the share raising “performance condition” under the Anti-Dilution Options has previously been satisfied, and any other equity incentive awards granted to the Executive that are subject solely to time-based vesting conditions shall all vest in full upon such termination.

5.2 Other Termination. If the Executive resigns his employment at any time without Good Reason or the Executive’s employment is terminated by the Company at any time for Cause or due to death or Disability (as defined below), the Company shall pay the Executive (or his estate) any Base Salary and any unused vacation accrued (if applicable) through the date of such resignation or termination, at the rates then in effect, less standard deductions and withholdings. In addition, in the event of a termination due to death or Disability, the Executive (or his estate) will be paid an amount equal to the Executive’s target Annual Performance Bonus amount for the year in which such termination occurs prorated to the date of such termination. The Company shall thereafter have no further obligations to the Executive, except as may otherwise be required by law.

5.3 Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

(a) “Cause” shall mean the occurrence of any of the following, the Executive’s: (i) conviction of any felony or any crime involving moral turpitude or dishonesty, (ii) participation in a fraud against the Company, (iii) willful and material breach of the Executive’s duties and obligations under this Agreement or any other agreement between the Executive and the Company or its affiliates that has not been cured (if curable) within thirty (30) days after receiving written notice from the Board of such breach, (iv) intentional and material damage to the Company’s property, or (v) violation of any law, rule or regulation (collectively, “Law”) relating in any way to the business or activities of the Company or its subsidiaries or affiliates, or other Law that is violated during the course of the Executive’s performance of services hereunder that results in the Executive’s arrest, censure, or regulatory suspension or disqualification, including, without limitation, the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a), or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities.

(b) “Disability” shall mean the Executive’s inability to perform his duties and responsibilities hereunder, with or without reasonable accommodation, due to any physical or mental illness or incapacity, which condition has continued for a period of 180 days (including weekends and holidays) in any consecutive 365-day period.

(c) “Good Reason” shall mean the occurrence of any of the following events without the Executive’s consent: (i) a material reduction of the Executive’s Base Salary or target Annual Performance Bonus as initially set forth herein or as the same may be increased from time to time, provided, however, that if such reduction occurs in connection with a Company-wide decrease in executive officer team compensation, such reduction shall not constitute Good Reason provided that it is a reduction of a proportionally like amount or percentage affecting the entire executive team not to exceed 10%; (ii) material reduction in the Executive’s authority, duties or responsibilities, as compared to the Executive’s authority, duties or responsibilities immediately prior to such reduction; or (iii) a change in the Executive’s principal location of employment,

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resulting in an increase in the Executive’s one-way driving distance by more than fifty (50) miles from the Executive’s then current principal residence on file with the Company; provided, however, any resignation by the Executive shall only be deemed for Good Reason pursuant to this definition if: (1) the Executive gives the Company written notice of the Executive’s intent to terminate for Good Reason within ninety (90) days following the first occurrence of the condition(s) that he believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice (the “Cure Period”); and (3) the Executive voluntarily terminates his employment within thirty (30) days following the end of the Cure Period.

(d) A “Change of Control” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) A merger or consolidation in which the Company is a constituent party (or a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation), other than a merger or consolidation in which the voting securities of the Company outstanding immediately prior to such merger or consolidation continue to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation; or

(ii) Any transaction or series of related transactions in which an excess of fifty percent (50%) of the Company’s voting power is transferred, other than the sale by the Company of stock in transactions the primary purpose of which is to raise capital for the Company’s operations and activities; or

(iii) A sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company.

Notwithstanding the foregoing definition, the term Change of Control will not include (x) a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company or Parent, or (y) a liquidation or dissolution ancillary to or in connection with an assignment for the benefit of creditors, a bankruptcy proceeding, appointment of receiver or similar proceeding or transaction.

5.4 “Release Date” shall mean the date that is fifty-five (55) days following the date of the Executive’s termination.

5.5 Effect of Termination. The Executive agrees that should his employment be terminated for any reason, he shall be deemed to have resigned from any and all positions with the Company.

5.6 Section 409A Compliance.

(a) It is intended that any benefits under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended (“Section 409A”), provided under Treasury Regulations
Sections 1.409A-1(b)(4), and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), the Executive’s right to receive any installment payments under this Agreement (whether severance payments, if any, or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits upon or following a termination of employment unless such termination is also a “separation from service” within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a “resignation,” “termination,” “termination of employment” or like terms shall mean separation from service. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of a separation from service to be a “specified employee” for purposes of Section 409A(a)(2)(B)(i), and if any payments or benefits that the Executive becomes entitled to under this Agreement on account of such separation from service are deemed to be “deferred compensation,” then to the extent delayed commencement of any portion of such payments or benefits is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided prior to the earliest of (i) the expiration of the six-month period measured from the date of separation from service, (ii) the date of Executive’s death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such period, all payments deferred pursuant to this paragraph shall be paid in a lump sum, and any remaining payments due shall be paid as otherwise provided herein. No interest shall be due on any amounts so deferred.

(b) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, and (iii) such payments shall be made on or before the last day of the Executive’s taxable year following the taxable year in which the expense was incurred. The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Code Section 409A but do not satisfy an exemption from, or the conditions of, Code Section 409A.

5.7 Section 280G.

(a) If any payment or benefit (including payments and benefits pursuant to this Agreement) that the Executive would receive in connection with a Change of Control or other transaction (the “Transaction”) from the Company or otherwise (“Transaction Payment”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the “Code”), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then (I) in the event of the
consummation of a Transaction prior to the earlier of (x) the consummation of an initial public offering of the Company or the Parent ("IPO") and (y) the 4th anniversary of the Start Date, the Company shall make payment to Executive of a Gross-Up Payment in accordance with the provisions of Exhibit B attached to this Agreement and (II) in the event of the consummation of a Transaction on or after the IPO or the 4th anniversary of the Start Date, whichever is earlier, then the Company shall cause to be determined, before any amounts of the Transaction Payment are paid to the Executive, which of the following two alternative forms of payment would result in the Executive’s receipt, on an after-tax basis, of the greater amount of the Transaction Payment notwithstanding that all or some portion of the Transaction Payment may be subject to the Excise Tax: (1) payment in full of the entire amount of the Transaction Payment (a “Full Payment”), or (2) payment of only a part of the Transaction Payment so that the Executive receives the largest payment possible without the imposition of the Excise Tax (a “Reduced Payment”). For purposes of determining whether to make a Full Payment or a Reduced Payment, the Company shall cause to be taken into account the value of all applicable federal, state and local income and employment taxes and the Excise Tax (all computed at the highest applicable marginal rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of such state and local taxes). If a Reduced Payment is made, (x) the Executive shall have no rights to any additional payments and/or benefits constituting the Transaction Payment, and (y) reduction in payments and/or benefits shall occur in the manner that results in the greatest economic benefit to the Executive as determined in this paragraph. If more than one method of reduction will result in the same economic benefit, the portions of the Transaction Payment shall be reduced pro rata.

(b) Notwithstanding the foregoing, in the event that no stock of the Company is readily tradeable on an established securities market or otherwise (within the meaning of Section 280G of the Code) at the time of the Change of Control of the Company, the Company shall cause a vote of shareholders to be held to approve the portion of the Transaction Payments that equals or exceeds three times (3x) the Executive’s “base amount” (within the meaning of Section 280G of the Code) (the “Excess Parachute Payments”) in accordance with Treas. Reg. §1.280G-1, and the Executive shall cooperate with such vote of shareholders, including the execution of any required documentation subjecting the Executive’s entitlement to all Excess Parachute Payments to such shareholder vote. In the event that the Company does not cause a vote of shareholder to be held to approve all Excess Parachute Payments, the provisions set forth in Section 5.7(a) of this Agreement shall apply.

(c) Unless the Executive and the Company otherwise agree in writing, any determination required under this section shall be made in writing by the Company’s independent public accountants (the “Accountants”), whose determination shall be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this section, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Accountants shall provide detailed supporting calculations to the Company and the Executive as requested by the Company or the Executive. The Executive and the Company shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this section. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this section as well as any costs incurred by Executive with the Accountants for tax planning under Sections 280G and 4999 of the Code.
6. ARBITRATION.

Except as otherwise set forth below in connection with equitable remedies, any dispute, claim or controversy arising out of or relating to this Agreement or the Executive’s employment with the Company (collectively, “Disputes”), including, without limitation, any dispute, claim or controversy concerning the validity, enforceability, breach or termination of this Agreement, if not resolved by the parties, shall be finally settled by arbitration in accordance with the then-prevailing Employment Arbitration Rules and Procedures of JAMS, as modified herein ("Rules"). The requirement to arbitrate covers all Disputes (other than disputes which by statute are not arbitrable) including, but not limited to, claims, demands or actions under the Age Discrimination in Employment Act (including Older Workers Benefit Protection Act); Americans with Disabilities Act; Civil Rights Act of 1866; Civil Rights Act of 1991; Employee Retirement Income Security Act of 1974; Equal Pay Act; Family and Medical Leave Act of 1993; Title VII of the Civil Rights Act of 1964; Fair Labor Standards Act; Fair Employment and Housing Act; and any other law, ordinance or regulation regarding discrimination or harassment or any terms or conditions of employment. There shall be one arbitrator who shall be jointly selected by the parties. If the parties have not jointly agreed upon an arbitrator within twenty (20) calendar days of respondent’s receipt of claimant’s notice of intention to arbitrate, either party may request JAMS to furnish the parties with a list of names from which the parties shall jointly select an arbitrator. If the parties have not agreed upon an arbitrator within ten (10) calendar days of the transmittal date of such list, then each party shall have an additional five (5) calendar days in which to strike any names objected to, number the remaining names in order of preference, and return the list to JAMS, which shall then select an arbitrator in accordance with the Rules. The place of arbitration shall be [Orange County], California. By agreeing to arbitration, the parties hereto do not intend to deprive any court of its jurisdiction to issue a pre-arbitral injunction, including, without limitation, with respect to the NDA. The arbitration shall be governed by the Federal Arbitration Act, 9 U.S.C. §§ 1-16. Judgment upon the award of the arbitrator may be entered in any court of competent jurisdiction. The arbitrator shall: (a) have authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator’s essential findings and conclusions on which the award is based. The Company shall pay all administrative fees of JAMS in excess of $435 (a typical filing fee in court) and the arbitrator’s fees and expenses. Each party shall bear its or his own costs and expenses (including attorney’s fees) in any such arbitration and the arbitrator shall have no power to award costs and attorney’s fees except as provided by statute or by separate written agreement between the parties. In the event any portion of this arbitration provision is found unenforceable by a court of competent jurisdiction, such portion shall become null and void leaving the remainder of this arbitration provision in full force and effect. The parties agree that all information regarding the arbitration, including any settlement thereof, shall not be disclosed by the parties hereto, except as otherwise required by applicable law.

11.
7. **GENERAL PROVISIONS.**

7.1 **Representations and Warranties.** The Executive represents and warrants that the Executive is not restricted or prohibited, contractually or otherwise, from entering into and performing each of the terms and covenants contained in this Agreement, and that the Executive’s execution and performance of this Agreement will not violate or breach any other agreements between the Executive and any other person or entity. In addition, the Executive represents and warrants that the Executive is not debarred and has not received notice of any action or threat with respect to debarment under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) or any similar legislation applicable in the United States or in any other country where the Company intends to develop its activities. The Executive understands and agrees that this Agreement is contingent on the Executive’s submission of satisfactory proof of identity and legal authorization to work in the United States, as well as verification of auditor independence.

7.2 **Advertising Waiver.** The Executive agrees to permit the Company, and persons or other organizations authorized by the Company, to use, publish and distribute advertising or sales promotional literature concerning the products and/or services of the Company in which the Executive’s name and/or pictures of the Executive appear. The Executive hereby waives and releases any claim or right the Executive may otherwise have arising out of such use, publication or distribution.

7.3 **Miscellaneous.** This Agreement, along with the NDA and any applicable equity awards that have been granted, constitutes the complete, final and exclusive embodiment of the entire agreement between the Executive and the Company with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both the Executive and a duly authorized officer or member of the Board. This Agreement will bind the heirs, personal representatives, successors and assigns of both the Executive and the Company, and inure to the benefit of both the Executive and the Company, and to his and its heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California as applied to contracts made and to be performed entirely within California. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. This Agreement may be executed in counterparts and facsimile signatures will suffice as original signatures.
IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first written above.

UROVANT SCIENCES, INC.

By: /s/ Matthew Gline

Name: Matthew Gline
Title: Chief Financial Officer

ACCEPTED AND AGREED:

/s/ Keith Katkin
KEITH KATKIN

[Signature Page to K. Katkin Employment Agreement]
EXHIBIT A

Form Of Release

Reference is hereby made to the employment agreement, dated as of September 14, 2017 between Urovant Sciences Inc. (the “Company”) and Keith Katkin (the “Executive”) (the “Employment Agreement”). Capitalized terms not defined herein shall have the meanings ascribed to them in the Employment Agreement.

WHEREAS, pursuant to the Employment Agreement, as a condition to the right to receive the severance payments in accordance with the terms of the Employment Agreement (the “Separation Benefits”) in the event that the Executive’s employment is terminated without Cause or the Executive resigns for Good Reason, the Executive must, among other things, sign, return and not revoke this general release of claims (this “General Release”); and

WHEREAS, [the Company has terminated the Executive’s employment without Cause] [the Executive has resigned for Good Reason], effective , 20     (the “Separation Date”).

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements contained herein and in the Employment Agreement, and for other good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, the Executive and the Company hereby agree as follows:

1. Separation Benefits/Consideration. Subject to the Executive signing and returning this General Release and this General Release becoming effective and irrevocable within the time periods set forth below, Executive will have the right to receive the Separation Benefits in accordance with the terms of the Employment Agreement. The Executive agrees that (i) he would not have any right to receive the Separation Benefits but for his execution (and non-revocation) of this General Release, and (ii) the Separation Benefits are in full satisfaction of and in fact exceed all amounts and benefits to which the Executive may be eligible to receive arising out of or related to his employment if this General Release does not become effective and irrevocable within the time periods set forth below.

2. General Release. (a) In consideration for the right to receive the Separation Benefits and the mutual promises contained in the Employment Agreement and in this General Release, the Executive (on behalf of himself or herself and his heirs, administrators, representatives, executors, successors and assigns) hereby knowingly and voluntarily releases and discharges, to the fullest extent permitted by law, the Company and its predecessors, successors and assigns, its and their direct or indirect parents, subsidiaries and affiliated entities, and, with respect to each and all of the foregoing entities (including the Company), all of its and their respective present and former officers, directors, employees, agents, attorneys, members, owners, shareholders, partners, members, representatives, trustees, employee benefit plans and administrators or fiduciaries of such plans (all of the foregoing, including the Company, collectively referred to as “Released Parties”), each individually and in their representative capacities, of and from any and all actions, agreements, claims, damages, expenses (including attorney’s fees and costs), judgments, liabilities, obligations or suits of any kind whatsoever, in law, equity or otherwise, in any jurisdiction, whether known or unknown, suspected or claimed,
specifically mentioned herein or not, which the Executive had, has or may have against any of the Released Parties by reason of any actual or alleged act, event, occurrence, omission, practice or other matter whatsoever from the beginning of time up to and including the date that the Executive signs this General Release (collectively, “Claims”), specifically including but not limited to Claims arising out of or in any way relating to:

- the Executive’s services as an employee, officer or director of the Company and/or its predecessors, successors and assigns, and its and their direct or indirect parents, subsidiaries and affiliated entities;
- the Employment Agreement and the termination thereof, any other employment agreement and any compensation, benefits and/or equity interests of any kind in connection with the Executive’s employment;
- any common law, public policy, company policy, contract (whether oral or written, express or implied) or tort law having any bearing whatsoever on the terms and conditions of the Executive’s employment;
- any federal, state or local law, ordinance or regulation including, but not limited to, the following (each as amended, if applicable): Age Discrimination in Employment Act (including Older Workers Benefit Protection Act); Americans with Disabilities Act; Civil Rights Act of 1866; Civil Rights Act of 1991; Employee Retirement Income Security Act of 1974 (except as to any vested benefits under the Company’s ERISA-covered employee benefit plans, if any); Equal Pay Act; Family and Medical Leave Act of 1993; National Labor Relations Act; Title VII of the Civil Rights Act of 1964; Worker Adjustment and Retraining Notification Act; any provision of the California Labor, Civil or Government Code; IWC Wage Orders; and any other law, ordinance or regulation regarding discrimination or harassment or any terms or conditions of employment.

The Executive agrees that he has entered into this General Release as a compromise and in full and final settlement of all Claims, if any, that the Executive has, had or may have against any and all of the Released Parties up to and including the date that the Executive signs this General Release. The Executive also agrees that, although he may hereafter discover Claims presently unknown or unsuspected, or new or additional facts from those which he now knows or believes to be true, the Executive intends to provide a complete waiver of all Claims based on any facts and circumstances, whether known or unknown, up to and including the date that the Executive signs this General Release. In this regard, the Executive further agrees that all of his rights under Section 1542 of the Civil Code of the State of California (and any equivalent provision of any statute of the United States or any other state or jurisdiction) are hereby waived. Section 1542 provides as follows:

A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor.

2.
(b) Notwithstanding the foregoing, “Claims” does not include (i) claims to enforce the terms of this General Release, (ii) claims that arise after the date that Executive signs this General Release (other than any claims relating to continuing or future effects of alleged past discrimination), and/or (iii) claims that cannot be released by a private settlement agreement (such as statutory claims for worker’s compensation/disability insurance benefits and unemployment insurance benefits), the rights to all of which are hereby specifically reserved.

(c) The Executive represents that he has not assigned or transferred his rights with respect to any Claims and that he has not filed, directly or indirectly, any legal proceeding against any Released Parties regarding any Claims. If the Executive commences (or commenced) or participates in any action or proceeding (including as a member of a class of persons) relating to any Claims, this General Release shall be a complete defense in such action or proceeding with respect to such Claims and, to the maximum extent permitted by law, the Executive (and his heirs, administrators, executors, representatives, successors and assigns) will have no right to obtain or receive, and will not seek or accept, any damages, settlement or relief of any kind (including attorneys’ fees and costs) in connection with such Claims.

3. Covenants of the Executive. The Executive acknowledges and agree that he continues to be bound by the terms and covenants set forth in the Employee Non-Disclosure and Inventions Assignment Agreement between the Executive and the Company (the “NDA”), which will continue to remain in full force and effect for the periods set forth therein. The Executive also agrees that any obligations of his or hers pursuant to provisions of the Company’s employee handbook and/or any other Company policies or agreements relating to confidential or proprietary information and intellectual property (the “Confidentiality/IP Policies”) will continue to remain in full force and effect in accordance with their terms.

4. Entire Agreement; Severability. (a) Upon its effectiveness, this General Release (the NDA and the Confidentiality/IP Policies, all of which are incorporated herein by reference) contains the entire agreement and understanding of the parties relating to the subject matter hereof and supersedes and replaces all prior and contemporaneous agreements, representations and understandings (whether oral or written) regarding the subject matter hereof. The Executive acknowledges that no promises or representations, oral or written, have been made relating to the subject matter hereof, and that the Executive has not relied on any other promises or representations in signing this General Release. This General Release may be modified only in a document signed by the Executive and the Company and referring specifically hereto, and no handwritten changes to this General Release will be binding unless initialed by the Executive and the Company.

(b) If any provision of this General Release is held to be unenforceable for any reason, the parties intend that such portion be modified to make it enforceable to the maximum extent permitted by law. If any such provision (other than the general release provisions contained in Section 2(a) hereof) cannot be modified to be enforceable, such provision shall become null and void leaving the remainder of this General Release in full force and effect.

5. Governing Law. This General Release shall be governed by and construed and enforced in accordance with the laws of the State of California, without regard to its rules regarding conflict of laws.

3.
6. **Miscellaneous; Breach.** (a) This General Release shall be binding upon and inure to the benefit of (i) the Released Parties, including the successors and assigns of the Released Parties, all of which are intended third-party beneficiaries, and (ii) the Executive and his heirs, executors, administrators, representatives, successors and assigns (but, in any event, this General Release is not assignable by the Executive and any purported assignment by the Executive shall be null and void). This General Release is not an admission of liability or wrongdoing by the Executive or any of the Released Parties, and such wrongdoing or liability is expressly denied. This General Release may be executed in counterparts, each of which will be deemed an original, but all of which will be deemed one and the same instrument. Any facsimile or pdf copy of any party’s executed counterpart of this General Release will be deemed to be an executed original thereof. All payments and benefits provided hereunder shall be subject to the withholding of all applicable taxes and deductions required by any applicable law.

(b) In the event of a breach (or threatened breach) by the Executive, the Executive agrees that the Released Parties (i) would have no adequate remedy at law and would be irreparably harmed, (ii) shall therefore be entitled to injunctive relief (without proving actual damages or posting a bond or other security), both preliminary and permanent, enjoining such breach (or threatened breach) and (iii) in the event of a breach of the NDA or the Confidentiality/IP Policies, shall not be required to make any further Separation Benefits to the Executive, for the period starting immediately following such breach and the Executive shall be required to return any Separation Benefits made from the date such breach is determined to have occurred (but, in any event, the Executive shall continue to be subject to and bound by the terms of this General Release and also the NDA and the Confidentiality/IP Policies in accordance with the terms stated therein). Such remedies shall be in addition to all other remedies available at law or in equity.

7. **Review/Revocation.** The Executive acknowledges that he has been given at least 21 days from his receipt of this General Release to consider its meaning and effect and to determine whether he wishes to sign it. If the Executive signs this General Release before the 21 days are over, the Executive agrees that he is voluntarily waiving the rest of the 21 days without any encouragement or pressure from any of the Released Parties to do so. The Executive also agrees that any modifications to this General Release, whether material or immaterial, will not restart the 21-day period. **UPON ITS EFFECTIVENESS, THIS GENERAL RELEASE WILL BE A LEGAL AND BINDING CONTRACT. AS SUCH, THE EXECUTIVE IS AND HAS BEEN ADVISED AND ENCOURAGED TO CONSULT WITH AN ATTORNEY OF HIS CHOOSING (AT HIS OWN EXPENSE) BEFORE SIGNING THIS GENERAL RELEASE.** Once the Executive signs this General Release, he may change his mind and revoke his acceptance of this General Release but only within seven (7) days after the date that he signed it. In order to do so, any revocation must be in writing and sent to the Executive by overnight mail, signature required, within the seven (7) days after the date that the Executive signed this General Release. This General Release shall not become effective until after the expiration of the revocation period described in this paragraph. If the Executive does not revoke this General Release within the seven (7) day period, this General Release will become effective, enforceable and irrevocable on the eighth (8th) day after the date on which the Executive signed this General Release.

*        *        *

4.
BY SIGNING THIS GENERAL RELEASE, THE EXECUTIVE AGREES THAT HE HAS READ IT IN ITS ENTIRETY AND UNDERSTANDS ALL
OF ITS TERMS AND EFFECTS, INCLUDING THAT HE IS PROVIDING A COMPLETE RELEASE OF ALL “CLAIMS,” WHETHER KNOWN OR
UNKNOWN, UP TO AND INCLUDING THE DATE THAT HE SIGNS THIS GENERAL RELEASE. THE EXECUTIVE ACKNOWLEDGES THAT HE
HAS HAD AMPLE TIME TO REVIEW THIS GENERAL RELEASE AND TO CONSULT WITH AN ATTORNEY (IF HE SO CHOSE) AND THAT HE IS
SIGNING IT KNOWINGLY AND VOLUNTARILY. THE EXECUTIVE ALSO ACKNOWLEDGES THAT THE “SEPARATION BENEFITS” ARE
GREATER THAN ANY PAYMENTS OR BENEFITS TO WHICH THE EXECUTIVE MAY OTHERWISE BE ENTITLED IF HE DID NOT EXECUTE
THIS GENERAL RELEASE.

For the right to receive the Separation Benefits in accordance with the terms of this General Release and the mutual promises contained in the
Employment Agreement and in this General Release, the Executive must (i) sign and date this General Release where indicated below, (ii) return the
signed General Release to , on or before 2018 and (iii) not revoke this General Release within the time period set forth in
Section 7 above. If the Executive does not sign and return this General Release on or before such date (or if the Executive revokes it as set forth above),
the Executive will not be eligible to receive the Separation Benefits; however, in any event, the termination of the Executive’s employment will still
be effective as of the Separation Date.

IN WITNESS WHEREOF, and intending to be legally bound hereby, the parties hereto have executed this General Release as of the dates and
years written below.

UROVANT SCIENCES INC.: EXECUTIVE:

By: ________________________________ By: ________________________________

Name: Executive

Title: 

Date: Date:

5.
EXHIBIT B

(a) Except as set forth below, in the event it shall be determined that any Payment would be subject to the Excise Tax, then the Executive shall be entitled to receive from the Company an additional payment (the “Gross-Up Payment”) in an amount such that after payment by Executive of all taxes (including any interest or penalties imposed with respect to such taxes), including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Tax imposed upon the Gross-Up Payment, but excluding any income taxes and penalties imposed pursuant to Section 409A, the Executive retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. For the avoidance of doubt, the Company’s obligation to make Gross-Up Payments under this Exhibit B shall not be conditioned upon the Executive’s termination of employment.

(b) All fees and expenses of the Accountants shall be borne solely by the Company. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accountants hereunder, it is possible that Gross-Up Payments that will not have been made by the Company should have been made (the “Underpayment”) or Gross-Up Payments that have been made by the Company should not have been made (“Overpayment”), consistent with the calculations required to be made hereunder. In the event that the Company exhausts its remedies set forth below and the Executive thereafter is required to make a payment of any Excise Tax, the Accountants shall determine the amount of the Underpayment or Overpayment, as applicable, that has occurred and any such Underpayment shall be promptly paid by the Company to or for Executive’s benefit and any such Overpayment shall be promptly paid by the Executive to the Company, as applicable.

(c) Any Gross-Up Payment, as determined by the Accountants, shall be paid by the Company to Executive within ten (10) days of the receipt of the Accountants’ determination; provided that, the Gross-Up Payment shall in all events be paid no later than the end of Executive’s taxable year next following Executive’s taxable year in which the Excise Tax (and any income or other related taxes or interest or penalties thereon) on a Payment are remitted to the Internal Revenue Service or any other applicable taxing authority.

(d) To the extent requested by the Company, Executive shall cooperate with the Company in good faith in valuing, and the Accountants shall take into account the value of, services provided or to be provided by Executive (including without limitation, Executive agreeing to refrain from performing services pursuant to a covenant not to compete or similar covenant) before, on or after the date of a change in ownership or control of the Company (within the meaning of Q&A-2(b) of Section 280G of the Code), such that payments in respect of such services (or refraining from performing such services) may be considered reasonable compensation within the meaning of Q&A-9 and Q&A-40 to Q&A-44 of Section 280G of the Code and/or exempt from the definition of the term “parachute payment” within the meaning of Q&A-2(a) of Section 280G of the Code in accordance with Q&A-5(a) of Section 280G of the Code.
Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated June 4, 2018, in Amendment No. 3 to the Registration Statement (Form S-1 No. 333-226169) and related Prospectus of Urovant Sciences Ltd. for the registration of its common shares.

/s/ Ernst & Young LLP
Iselin, New Jersey
August 30, 2018