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

FORM 10-K

☐ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended March 31, 2020

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

Commission File Number 001-38667

Urovant Sciences Ltd.
(Exact name of Registrant as specified in its Charter)

Bermuda
(State or other jurisdiction of incorporation or organization)

98-1463099
(L.R.S. Employer Identification No.)

11-12 St. James's Square
London SW1Y 4LB, United Kingdom
(Address of principal executive offices)

Registrant’s telephone number, including area code: +44 (0)207 400-3347

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

Common Shares, $0.000037453 par value

UROV
Nasdaq Global Select Market

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

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

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

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

The aggregate market value of the voting common shares held by non-affiliates of the registrant as of the end of the registrant’s most recently completed second fiscal quarter ended September 30, 2019 was approximately $71,228,000 based on the closing price of the registrant’s common shares as reported on the Nasdaq Global Select Market on September 30, 2019 of $9.47 per share. As of June 18, 2020, there were 30,799,340 common shares issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

With the exception of the portions of the 2020 Proxy Statement expressly incorporated into this Annual Report on Form 10-K by reference, such document shall not be deemed filed as part of this Annual Report on Form 10-K.
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**Signatures**

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PART I

Introduction

Unless the context requires otherwise, references in this Annual Report on Form 10-K to “Urovant,” the “Company,” “we,” “us,” and “our” refer to Urovant Sciences Ltd. and its wholly owned subsidiaries.

All brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K may appear without the ® or ™ symbols. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We maintain our books and records in U.S. dollars, and prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States as issued by the Financial Accounting Standards Board. All references to “shares” in this Annual Report refer to common shares of Urovant Sciences Ltd., par value $0.000037453 per share.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The forward-looking statements involve substantial risks and uncertainties and are contained principally in the sections titled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” but are also contained elsewhere in this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “intend,” “likely,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “to be,” “will” and “would,” or the negative or plural of these words or similar expressions or variations, although not all forward-looking statements contain these identifying words. 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 Annual Report on Form 10-K, 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.

The forward-looking statements appearing in a number of places throughout this Annual Report on Form 10-K include, but are not limited to, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- expectations regarding the timing, costs and results of clinical trials;
- expectations regarding the progress, timing and costs associated with submissions for regulatory approvals and our ability to obtain and maintain such approvals;
- the potential advantages and differentiated profile of vibegron compared to existing therapies for OAB;
- expectations regarding product development and commercialization activities, if approved, including our sales force plans;
- expectations regarding market opportunity, acceptance and success of our product candidates, if approved;
- expectations regarding the scalability of the manufacturing capabilities of our third-party manufacturers if our product candidates are approved;
- expectations regarding intellectual property protection for our product candidates;
- our estimates regarding our future results of operations and sources of funding;
- developments and projections relating to our competitors or our industry; and
- the impact of the COVID-19 pandemic on our supply chain, business operations, future commercialization efforts, clinical trials and other aspects of our business.
Forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled “Risk Factors” set forth in Part I. Item 1A. of this Annual Report on Form 10-K, elsewhere in this Annual Report on Form 10-K and in our other filings with the U.S. Securities Exchange Commission, or SEC. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, 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. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Item 1. Business.

Overview and Recent Developments

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Our goal is to be a leading urology company by developing, commercializing and acquiring innovative therapies. Our lead product candidate, vibegron, is an oral, once-daily, small molecule that was observed to be a highly selective agonist of the human beta-3 adrenergic receptor in in vitro assays. Vibegron is currently being developed for three potential indications: overactive bladder, or OAB, the treatment of OAB in men with benign prostatic hyperplasia, or BPH, and the treatment of abdominal pain due to irritable bowel syndrome, or IBS. Our second product candidate, URO-902, is a novel gene therapy that we are developing for patients with OAB who have failed oral pharmacological therapy.

Vibegron Development

OAB is a highly prevalent condition, with more than 30 million Americans over the age of 40 suffering from bothersome symptoms. We believe vibegron, 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. In large, randomized, placebo-controlled, international Phase 2b and Japanese Phase 3 clinical trials conducted by third parties with 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.

In March 2018, we initiated an international pivotal Phase 3 EMPOWUR trial evaluating vibegron for the treatment of OAB. See “Vibegron for the Treatment of Overactive Bladder—Phase 3 EMPOWUR Trial for Overactive Bladder” below for further information. Our Phase 3 clinical trial had a design in line with the international Phase 2b and Japanese Phase 3 clinical trials. In March 2019, we reported positive top-line results from this pivotal Phase 3 clinical trial with over 1,500 patients, with vibegron 75 mg meeting both co-primary efficacy endpoints and all seven key secondary endpoints. Onset of action for the co-primary endpoints was observed as early as week two, the first timepoint measured, and statistically significant efficacy was maintained at all timepoints measured through the end of the study. In September 2019, we reported positive long-term data from the double-blind extension of our pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. In this double-blind extension of the Phase 3 EMPOWUR trial with over 500 patients, vibegron 75 mg further improved the treatment benefit on key OAB symptoms such as acts of urination, or micturitions, urge urinary incontinence, or UUI, urgency and total incontinence over the 40-week extension period. We submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in December 2019. The FDA accepted our NDA submission in March 2020 and our NDA submission has been assigned a Prescription Drug User Fee Act, or PDUFA, goal date of December 26, 2020. 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 clinically relevant QTc signal at any of the human doses tested.
In March 2019, we initiated the Phase 3 COURAGE randomized, double blind, placebo-controlled trial for OAB in men with BPH who are also taking BPH medications but continue experiencing OAB symptoms. The Phase 3 COURAGE trial will enroll approximately 1,000 patients. The study is being conducted in two phases, with the first phase focusing on safety and the second phase, which began enrollment in October 2019, assessing efficacy and safety, and is testing vibegron 75 mg versus placebo, the same dose studied in our Phase 3 EMPOWUR trial. The primary efficacy analysis for the co-primary efficacy endpoints will be measured at 12 weeks and include change from baseline in the average number of micturitions per 24 hours and change from baseline in the average number of urgency episodes per 24 hours. Secondary endpoints include change from baseline in the average number of nocturia episodes per night, which is awakening at night to use the bathroom to urinate. The duration for the double-blind study is 24 weeks. In addition, a 28-week open-label extension study will evaluate the long-term safety and efficacy of vibegron in men with OAB symptoms and on another therapy for BPH. We completed the first part of the Phase 3 COURAGE trial and began the second part of the trial in October 2019. We expect to receive top-line data from the Phase 3 COURAGE trial in the second half of 2021.

In December 2018, we enrolled our first patient in a 200 patient Phase 2a randomized, double blind, placebo-controlled trial with vibegron 75 mg for abdominal pain in women due to IBS with predominant diarrhea, or IBS-D, or mixed episodes of diarrhea and constipation, or IBS-M. The primary endpoint is a 30% reduction in abdominal pain intensity, while secondary endpoints will include Global Improvement Scale ratings, stool symptoms and safety. We expect to complete enrollment in the summer of 2020 and receive top-line data from the Phase 2a clinical trial in the fourth calendar quarter of 2020.

We received an exclusive license to develop, manufacture and commercialize vibegron worldwide, excluding Japan, China, and certain other Asian territories, pursuant to our license agreement with Merck Sharp & Dohme Corp., or Merck, which we entered into in February 2017. The licensed patents and patent applications under this license agreement cover composition of matter, methods of use and manufacture of vibegron, and we expect to maintain patent exclusivity until approximately 2034, including through grant of patent term extension on a composition of matter patent. Vibegron is also being developed and marketed by Kyorin Pharmaceutical Co., Ltd., or Kyorin, for the treatment of OAB in Japan and certain other Asian territories. Kyorin received marketing approval from Japan’s Ministry of Health, Labour and Welfare for vibegron for the treatment of adults with OAB in September 2018.

**URO-902 Development**

Our second product candidate, URO-902, 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. In December 2019, we enrolled our first patient in the placebo-controlled, randomized, multicenter proof-of-concept Phase 2a clinical trial to evaluate the safety and efficacy of URO-902 for the treatment of OAB in 78 female patients who have not responded to oral pharmacological therapies. The Phase 2a trial is expected to enroll patients in two cohorts: the first cohort will receive either a single administration of 24 mg of URO-902 or matching placebo, and the second cohort will receive 48 mg of URO-902 or matching placebo into the bladder wall. An unblinded review of safety data via an independent Data Safety Monitoring Board will be performed after all subjects in the first cohort reach week 6. Study treatment for the second cohort will begin only after the Data Safety Monitoring Board has agreed that we can proceed with the second cohort. Patients are followed for up to 48 weeks after initial administration. The key efficacy endpoints for this Phase 2a clinical trial include reductions per day in micturitions, urgency episodes and UUI episodes. We expect to receive the week 12 primary efficacy and safety top-line data from both cohorts in the Phase 2a clinical trial in the second half of 2021 and full trial data after the completion of the 48-week post-treatment period in 2022.

We received an exclusive license to develop, manufacture and commercialize URO-902 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 an international patent application relating to URO-902 gene therapy, covering the use of URO-902 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 URO-902 would receive 12 years of marketing exclusivity if approved by the FDA given its status as a biological product.
Sale of RSL’s Interest in the Company

In December 2019, Sumitovant Biopharma Ltd., a subsidiary of Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo, became our majority shareholder and a related party after acquiring approximately 74.9% of our common shares outstanding. These common shares were acquired from our former majority shareholder, Roivant Sciences Ltd., or RSL, at the closing of a transaction between RSL and Sumitomo. As of March 31, 2020, Sumitovant directly, and Sumitomo indirectly, owns approximately 75.0% of our outstanding common shares. As a result of the transfer of these common shares, RSL no longer beneficially owns any of our common shares. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Fiscal Year Ended March 31, 2020 and Recent Clinical and Business Highlights—Sale of RSL’s Interest in the Company” for additional information.

Our Development Program

Our development programs and expected upcoming milestones are summarized in the following figure:

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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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<td>Vibegron</td>
<td>Overactive Bladder (OAB)</td>
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<td>PDUFA goal date December 26, 2020</td>
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<td></td>
<td>OAB in Men with BPH</td>
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<td>Phase 3 top-line data 2H 2021</td>
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<td>IBS-Associated Pain</td>
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<td>Phase 2a top-line data 4Q 2020</td>
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<td>URO-902</td>
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<td>Phase 2a primary top-line data 2H 2021</td>
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</table>

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 2019, we reported positive top-line results from our international pivotal Phase 3 EMPOWUR trial evaluating vibegron for the treatment of OAB. In this pivotal Phase 3 clinical trial, vibegron 75 mg met both co-primary efficacy endpoints and all seven key secondary endpoints. We submitted our NDA to the FDA in December 2019 and have been assigned a PDUFA goal date of December 26, 2020.

- Expand and complete the clinical development of vibegron for additional indications. In December 2018, we initiated a Phase 2a clinical trial of vibegron for abdominal pain due to IBS. We also initiated a Phase 3 clinical trial of vibegron for OAB in men with BPH in March 2019. 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 an initial sales force of approximately 160 persons in the United States, targeting high-prescribing urologists and other specialists that treat a high number of patients with urologic conditions and prescribers in long-term care facilities. We intend to scale the commercial presence to reach additional health care professionals as vibegron sales grow. We believe that our commercial leadership team, with experience launching prescription products in the OAB market, 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. Where appropriate, we may seek to partner with Sumitomo or its subsidiaries to leverage their existing commercial infrastructure.
Advance the clinical development of URO-902 as a novel treatment for OAB patients who have not responded to oral pharmacological therapies. We initiated a Phase 2a clinical trial of URO-902 for the treatment of OAB patients who have not responded to other pharmacological therapies in December 2019. 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 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, Sumitovant, and its subsidiaries and affiliates have extensive experience in 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.

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. In 2019, over 18 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. The OAB patient experience is depicted below.

OAB presents a significant burden on healthcare systems. A study performed in 2018 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 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 2019, over 18 million prescriptions for oral OAB medications were written for an estimated 3.3 million patients in the United States. We estimate that approximately 72% of treated OAB patients discontinue oral therapy within one year. 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 $39 million per year in net sales based on mirabegron’s market share of 21% and net sales of $821 million reported for fiscal year 2019.

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 were initially prescribed anticholinergic drugs. Of these, 71% discontinue 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, 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. 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 for several weeks due to urinary retention. 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. According to IQVIA NPA and IQVIA Launch Edition, of the 18.6 million total oral OAB prescriptions in the United States in 2019, mirabegron’s total prescriptions increased to 3.9 million, or a growth of 19% from 2018. Further, mirabegron’s market share of total oral OAB prescriptions grew from 17% in 2018 to 21% in 2019. Astellas reported net sales of mirabegron in the Americas of $821 million for the fiscal year ended March 31, 2020, representing growth of approximately 13% over the prior fiscal year. The graph below shows the total beta-3 OAB prescription share since the launch of mirabegron in 2012.

Despite its success, mirabegron requires a stepwise increase in dose, or dose titration, that results in a slow onset of action. Mirabegron is also 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 an IQVIA Longitudinal Study Among Diagnosed OAB patients (March 2014 to September 2017), 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 a highly selective agonist of the human beta-3 adrenergic receptor in *in vitro* assays. We are developing vibegron for the treatment of OAB.

We believe vibegron, 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 both co-primary endpoints (statistically significant reduction in daily micturitions and daily UUI episodes) and all seven key secondary endpoints in our international pivotal Phase 3 EMPOWUR trial.** In this pivotal Phase 3 clinical trial, vibegron 75 mg met both co-primary efficacy endpoints and all seven key secondary endpoints, including a clinically meaningful reduction in daily urgency episodes. In the primary efficacy analysis, once-daily vibegron met the co-primary endpoints at week 12, achieving statistical significance over placebo on both reduction in daily UUI episodes (p<0.0001) and reduction in daily micturitions (p<0.001). The difference from placebo was statistically significant as early as week 2, which was the first timepoint measured, for both episodes and micturitions (p<0.0001 and p<0.001, respectively), and statistically significant efficacy was maintained at all timepoints measured through the end of the study for both endpoints. Additionally, at all measured timepoints, vibegron achieved numerically better efficacy than tolterodine, the active control in this study, which is a currently available OAB treatment. All seven pre-specified key secondary endpoints were met, including a statistically significant reduction in daily urgency episodes compared to placebo (p=0.002).
Statistically significant reduction in daily UUI and total incontinence episodes from baseline to week 52 between vibegron and tolterodine. A post-hoc analysis was performed on the results from the double-blind extension of our pivotal Phase 3 EMPOWUR trial to compare the change from baseline to week 52 results between vibegron and the active control, tolterodine. In the post-hoc analysis, vibegron showed a statistically significant reduction in daily UUI and total incontinence episodes from baseline to 52 weeks compared to tolterodine.

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 previously conducted by third parties, 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 a highly selective agonist of the human beta-3 adrenergic receptor in vitro assays. In vitro studies conducted comparing the selectivity of vibegron with mirabegron have demonstrated that vibegron is a highly selective agonist of beta-3 relative to beta-1 and beta-2 agonism.

Rapid onset of action. In clinical trials, vibegron has demonstrated an onset of action in as early as two weeks. In our international pivotal Phase 3 EMPOWUR trial, vibegron achieved rapid onset by two weeks in both co-primary endpoints and reduction in daily urgency episodes, making vibegron the only beta-3 agonist to demonstrate an onset of action by two weeks.

Potential for broader efficacy claims, including urgency data, based on successfully meeting the co-primary and all seven key secondary 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 the most important secondary endpoint, as well as additional data to support potentially broader efficacy claims, in the vibegron label, if approved by the FDA.

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.

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.

Single, convenient dose. Our pivotal Phase 3 EMPOWUR trial studied a single, fixed dose of vibegron. If approved, vibegron will be the only beta-3 agonist available that does not require dose titration.

Crushable dose formulation. We completed the pharmacokinetic study on food effect and the crushed tablet of vibegron 75 mg. The study results potentially support the proposed labeling for administration of vibegron with or without food. The study results also support the proposed labeling for administration of vibegron as a crushed tablet in soft food. If the proposed labeling is approved, 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.

**Phase 3 EMPOWUR Trial 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 was a randomized, double-blind, placebo- and active comparator-controlled clinical trial in men and women with OAB having or not having UUI episodes. The trial had a design in line with the Phase 2b clinical trial conducted by Merck and the Japanese Phase 3 clinical trial conducted by Kyorin. Enrollment of more than 1,500 patients into the EMPOWUR trial was completed in October 2018.

Enrolled patients were randomized across more than 200 sites into 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. Additionally, more than 500 patients completing the initial 12-week blinded assessment enrolled in a 40-week double-blind extension study to evaluate the safety and efficacy of longer-term treatment.

In March 2019, we reported positive top-line results from our international pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. Vibegron met co-primary endpoints demonstrating highly significant reduction in daily urge urinary incontinence episodes and micturitions. Vibegron also met all seven key secondary endpoints, including a clinically meaningful reduction in daily urgency episodes and micturitions. Vibegron also met all seven key secondary endpoints, including a clinically meaningful reduction in daily urgency episodes.

To be eligible for the EMPOWUR trial, patients had to 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, patients were required to 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 exceeding stress urinary incontinence episodes.

The co-primary efficacy endpoints at week 12 of our Phase 3 EMPOWUR trial were:

- 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 having UUI episodes.

Secondary endpoints included, 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. In addition, adverse events were monitored during both the trial and the extension study. Two patients, ages 63 and 75 and with multiple comorbidities, died in our EMPOWUR clinical program enrolling over 1,500 patients. In both cases, the investigators deemed the deaths not treatment-related. Separately, our independent assessment also deemed each death not treatment-related. The death in the 75-year-old patient occurred in the tolterodine ER treatment group. The death of the 63-year-old patient (arteriosclerotic cardiovascular disease) occurred in the vibegron treatment group of the 40-week extension study.

In the primary efficacy analysis, once-daily vibegron met the co-primary endpoints at week 12, achieving statistical significance over placebo on both reduction in daily UUI episodes (p<0.0001) and reduction in daily micturitions (p<0.001). The difference from placebo was statistically significant as early as week 2, which was the first timepoint measured, for both UUI episodes and micturitions (p<0.0001 and p<0.001, respectively), and statistically significant efficacy was maintained at all timepoints measured through the end of the study for both endpoints. Additionally, at all measured timepoints, vibegron achieved numerically better efficacy than tolterodine, the active control in this study, which is a currently available OAB treatment.
Vibegron met all seven pre-specified key secondary endpoints, including a statistically significant reduction in daily urgency episodes compared to placebo (p=0.002). Secondary endpoints included, 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.

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 typically requires a p-value of 0.05 or less to demonstrate statistical significance. The results of the co-primary and key secondary endpoints used in our Phase 3 EMPOWUR trial at the end of the study are depicted below.

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Vibegron</th>
<th>n</th>
<th>p-value</th>
<th>Tolterodine</th>
<th>n</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UUI Episodes¹</td>
<td>-0.6</td>
<td>383</td>
<td>&lt;0.0001</td>
<td>-0.4</td>
<td>286</td>
<td>0.0123</td>
</tr>
<tr>
<td>Micturitions¹</td>
<td>-0.5</td>
<td>492</td>
<td>&lt;0.001</td>
<td>-0.3</td>
<td>378</td>
<td>0.0988</td>
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<tr>
<td>Urgency Episodes²</td>
<td>-0.7</td>
<td>492</td>
<td>0.0020</td>
<td>-0.4</td>
<td>378</td>
<td>0.0648</td>
</tr>
<tr>
<td>Total Incontinence Episodes²</td>
<td>-0.7</td>
<td>383</td>
<td>&lt;0.0001</td>
<td>-0.5</td>
<td>286</td>
<td>0.0074</td>
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<td>Volume Voided (mL²)</td>
<td>21.2</td>
<td>490</td>
<td>&lt;0.0001</td>
<td>13.3</td>
<td>375</td>
<td>&lt;0.001</td>
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<tr>
<td>OAB-q Coping Score²</td>
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<td>512</td>
<td>0.0038</td>
<td>3.1</td>
<td>401</td>
<td>0.0212</td>
</tr>
</tbody>
</table>

1. Co-primary endpoint; 2. Key Secondary Endpoint; LS=Least Squares

The EMPOWUR Phase 3 clinical trial data showing reductions in daily UUI episodes over time are shown in the graphs below.
The EMPOWUR Phase 3 clinical trial data showing reductions in daily UUI episodes at the end of the study for patients in the vibegron treatment group, compared to the tolterodine treatment group and placebo treatment group, are shown in the graphs below.

Vibegron was well tolerated and the most common adverse events reported versus placebo (>2% in vibegron and greater than placebo) were headache (4.0% vs 2.4%), nasopharyngitis (commonly known as a cold) (2.8% vs 1.7%), diarrhea (2.2% vs 1.1%), and nausea (2.2% vs 1.1%). The frequency of serious adverse events was similar across treatment arms (1.1% in placebo, 1.5% in vibegron, and 2.3% in tolterodine). The incidence of the reported adverse event of hypertension was equal to placebo (1.7% in vibegron, 1.7% in placebo, and 2.6% in tolterodine).

In the Phase 3 EMPOWUR trial there were two serious adverse events, or SAEs, reported in two patients in the vibegron treatment group considered to be treatment related by the investigator: (1) non-cardiac chest pain in one patient (with no evidence of an acute cardiac event) and (2) pneumonia in one patient. Our independent assessment did not consider these SAEs to be treatment related.

In September 2019, we reported positive long-term data from the double-blind extension of our pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. In this double-blind extension of the Phase 3 EMPOWUR trial with over 500 patients, vibegron 75 mg further improved the treatment benefit on key OAB symptoms such as micturitions, UUI, urgency and total incontinence over the 40-week extension period. Among the 52-week EMPOWUR vibegron treatment group, the reduction in micturitions at week 52 was 2.4 episodes per day from a baseline of 11.32 episodes and the reduction in urgency episodes was 3.4 episodes per day from a baseline of 8.0 episodes. Vibegron demonstrated sustained efficacy for urge urinary incontinence as the reduction in urge urinary incontinence was 2.2 episodes at week 52 from a baseline of 3.18 per day. In addition, a total of 61% of patients on vibegron achieved at least a 75% reduction in their daily urge urinary incontinence episodes from baseline at week 52 and 41% of patients on vibegron became “dry” which is defined as having no urge urinary incontinence episodes at week 52. In the 40-week extension of our Phase 3 EMPOWUR trial, there was one death in the vibegron treatment group, a 63-year old patient due to arteriosclerotic disease, assessed by the investigator and the sponsor to not be treatment related. The overall adverse event profile of vibegron from the 40-week extension study was consistent with the 12-week EMPOWUR Phase 3 study. Vibegron was well tolerated and the most common adverse events reported versus tolterodine were hypertension (8.8% vs. 8.6%), urinary tract infections (6.6% vs. 7.3%), and headache (5.5% vs. 3.9%). All other common adverse events such as upper respiratory tract infection and diarrhea were below 5% for both vibegron and tolterodine. Overall, vibegron 75 mg demonstrated a continued improvement in symptoms with sustained efficacy and a favorable long-term safety and tolerability profile.
For the double-blind extension of our pivotal Phase 3 EMPOWUR trial, a post-hoc analysis was performed to compare the change from baseline to week 52 results between vibegron and tolterodine. In the post-hoc analysis, vibegron showed a statistically significant reduction in daily UUI and total incontinence episodes from baseline to 52 weeks compared to the active control, tolterodine. The trial data analysis showing reductions in daily UUI episodes between vibegron and tolterodine over time is in the graph below.

In December 2019, we submitted an NDA to the FDA seeking approval of once-daily 75mg vibegron for the treatment of patients with OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency. Our PDUFA goal date is December 26, 2020.

**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 Myrbetriq. As of March 2020, 95% of commercial plans and 100% of Medicare plans covered Myrbetriq, the only currently marketed beta-3 agonist. According to IMS PayerTrak, in 2019, the U.S. payor mix for the oral OAB prescription market was approximately 52% Medicare Part D, 38% commercial or cash and 10% other payors. In addition, the long-term care channel accounted for approximately 19% of all oral OAB prescriptions in the United States. Based on a third-party database analysis of 3,285 commercial plans and 1,816 Medicare Part D plans, Myrbetriq has approximately 62% preferred access and 98% unrestricted access of Medicare Part D covered lives and approximately 50% preferred access and 59% unrestricted access of commercial lives.

In November 2019, 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, coverage and reimbursement decisions. Such interviewees represented payors covering over 147 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 restrictions by a majority of payors, allowing 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 early 2024. Based on this study, we also believe that access to vibegron, if approved, will not be restricted by a majority of payors for patients who first fail any other oral therapies for OAB. As with all pharmacologic branded products, access decisions will require formulary review through the formulary review process.

**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.
According to IQVIA NDTI, as of December 2019, 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 believe that developing vibegron specifically for the treatment of OAB in men with BPH would be highly complementary to our overall OAB program. In March 2019, we initiated the Phase 3 COURAGE randomized, double blind, placebo-controlled trial for OAB in men with BPH who are also taking BPH medications but continue experiencing OAB symptoms in approximately 1,000 patients. The study is being conducted in two phases. In part one, we assessed the initial safety in 82 patients via an independent Data Safety Monitoring Board. Part one of the study was completed and after reviewing the safety data, the independent Data Safety Monitoring Board agreed that we could begin part two of the study, which we initiated in October 2019. Part two is assessing efficacy and safety in all patients, and testing 75 mg of vibegron versus placebo, the same dose studied in our Phase 3 EMPOWUR trial. The primary efficacy consists of the co-primary efficacy endpoints, change from baseline in the average number of micturitions per 24 hours and change from baseline in the average number of urgency episodes per 24 hours. The primary efficacy timepoint is Week 12 after treatment. Secondary endpoints include change from baseline in the average number of nocturia episodes per night, which is awakening at night to use the bathroom to urinate, UUI episodes per day, the average volume voided per micturition, prostate symptom scores and safety. The duration for the double-blind study is 24 weeks. In addition, a 28-week open-label extension study will evaluate the long-term safety and efficacy of vibegron in men with OAB symptoms and on another therapy for BPH. We expect to receive top-line data from the Phase 3 COURAGE trial in the second half of 2021.

**Vibegron for the Treatment of Abdominal Pain due to 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. IBS presents a significant health care burden and can severely impair a patient’s quality of life. Based on available information regarding sales of currently approved IBS therapies, we believe that 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 (in millions).

**IBS Branded Sales (2019)**

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.

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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 for the initial six-week treatment period.

In December 2018, we enrolled our first patient in this trial. The Phase 2a trial is a double-blind, placebo-controlled study in women with abdominal pain due to IBS with predominant diarrhea, or IBS-D, or mixed episodes of diarrhea and constipation, or IBS-M. The trial is expected to enroll approximately 200 patients in the United States, randomized to receive either 75 mg of vibegron or placebo, administered orally once daily for a 12-week period. The primary endpoint is a 30% reduction in abdominal pain intensity, while secondary endpoints include Global Improvement Scale ratings, stool symptoms and safety. We expect to complete enrollment in the summer of 2020 and receive top-line data from the Phase 2a clinical trial in the fourth calendar quarter of 2020.

**Phase 1 Clinical Trials and Preclinical Studies of Vibegron**

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

In August 2019, we completed the ambulatory blood pressure study for vibegron. The purpose of the study was to rule out an effect of vibegron relative to placebo on daytime systolic blood pressure. The primary endpoint variable was the change from baseline to day 28 in mean daytime ambulatory systolic blood pressure. Secondary endpoints included: 1) change from baseline in mean daytime diastolic blood pressure and heart rate, 2) full 24 hour mean change in systolic and diastolic blood pressure and heart rates as well as 3) maximum changes 30 minutes to 6.5 hours post dosing.

Vibegron achieved its primary endpoint demonstrating that vibegron does not have an effect on daytime systolic ambulatory blood pressure compared to placebo (where no effect was defined as a change from baseline of less than 3.5mm Hg compared to placebo within a 90% confidence interval). For mean ambulatory daytime systolic blood pressure, there was no statistically significant or clinically relevant difference for vibegron compared to placebo. The treatment differences from baseline to day 28 for vibegron in mean ambulatory systolic blood pressure over placebo were +0.81 mm Hg, for mean diastolic blood pressure -0.04 mm Hg and for mean daytime heart rate +0.88 beats/minute. Regarding the categorical changes from baseline in systolic blood pressure for the in clinic visit vital signs, there were small, not clinically relevant, increases in the percentage of patients having a 10 mm Hg or 15mm Hg increase in systolic blood pressure for vibegron compared to placebo. The adverse event profile was consistent with the EMPOWUR phase 3 study with the most common adverse events being headache, diarrhea, upper respiratory tract infection and urinary tract infection at rates below 5%.

We also completed the pharmacokinetic study on food effect and the crushed tablet of vibegron 75 mg. The study results support the proposed labeling for administration of vibegron with or without food and as a crushed tablet in soft food.

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 patients. 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$_{50}$, of vibegron is 2.1 nanomolar at the beta-3 adrenergic receptor. EC$_{50}$ is a commonly used measure of a drug’s potency, representing the concentration of a drug that induces a response halfway between baseline and maximum after a specified exposure time. Further, vibegron does not appear to bind to either beta-1 or beta-2 adrenergic receptors in binding competition assays, confirming that the compound is neither an agonist nor an antagonist at beta-1 or beta-2 adrenergic receptors. In animal studies, vibegron was observed to induce relaxation in isolated rat urinary smooth bladder muscle, decrease micturition pressure in a rat bladder hyperactivity model in a dose-dependent manner, and increase bladder capacity in rhesus monkeys. Additionally, Merck completed long-term animal toxicity and carcinogenicity studies of vibegron, which are studies required by the FDA prior to approval.

**URO-902 for the Treatment of Overactive Bladder**

URO-902 is a novel gene therapy product candidate that we are developing for patients with OAB who have failed oral pharmacological therapy. URO-902 is under development as a potential injectable treatment option for smooth muscle-based disorders such as OAB. URO-902 is a plasmid vector containing a human cDNA encoding the pore-forming component of the Maxi-K ion channel. Expression of the Maxi-K 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 URO-902 as a repeat administration that can be administered under local anesthesia to the bladder wall 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. We estimate that only 300,000 patients utilize current third-line procedural therapies that generate aggregate annual sales in excess of approximately $700 million in the U.S. market. We believe a third-line treatment option that is non-surgical and not a toxin would be appealing to physicians and patients, potentially meeting the unmet needs of this patient population.

In December 2019, we enrolled our first patient in the placebo-controlled, randomized, multicenter proof-of-concept Phase 2a clinical trial to evaluate the safety and efficacy of URO-902 for the treatment of OAB in 78 female patients who have not responded to oral pharmacological therapies. The Phase 2a trial is expected to enroll patients in two cohorts: the first cohort will receive either a single administration of 24 mg of URO-902 (24,000 µg) or matching placebo, and the second cohort will receive 48 mg of URO-902 (48,000 µg) or matching placebo into the bladder wall. An unblinded review of safety data via an independent Data Safety Monitoring Board will be performed after all subjects in the first cohort reach week 6. Study treatment for the second cohort will begin only after the Data Safety Monitoring Board has agreed that we can proceed with the second cohort. Patients will be followed for up to 48 weeks after initial administration. The key efficacy endpoints for this Phase 2a clinical trial include reductions per day in micturitions and urgency episodes. In addition, our design of the Phase 2a clinical trial considers the safety data and preliminary efficacy data available from the two Phase 1b clinical trials in OAB conducted by ICI. We expect to receive the week 12 primary efficacy and safety top-line data from both cohorts in the Phase 2a clinical trial in the second half of 2021 and full trial data after the completion of the 48-week post-treatment period in 2022.
Development of URO-902 was initiated by ICI and has been studied in four clinical trials to date, one Phase 1 clinical trial and one Phase 1b clinical trial in OAB, as well as one Phase 1 clinical trial and one Phase 2a clinical trial in erectile dysfunction. In the trials for treatment of OAB, URO-902 was studied in a total of 22 women in doses up to 24,000 µg of URO-902. There were no gene transfer–related adverse events or other serious safety issues observed in these trials. There were five SAEs reported across all clinical trials of URO-902 conducted to date, all of which were determined to be unrelated to treatment. Two SAEs occurred at the lowest dose group (500 µg) in the Phase 1 clinical trial in erectile dysfunction (atrial flutter and urinary tract infection). Additionally, one SAE occurred in the 8,000 µg dose group and one SAE occurred in the placebo group in the Phase 2a clinical trial in erectile dysfunction (eye surgery for lens replacement and acute Charcot’s osteoarthropathy, respectively) and one SAE occurred in the 16,000 µg dose group in a Phase 1b clinical trial in OAB, as described below.

In 2017, ICI completed a multicenter, double-blind, imbalanced placebo-controlled Phase 1b clinical trial evaluating the potential activity and safety of URO-902 gene transfer by multiple direct injections in women with OAB and detrusor overactivity. The Phase 1b clinical trial, which began in 2014, had two sequential active treatment groups. URO-902 was delivered into the bladder wall by direct injection in a total of 13 female OAB patients at two escalating dose levels of 16,000 µg (n=6) and 24,000 µg (n=3). URO-902 was observed to be generally well tolerated in this trial. There was one SAE reported in this trial in the 16,000 µg dose group (exacerbation of pre-existing asthma), which was determined to be unrelated to treatment and completely resolved. No other SAEs were reported in this trial.

Efficacy results of the trial, which included a limited number of patients (n=13), showed dose-dependent improvements in reductions per day in number of micturitions, urgency episodes and UUI episodes in both URO-902 treatment groups (16,000 µg and 24,000 µg), achieving statistical significance (p<0.05) in the high dose cohort (24,000 µg). Reductions of the measured endpoints in number of micturitions, urgency episodes, UUI episodes and improvements in the measured endpoint of quality of life (as measured by the King’s Health Questionnaire, a commonly used questionnaire designed to evaluate the impact of OAB on quality of life) lasted through the 24-week length of the trial. The improvements for the active treatment groups, in particular the 24,000 µg group, on the King’s Health questionnaire included improvements on the domains of impact on life, physical limitations, social limitations and sleep/energy.

In the double-blind placebo-controlled Phase 1 clinical trial conducted by ICI in 2007, potential activity and safety of one-time bladder instillation of URO-902 gene transfer in women with OAB and detrusor overactivity was evaluated. The patients were observed for 24 weeks. URO-902 in this trial was instilled into the bladder by catheter in female OAB patients at dose-escalating levels of 5,000 µg and 10,000 µg. Efficacy endpoints included reductions per day in number of micturitions and UUI episodes. No clinically significant changes for the mean number of micturitions or UUI episodes were observed compared to placebo. There were no SAEs reported in this trial.

Our Key Agreements

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. During the year ended March 31, 2020, we made a regulatory milestone payment of $10.0 million to Merck upon acceptance of our NDA submission by the FDA. 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 former 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.

**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 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 and, in December 2019, we achieved a certain regulatory milestone which triggered a milestone payment of $2.5 million. The remaining obligation under this agreement would be due upon the achievement of a certain regulatory milestone by us in the United States, subject to certain specific conditions which we believe are not probable to occur.

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 an enzyme 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 an non-exclusive basis, or the Codexis Agreement. Pursuant to the Codexis 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 the Codexis Agreement, Codexis granted us a non-exclusive, non-transferable, non-sublicensable 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 the Codexis Agreement continues for six years after the first regulatory approval of vibegron in either the United States, Europe or Canada. We may terminate the Codexis 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 the Codexis 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 patent rights and know-how controlled by ICI, to develop, manufacture and commercialize the gene therapy that we refer to as URO-902 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 $0.25 million 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.

Loan Agreement with Sumitomo Dainippon Pharma Co., Ltd.

In December 2019, we entered into a $300 million unsecured revolving debt facility with Sumitomo, as lender, or the Sumitomo Loan Agreement. Sumitomo funded an initial amount of $87.5 million in December 2019 under the terms of the Sumitomo Loan Agreement. In April 2020, Sumitomo funded an additional amount of $41.0 million. Additional funds may be drawn down by us, upon request, no more than once in any calendar quarter, subject to certain terms and conditions.

Loans under the Sumitomo Loan Agreement, or Loans, bear a variable interest rate per annum equal to the London Inter-bank Offered Rate, or LIBOR, plus a margin of 3% payable on the last day of each calendar quarter. LIBOR is currently expected to be phased out by the end of 2021, and if it becomes unavailable, we and Sumitomo will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate, margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. The Loans mature and are payable in full on the five-year anniversary of the closing date of the Sumitomo Loan Agreement or December 27, 2024.

Our obligations under the Sumitomo Loan Agreement are fully and unconditionally guaranteed by each of our direct and indirect subsidiaries. The Sumitomo Loan Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The Sumitomo Loan Agreement required that, within ten business days of funding, a portion of the proceeds of the Loans shall be used to repay in full all outstanding obligations under the loan agreement with Hercules Capital, Inc., or Hercules. The loan agreement with Hercules was repaid in full in January 2020.
The Sumitomo Loan Agreement also contains customary events of default (subject, in certain instances, to specified grace periods). If any event of default occurs, the principal, premium, if any, interest and any other monetary obligations on all the then outstanding amounts under the Loans may become due and payable immediately. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding principal balance, and Sumitomo may declare all outstanding obligations immediately due and payable (subject, in certain instances, to specified grace periods) and take such other actions as set forth in the Sumitomo Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations under the Sumitomo Loan Agreement would automatically become due and payable.

Sales and Distribution

We do not currently have our own sales or distribution capabilities. In order to commercialize vibegron, if approved for commercial sale, we must develop a sales infrastructure. We intend to build an initial sales force of approximately 160 persons in the United States, targeting urologists and other specialists that treat a high number of patients with urologic conditions and prescribers in long-term care facilities. We intend to scale the commercial presence to reach additional health care professionals as vibegron sales grow. We believe that our commercial leadership team, with experience launching prescription products in the OAB market, 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. Where appropriate, we may seek to partner with Sumitomo or its subsidiaries to leverage their existing commercial infrastructure.

Manufacturing

We do not have the capabilities to conduct 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 URO-902 were being developed by Merck and ICI, respectively, vibegron was also being manufactured by Merck and URO-902 through contract manufacturing organizations by ICI.

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 structure and synthesis of the compound.

We expect that the vibegron drug substance transferred to us under the Merck Agreement and drug substance manufactured at our planned commercial supplier will be sufficient for us to complete our ongoing clinical trials for the treatment of OAB in men with BPH and abdominal pain due to IBS. 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. A described below, we currently rely on a single source for synthesis of vibegron. If we are unable to continue our relationships with any of our third-party manufacturers, we could experience delays in our commercialization efforts as we locate and qualify new manufacturers.

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.

URO-902 is a naked DNA plasmid vector containing a cDNA encoding the pore-forming component of the human smooth muscle Maxi-K ion channel. We expect the manufacturing process for URO-902 to be typical for that of biologics. Prior to our acquisition of URO-902, it was developed and manufactured in academic and manufacturing facilities suitable to support manufacturing of early clinical development. We expect our existing supply of URO-902, which was transferred to us under the ICI license agreement, to be sufficient for us to complete our ongoing Phase 2a study if materials continue to meet all specifications. We have recently contracted with a third-party vendor for the manufacturing of URO-902 for future preclinical studies and clinical trials, but the vendor has not yet manufactured any URO-902. We intend to contract with third-party vendors for commercialization if and when URO-902 receives marketing approval. We have not determined at this time whether to develop our own technology and process or to use third-party patented or proprietary DNA delivery-related technology for the manufacture and commercialization of URO-902.
If we are unable to initiate or continue our relationships with one or more third-party manufacturers for the development and manufacture of URO-902, 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.

In addition to vibegron, solabegron is the only other beta-3 agonist that is in clinical development. GlaxoSmithKline plc conducted a Phase 2 clinical trial in which solabegron, dosed twice daily, demonstrated efficacy in treating OAB. Velicept Therapeutics, Inc., which has acquired the rights to solabegron, has developed a once-daily formulation and is advancing development of both its twice-daily and once-daily formulations.

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 2 clinical trial in South Korea. Taris Biomedical LLC is developing TAR-302, an intravesical drug-delivery system for trospium, an anticholinergic drug, currently in Phase 1b clinical trials. 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. Duchesnay USA has also signed an agreement with Apogepha to market Mictoryl® (propiverine hydrochloride) an anticholinergic and calcium antagonist in the United States once all FDA regulatory reviews have been completed. Propiverine hydrochloride was first approved in Germany in 1992 and is widely marketed outside of the United States. 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 generic products as the patent protection for competitor’s products expire. For example, we expect to face competition from a generic version of mirabegron following Myrbetriq’s loss of marketing exclusivity, which we expect to occur in early 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.

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, URO-902, 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 with symptoms of urinary frequency, 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 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. In addition to the patent rights licensed from Merck, we also have three international patent applications directed to use of vibegron at certain dosages to treat overactive bladder. Two of these international patent applications have entered national examination in the U.S. and in several foreign jurisdictions. Any patents issuing from these applications would naturally expire in 2038, subject to any adjustment or extension of patent term that may be available in a particular country. We also have two international patent applications directed to use of vibegron to treat overactive bladder in men with BPH and use of vibegron to treat abdominal pain due to IBS.

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 an international patent application directed to the use of URO-902 gene therapy to treat signs or symptoms of overactive bladder or detrusor overactivity. This international patent application has entered national examination in the U.S. and in several foreign jurisdictions. 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. In addition to the patent rights licensed from ICI, we also have an international patent application directed to the use of URO-902 gene therapy to treat signs or symptoms of overactive bladder or detrusor overactivity.
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.

We have trademark registrations in the United States for UROVANT and for UROVANT SCIENCES. 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 investigational new drug application, or 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 biologics license application, 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 trial 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 trial 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 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 adversely 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 issuance of safety alerts, “Dear Healthcare Provider” letters, press releases, or other communications containing warnings or other safety information about the product.

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 National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid 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 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 closed 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 Affordable Care Act, 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 approve biosimilars.

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. At present, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.
The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, past government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and meaning of the BPCIA remains subject to significant uncertainty.

**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, or 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, referrals 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 Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act 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 for each violation. Civil penalties and treble damages also can be assessed under the federal False Claims Act for violations of the federal Anti-Kickback Statute. In addition, 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 prohibit, 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 for each separate false claim, and the potential for exclusion from participation in federal healthcare programs. Although the federal False Claims Act is a civil statute, violations of the false claims laws also may 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. As it did for the federal Anti-Kickback Statute, the Affordable Care Act 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 a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, 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 the Affordable Care Act 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.

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, or information related to 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.

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Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we are in the process of developing 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.

**Foreign Corrupt Practices Act**

We and our subsidiaries are subject to the Foreign Corrupt Practices Act of 1977, as amended, or FCPA. The FCPA prohibits U.S. companies and their representatives from processing, offering, or making payments of money or anything of value to foreign officials with the intent to obtain or retain business or seek a business advantage. In certain countries, the health care professionals we regularly interact with may meet the definition of a foreign government official for the purposes of the FCPA. Our international activities create the risk of unauthorized payments or offers of payments by our employees, consultants and agents, even though they may not always be subject to our control. We discourage these practices by our employees, consultants, and agents. However, our existing safeguards may prove to be less than effective, and our employees, consultants, and agents may engage in conduct for which we might be held responsible. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement activity by both the Department of Justice and the SEC. A determination that our operations or activities are not, or were not, in compliance with U.S. or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of suppliers, vendor or other third-party relationships, termination of necessary licenses or permits, and legal or equitable sanctions. Other internal or governmental investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

**Other Applicable Laws**

We are subject to a variety of financial disclosure and securities trading regulations, both in the United States and in other jurisdictions in which we operate, as a public company in the U.S., including laws relating to the oversight activities of the SEC and the regulations of the Nasdaq Stock Market LLC, on which our common shares are traded.

We are also subject to various other federal, state, and local laws and regulations, including those related to safe working conditions, and the storage, transportation, or discharge of items that may be considered hazardous substances, hazardous waste, or environmental contaminants.

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

We are also subject to or affected by federal, state and foreign privacy, security and data protection laws, regulations, standards and regulatory guidance that govern the collection, use, disclosure, retention, security and transfer of personal data. Our operations extend to countries around the world, and many of these jurisdictions have established privacy legal frameworks with which we, our customers or our vendors must comply.

**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, the Affordable Care Act 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, the Affordable Care Act 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, or CMS, issued a final rule regarding the Medicaid Drug Rebate Program, effective April 1, 2016, that, among other things, revises the manner in which the AMP is to be calculated by manufacturers participating in the program and implements certain amendments to the Medicaid rebate statute created under the Affordable Care Act. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare providers and entities, and other provisions are not yet, or have only recently become, effective.

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.

Further, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. 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 the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. 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 the Affordable Care Act 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 Affordable Care Act 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 the Affordable Care Act.

Further, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and non-severable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the Affordable Care Act are invalid as well. The Trump Administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal. Although we cannot predict the ultimate content, timing or effect of any changes to the Affordable Care Act or other federal and state reform efforts, we continue to evaluate the effect that the Affordable Care Act, 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 the Affordable Care Act 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 proposed and enacted 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.

**Brexit and the Regulatory Framework in the United Kingdom**

In June 2016, the electorate in the UK held a referendum in which voters approved an exit from the EU, commonly referred to as “Brexit.” Following protracted negotiations, the UK left the EU on January 31, 2020. The UK and the EU entered into a transition period of 11 months which may be extended once by agreement of the UK and the EU before July 2020 for up to one or two years. Despite delays in negotiations due to the global novel coronavirus disease, or COVID-19, pandemic, the UK government has maintained opposition to such extension.

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The transition agreement between the two parties means that the UK will abide by current regulatory and trading frameworks at least until December 31, 2020 pending the agreement of their future relationship. Since the regulatory framework for pharmaceutical products in the UK covering quality, safety and efficacy of pharmaceutical products, clinical studies, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the UK. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the UK and/or EU for our product candidates, which could significantly harm our business.

The UK’s vote to exit the EU could also result in similar referendums or votes in other European countries in which we conduct business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the UK from the EU will have and how such withdrawal may affect us.

Financial History

We have never been profitable, have incurred significant losses since our inception and we expect to continue to incur significant operating losses and negative cash flows for the foreseeable future. We have not generated any revenue from product sales to date, and may never generate any revenue from product sales.

Prior to the completion of our initial public offering, or IPO, our operations were primarily funded through capital contributions or short-term advances from RSL or its affiliates. In October 2018, we completed our IPO in which we sold 10,297,813 common shares, including the partial exercise of the underwriters’ over-allotment option to purchase additional shares, at a public offering price of $14.00 per common share. The net proceeds to us were approximately $132.9 million, after deducting $10.1 million in underwriting discounts and commissions and $1.2 million in offering expenses.

In February 2019, we and our subsidiaries, entered a secured debt financing agreement, with Hercules, as agent and lender, or the Hercules Loan Agreement, in the amount of $100.0 million. A first tranche of $15.0 million was funded upon execution of the Hercules Loan Agreement, a second tranche of $30.0 million was funded in September 2019. In January 2020, we terminated the Hercules Loan Agreement in connection with, and as a requirement under, the Sumitomo Loan Agreement. Our obligations under the Hercules Loan Agreement were repaid in full in January 2020, using the financing we obtained pursuant to the Sumitomo Loan Agreement. Additional information regarding this financing commitment is included in Note 5[A], “Long-term debt,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

In December 2019, we entered into a $300 million unsecured revolving debt facility with Sumitomo, as lender. Sumitomo funded an initial amount of $87.5 million in December 2019 and an additional amount of $41.0 million in April 2020 under the terms of the Sumitomo Loan Agreement. Additional information regarding this financing commitment is included in Note 5[B], “Long-term debt,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

The majority of our operating expense is related to research and development activities. Our research and development activities primarily include activities related to the Phase 3 development of our lead product candidate, vibegron, for the treatment of OAB, as well as for the treatment of OAB in men with BPH and our Phase 2a clinical trial for the treatment of abdominal pain due to IBS. Our research and development expenses totaled $92.4 million and $92.2 million for the years ended March 31, 2020 and 2019, respectively. We expect our net losses, negative cash flows, and operating expenses to increase as we continue the development of, and seek regulatory approval for, our product candidates, prepare for commercialization, if approved, and grow our company.

As of March 31, 2020, we had approximately $51.4 million of cash and $212.5 million of financing commitments available to us under the Sumitomo Loan Agreement. In April 2020, we received gross proceeds of $41.0 million pursuant to the Sumitomo Loan Agreement. Subsequent to this draw, $171.5 million of borrowing capacity remains available to us under the Sumitomo Loan Agreement.

We manage our operations and allocate resources as a single operating and reporting segment. Additional financial information regarding our operations, assets and liabilities, including our net loss for the years ended March 31, 2020 and 2019 and our total assets as of March 31, 2020 and 2019, is included in our consolidated financial statements incorporated by reference into Part II, Item 8, and included immediately after the signature page, of this Annual Report on Form 10-K.
Employees
As of March 31, 2020, we had no employees, and our wholly owned subsidiary, Urovant Sciences, Inc., or USI, had 70 employees, of which all were full-time employees. Of the 70 employees, 28 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.

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 5281 California Avenue, Suite 100 and 250, Irvine, California 92617 and 324 Blackwell Street Bay 11, Suite 1104, Durham, North Carolina 27701. We are an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, and therefore we are subject to reduced public company reporting requirements. Our common shares are currently listed on The Nasdaq Global Select Market under the symbol “UROV.”

Available Information
Our website is www.urovant.com. The contents of our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. We also show detail about stock trading by corporate insiders by providing access to SEC Forms 3, 4 and 5. The SEC maintains an internet site that contains reports, proxy and information statements, and other information. The address of the SEC’s website is www.sec.gov.

U.S. Securities Laws
As a Bermuda exempted company, our corporate affairs are governed by Bermuda laws, which differ in some material respects from laws typically applicable to U.S. corporations and shareholders. As a result, it may be difficult for investors to bring and enforce actions against the Company under the civil liability provisions of the U.S. Federal securities laws. For more information, see the following “Risk Factors” set forth in Part I. Item 1A. of this Annual Report on Form 10-K: “We are a Bermuda company and it may be difficult for shareholders to enforce judgments against us or our directors and executive officers” and “Bermuda law differs from the laws in effect in the United States and may afford less protection to our shareholders.”
Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this Annual Report on Form 10-K, including the section of this Annual Report on Form 10-K titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the events described in the following risk factors and the risks described elsewhere in this Annual Report on Form 10-K occurs, our business, operating results, and financial condition could be seriously harmed and the trading price of our common shares could decline and you could lose all or part of your investment in our common shares. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K. See the section of this Annual Report on Form 10-K titled “Cautionary Note Regarding Forward-Looking Statements.”

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 primarily been developing vibegron for the treatment of OAB, organizing and staffing our company, and acquiring rights to vibegron and URO-902. We have not yet demonstrated an ability to successfully obtain marketing approval, manufacture a commercial scale product, 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 abdominal pain due to IBS, as well as URO-902 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;
- 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;
- raise additional funds when needed and on terms acceptable to us;
- commercial launch 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.

**We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.**

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 $146.7 million and $111.3 million for the years ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had an accumulated deficit of $322.3 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.

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 development, regulatory approval, and commercialization of vibegron.

Even though we have submitted our new drug application, or NDA, for 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 our NDA, or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization.
The top-line results from our Phase 3 EMPOWUR trial demonstrated a statistically significant difference for the active vibegron 75 mg dose compared to placebo for the co-primary endpoints, which are reductions in daily UUI episodes and reduction in daily micturitions, in the primary efficacy analysis. In addition, we reported a statistically significant reduction in daily urgency episodes compared to placebo (p=0.002), which is the first of the seven pre-specified key secondary endpoints. All seven pre-specified secondary endpoints achieved statistical significance over placebo for vibegron. As such, even if we were able to obtain approval for vibegron, these secondary endpoints may not be mentioned in the U.S. label, which could potentially adversely affect product differentiation.

We submitted our NDA for vibegron in December 2019 but have not yet submitted a Biologics License Application, or BLA, for URO-902. 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 FDA or other relevant regulatory authorities may identify unexpected efficacy or safety concerns while reviewing an NDA or similar application;
- the FDA or other 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 FDA or other relevant regulatory authorities may disagree with our proposed analysis plans for any clinical trials of our product candidates;
- 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 and third-party manufacturers may not pass the pre-approval inspections by regulatory authorities;
the FDA or other relevant regulatory authorities may have slower response times or be under-resourced due to the global novel coronavirus disease, or COVID-19, pandemic and, as a result, review, inspection and other timelines may be materially delayed; or

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

**Our business, financial condition, results of operations and ongoing clinical trials could be harmed by the effects of the COVID-19 pandemic.**

We are subject to various risks related to the global pandemic associated with COVID-19. For example, many geographic regions have imposed, or in the future may impose, “shelter-in-place” orders, quarantines or similar orders or restrictions to control the spread of COVID-19. These types of restrictions have resulted in most of our employees working from home, and could result in the employees of our key third-party vendors and manufacturers working from home. As shelter-in-place orders start to be lifted, we, or our suppliers or manufacturers, may continue to require employees to work from home after the orders are lifted to protect the health and safety of employees. We rely exclusively on third-party manufacturers to manufacture vibegron and URO-902. Neither we, nor our suppliers or manufacturers have significant experience operating with the majority of our respective work forces working from home, and this may disrupt standard operations for us or them, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our respective abilities to conduct business in the ordinary course. In addition, this may increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

As our starting materials for vibegron are purchased outside of the U.S., a disruption in our ability to procure such materials may occur if exportation out of the countries where our third-party manufacturers are located is halted or delayed for a significant period of time due to COVID-19. Such a disruption could have a material adverse impact on our ability to timely manufacture sufficient product quantities for our expected future customer demand, if vibegron is approved. Additionally, timely enrollment in our clinical trials is dependent upon global clinical trial sites, which may be adversely affected by the COVID-19 pandemic. We are currently conducting clinical trials for our product candidates in many countries. Many of these regions are currently being affected or may in the future be affected by the COVID-19 pandemic. For vibegron, from March 19, 2020 to April 27, 2020, we temporarily halted the screening of new subjects into our Phase 3 COURAGE trial and Phase 2a trial for abdominal pain due to IBS and, for URO-902, from March 19, 2020 to May 4, 2020, we temporarily halted the screening of new subjects in our Phase 2a trial due to the COVID-19 pandemic. Subjects that were in the run-in phase or already enrolled in our ongoing studies continued with treatment pursuant to the clinical trial protocol and treatments were not halted or delayed. If the COVID-19 pandemic continues to spread in the geographies in which we are conducting clinical trials, we may experience further disruptions in those clinical trials, which could have a material adverse impact on our clinical trial plans and timelines, including:

- delays in receiving authorizations from local regulatory authorities and ethics committees to initiate planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
risk that participants enrolled in our clinical trials may acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial due to missed study visits and/or data, as well as adverse events due to the COVID-19 infection;

- delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and

- refusal of the FDA to accept data from clinical trials in affected geographies.

Health regulatory agencies globally may also experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection and other timelines may be materially delayed. For example, in March 2020, the FDA announced its intention to temporarily postpone certain inspections of both foreign and domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. It is unknown how long such delays or disruptions could last. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions, in particular any delays to our PDUFA date of December 26, 2020 for vibegron, could materially affect the development and study of our product candidates and commercialization efforts.

The COVID-19 pandemic could have an adverse impact on our commercial launch plans for vibegron, if approved, due to the continuation of government-imposed quarantines, stay at home orders, travel restrictions, mandated business closures and other public health safety measures which may result in limiting our ability to hire a sales force prior to launch, conduct necessary trainings of such sales force and attending and presenting at various conferences or other programs. If vibegron is approved, continuation of these government-imposed orders may also result in patients not visiting their healthcare providers or their pharmacies to get their prescriptions filled, in-person interactions by sales and medical representatives in healthcare settings such as urologists’ offices and long-term care facilities may be suspended, and any remote interactions may be less effective than in-person interactions. In addition, due to the prioritization of healthcare resources toward pandemic efforts, even remote interactions may not be possible. These factors could have an adverse impact on our business and our ability to effectively launch vibegron, if approved.

The continued spread of COVID-19 has also led to extreme disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of COVID-19. Given the rapid and evolving nature of the virus and the uncertainty about its impact on society and the global economy, we cannot predict the extent to which it will affect our operations or the value of our common shares, particularly if these impacts persist or worsen over an extended period of time. To the extent the COVID-19 pandemic adversely affects our business, financial results, and value of our common shares, it may also affect our ability to raise capital when needed and to comply with certain covenants in our loan agreement or other agreements that are material to our business.

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 URO-902, 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.

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 disruption to our supply chains, business operations, commercialization efforts, if approved, or clinical trials or to the resulting from the COVID-19 pandemic, including any delay in the FDA’s approval of our NDA;
• the disruption to the business or operations of our contract manufacturers, CROs or other third parties with whom we conduct business resulting from the COVID-19 pandemic;

• future global financial crises and economic downturns, including those cause by widespread public health crises such as the COVID-19 pandemic;

• the timing, costs and results of our Phase 3 COURAGE clinical trial of vibegron for the treatment of OAB in men with BPH and our Phase 2a clinical trial of vibegron for the treatment of abdominal pain due to IBS;

• the timing, costs and results of our Phase 2a clinical trial for URO-902 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 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;

• the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale;

• 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; and

• the effect of competing technological and market developments.

We currently believe that our existing cash, together with the proceeds of $41.0 million received in April 2020 pursuant to the Sumitomo Loan Agreement and the current remaining financing commitment available to us of $171.5 million from Sumitomo, will be sufficient to fund our committed operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this Annual Report on Form 10-K. This estimate is based on assumptions that may prove to be wrong and changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and the impact of measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities and the impact of commercialization efforts due to the COVID-19 pandemic. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. We cannot be certain that additional capital when needed will be available on acceptable terms, or at all. If we are unable to raise additional capital, as needed, in sufficient amounts or on terms acceptable to us, or if the current remaining financing commitment of $171.5 million available to us under the Sumitomo Loan Agreement is no longer available to us despite our future funding requests being in accordance with our board approved operating budget, we may have to significantly delay or scale back our operations to reduce working capital requirements beginning in the fourth calendar quarter of 2020, including but not limited to actions such as reducing personnel-related costs, curtailment of our pre-commercial launch efforts, development activities and other discretionary expenditures that are within our control. Additionally, we may have to discontinue the development or commercialization of our current and any future product candidates, or potentially discontinue operations altogether. Attempting to secure additional capital, as needed, 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.
Our Loan Agreement with Sumitomo contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

Pursuant to the Sumitomo Loan Agreement, we have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Sumitomo. The Sumitomo Loan Agreement contains affirmative and negative covenants that, among other things, restrict our ability to:

- incur additional indebtedness;
- incur liens;
- make investments;
- dispose of any property;
- make distributions, including dividends;
- enter into certain transactions with affiliates of Sumitomo;
- consolidate or merge; and
- alter the business of the Company.

These terms of the Sumitomo Loan Agreement could prevent us from taking certain actions without the consent of our lender, who is also currently our majority shareholder, which may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our minority shareholders, placing us at a competitive disadvantage compared to our competitors who have less leverage and who therefore may be able to take advantage of opportunities that our leverage prevents us from exploiting.

The Sumitomo Loan Agreement also includes events of default, including, among other things, payment defaults; breaches of certain covenants or agreements; certain bankruptcy or insolvency events; the occurrence of certain events that could reasonably be expected to have a “material adverse effect”; and defaults in respect of certain other indebtedness.

Upon the occurrence of an event of default and following any cure periods (if applicable), a default interest rate of an additional 5.0% per annum may be applied to the outstanding principal balance, and Sumitomo may declare all outstanding obligations immediately due and payable (subject, in certain instances, to specified grace periods) and take such other actions as set forth in the Sumitomo Loan Agreement.

If an event of default under the Sumitomo Loan Agreement were to occur and Sumitomo declared all outstanding obligations immediately due and payable, we would be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, Sumitomo would be able to take remedies permitted under the Sumitomo Loan Agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and share price.

The LIBOR calculation method may change and LIBOR is expected to be phased out after 2021.

Loans under the Sumitomo Loan Agreement bear interest at a rate per annum equal to LIBOR plus a margin of 3.0% payable on the last day of each calendar quarter. On July 27, 2017, the U.K. Financial Conduct Authority announced that it will no longer require banks to submit rates for the calculation of LIBOR after 2021.

It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021. The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a newly created index, calculated with a broad set of short-term repurchase agreements backed by treasury securities. It is not possible to predict the effect of these changes, other reforms or the establishment of alternative reference rates in the United States or elsewhere. Pursuant to the Sumitomo Loan Agreement, if LIBOR becomes unavailable in the future, we and Sumitomo will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate, margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. To the extent our interest rates increase as a result, our interest expense will increase, in which event we may have difficulties making interest payments and funding our other fixed costs, and our available cash flow for general corporate requirements may be adversely affected.
Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt. Our ability to make the payment of the principal of, to pay interest on or to refinance the Sumitomo Loan Agreement, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control, including global macroeconomic effects of global pandemics such as the COVID-19 pandemic. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligation.

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, the Sumitomo Loan Agreement, additional 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 additional 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 URO-902, 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 URO-902 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 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 has transferred the manufacturing process to us or our designee for production of URO-902. If we require additional assistance from ICI after their obligation to assist us expires, our manufacture and development of URO-902 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 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 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, with many of our competitors seeking to hire and retain the same qualified personnel. We may, from time-to-time, hire personnel who work for our competitors or others in the industry, and our competitors may hire personnel who work for us, which could result in a material disruption to our business or even litigation. In the event we lose key personnel, we may be unable to hire, train, retain or motivate new key personnel to replace those we lose. 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 throughout the organization. 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, URO-902 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.
Following the closing of the Sumitomo Transaction, Sumitomo has committed to discuss terms on which they can support our commercialization and operations. If we are unable to obtain the contemplated commercial and operational support from Sumitomo on terms acceptable to us, our business could be adversely impacted.

Following the closing of the Sumitomo Transaction, Sumitomo committed to discuss with us, in good faith, terms on which Sumitomo can provide us access to their commercial infrastructure in the United States and operational support services, which may include access to certain distributors, managed care and back office support. Sumitomo, because of its own business considerations, may be unable or unwilling to support our commercialization and operations on acceptable terms, or at all, and we may not be able to realize the benefits of Sumitomo’s broader commercial network.

If we are unable to negotiate acceptable terms on which we can access Sumitomo’s commercial infrastructure in the United States and obtain services that support our operations, we will have to find alternative means to develop and commercialize our product candidates. Building this commercial infrastructure in the United States may be prohibitively expensive and time consuming. Accessing the distribution or support network of a third party could be costly or require us to agree to exclusivity or otherwise give up valuable rights. In addition, it may be difficult to find alternative service providers on terms acceptable to us.

Finally, attempting to secure alternative service providers or access to commercial infrastructure may divert the time and attention of our management from our day-to-day operations and impair the development of our product candidates.

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 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 to resolve allegations of non-compliance with these laws 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. As a result of the consummation of the Sumitomo Transaction, we are affiliated with different entities, and any misconduct or improper activities by the employees of these new affiliates could have an adverse effect on 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 we identify and decide to acquire product candidates may not be successful;
- 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.

Legal, political, and economic uncertainty surrounding the planned exit of the United Kingdom from the European Union are a source of instability and uncertainty.

The United Kingdom held a referendum on June 23, 2016 to determine whether the United Kingdom should leave the European Union, or remain as a member state, the outcome of which was in favor of leaving the European Union, which is commonly referred to as Brexit. Under Article 50 of the 2009 Lisbon Treaty, the United Kingdom will cease to be a member state when a withdrawal agreement is entered into (such agreement will also require parliamentary approval) or, failing that, two years following the notification of an intention to leave under Article 50, unless the European Council (together with the United Kingdom) unanimously decides to extend this period. On March 29, 2017, the United Kingdom formally notified the European Council of its intention to leave the European Union. In January 2020, the European Council and the United Kingdom entered into a withdrawal agreement, which sets the terms of the withdrawal of the United Kingdom from the European Union. The United Kingdom and the European Union entered into a transition period of 11 months which may be extended once by agreement of the United Kingdom and the European Union before July 2020 for up to one or two years. During this transition period, Brexit has involved a process of lengthy negotiations between the United Kingdom and EU members states to determine the future terms of the United Kingdom’s relationship with the European Union. Despite delays in these negotiations due to the COVID-19 pandemic, the United Kingdom government has maintained opposition to extending the transition period for withdrawing from the European Union. The transition agreement between the two parties means that the United Kingdom will abide by current regulatory and trading frameworks at least until December 31, 2020 pending the agreement of their future relationship.

Lack of clarity about future U.K. laws and regulations as the United Kingdom determines which EU rules and regulations to replace or replicate in the event of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could decrease foreign direct investment in the United Kingdom, increase costs, depress economic activity and restrict access to capital. In addition, if the United Kingdom and the European Union are unable to negotiate acceptable withdrawal terms or if other EU Member States pursue withdrawal, barrier-free access between the United Kingdom and other EU Member States or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the United Kingdom and the European Union and, in particular, any arrangements for the United Kingdom to retain access to European Union markets either during a transitional period or more permanently.

Such a withdrawal from the European Union is unprecedented, and it is unclear how the United Kingdom’s access to the European single market for goods, capital, services and labor within the European Union, or the European single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations. We may also face new regulatory costs and challenges that could have an adverse effect on our operations and development programs. For example, because the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical studies, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly harm our business.

Even prior to any change to the United Kingdom’s relationship with the European Union, the announcement of Brexit created economic uncertainty surrounding the terms of Brexit, and its consequences could negatively impact our financial condition, results of operations and cash flows. Further, the United Kingdom’s vote to exit the European Union could also result in similar referendums or votes in other European countries in which we conduct business. Given the lack of comparable precedent, it is unclear what financial, trade and legal implications the withdrawal of the United Kingdom from the European Union will have and how such withdrawal may affect us.
Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in harm to our business and/or subject us to costs, fines or lawsuits.

Our computer systems, as well as those of various third parties on which we rely, or may rely on in the future, including Sumitovant 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 sophisticated information technology systems and network infrastructure to operate and manage our business and 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. Our business therefore depends on the continuous, effective, reliable, and secure operation of our computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that our hardware or software malfunctions or access to our data by internal personnel or suppliers through the Internet is interrupted or compromised, it could result in a material disruption of our drug development programs and our business could suffer.

Although our computer and communications hardware is protected through physical and software safeguards, it is still vulnerable to system malfunction, computer viruses, malware and ransomware, and other cybersecurity threats such as phishing and social engineering attacks. These events could lead to the unauthorized access of our information technology systems and result in financial loss and the misappropriation or unauthorized disclosure of confidential information belonging to us, our employees, partners, or our suppliers. 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. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our information technology systems are compromised, further development of our current or future product candidates could be delayed and we could be subject to fines, damages, litigation and enforcement actions, incur financial losses, suffer reputational damage, lose trade secrets or other confidential information, each of which could significantly harm our business.

If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulations, we may be subject to liabilities that adversely affect our business, operations and financial performance.

We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future.
For example, the EU has adopted the General Data Protection Regulation, or GDPR, which introduces strict requirements for processing personal data. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR’s various requirements, significant effort and expense are required to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR and guidance issued by different EU member states may change periodically or may be modified, and such changes or modifications could have an adverse effect on our business operations if compliance becomes substantially costlier than under current requirements. It is also possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Further, Brexit has created uncertainty with regard to data protection regulation in the UK. In particular, it is unclear whether, post Brexit, the UK will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, the effects of the COVID-19 pandemic on its operations and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including those disruptions that may be caused by the COVID-19 pandemic, may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in March 2020, the FDA announced its intention to temporarily postpone certain inspections of both foreign and domestic manufacturing facilities. In addition, between December 22, 2018 and ending on January 25, 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If temporary reductions in operations due to the COVID-19 pandemic or repeated or prolonged government shutdowns occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Fluctuations in insurance cost and availability could adversely affect our results of operations or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors’ and officers’ liability insurance, general liability insurance, property insurance and workers’ compensation insurance and such policies contain customary conditions and exclusions. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Additionally, even if we maintain insurance coverage for a type of liability, a particular claim may not be covered if it is subject to a coverage exclusion or we do not otherwise meet the conditions for coverage. If we operate our business without insurance, or with inadequate insurance, we could be responsible for paying claims or judgments against us, which could adversely affect our results of operations or financial condition.

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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, BLA or other similar application for regulatory approval. While we submitted our NDA for vibegron in December 2019, we cannot provide you any assurance that we will submit an NDA for regulatory approval for any of our other product candidates within our projected timeframes or that our NDA for vibegron or any other 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, URO-902, 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 URO-902 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:

- impacts of the COVID-19 pandemic such as disruptions or delays to standard study monitoring practices, study drug shipments, biological pharmacokinetics sample shipments, data analysis and reporting of results due to changes in policies at various clinical sites, federal, state, local or foreign laws, rules and regulations, quarantines or other travel restrictions, prioritization of healthcare resources toward pandemic efforts, including diminished attention of physicians serving as our clinical trial investigators and reduced availability of site staff supporting the conduct of our clinical trials;
- 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 of trial participants to visit the study sites and continue with the studies and inability of the clinical investigators to see trial participants in a timely manner due to potential site closures;
- 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 trial 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 URO-902, 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 use supportive 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, URO-902, 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 with the assessment of the current drug supply and in the future with 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, which may prevent us from completing our clinical studies or commercializing URO-902 on a timely or profitable basis, if at all. We expect that the supply of URO-902 that was transferred to us under the ICI license agreement will only be sufficient for us to complete our Phase 2a study. Any issues we experience in the future with respect to the manufacturing or availability of URO-902 could significantly delay our URO-902 development program and harm our business prospects.

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 URO-902 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, Luxturna by Spark Therapeutics, Inc. for patients with an inherited form of vision loss, and Zolgensma by AveXis, Inc. for pediatric patients with a form of spinal muscular atrophy. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for URO-902 in either the United States, or other major markets or how long it will take to commercialize URO-902, 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 or Synthetic Nucleic Acid 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 closed 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 URO-902. 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 URO-902 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 URO-902. 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, URO-902, involves introducing genetic material into patients’ cells. The clinical and commercial success of URO-902 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 URO-902. 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 URO-902 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 URO-902 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 developed vibegron for the treatment of OAB in Japan and in September 2018, received marketing approval from Japan’s Ministry of Health, Labour and Welfare for vibegron for the treatment of adults with OAB. In November 2018, Kyorin launched vibegron for the treatment of OAB in Japan. Previously, Kyorin reported positive results from its Phase 3 clinical trial in Japan for the treatment of OAB. If subsequent announcements by Kyorin regarding vibegron are unfavorable, or post-marketing data 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 does not approve the inclusion of urgency data, rapid onset of action data, and a single, convenient once-daily and crushable 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.

Although we submitted our NDA for vibegron in December 2019, any delay in, or termination of, our clinical trials will delay the submission of 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. Any failure to support our claims for differentiation or obtain approval from the FDA for the differentiated claims we propose could adversely impact our ability to compete with other available therapies.
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. For example, the top-line data analysis from our Phase 3 EMPOWUR study did not include full vital sign data, including blood pressure. 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 regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

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 effects of the COVID-19 pandemic or due to 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 willingness of and ability for patients to visit clinical sites as a result of the COVID-19 pandemic, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to recruit clinical trial investigators with the appropriate competencies and experience, 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 willingness of and ability for patients to visit clinical sites as a result of the COVID-19 pandemic, 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.

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, including their abilities to perform during the COVID-19 pandemic.
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 URO-902 for the treatment of OAB. For example, Velicept Therapeutics, Inc. is advancing solabegron, a beta-3 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 2 clinical trial in South Korea. Taris Biomedical LLC is developing TAR-302, an intravesicular drug-delivery system for trospium, an anticholinergic drug, currently in Phase 1b clinical trials. 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 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. Duchesnay USA has also signed an agreement with Apogepha to market Mictoryl® (propiverine hydrochloride) an anticholinergic and calcium antagonist in the United States once all FDA regulatory reviews have been completed. Propiverine hydrochloride was first approved in Germany in 1992 and is widely marketed outside of the United States. 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 generic products as the patent protection for competitor’s products expire.

For example, we expect to face competition from a generic version of mirabegron following Myrbetriq’s loss of marketing exclusivity, which we expect to occur in early 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 materially 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. 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 and consultants 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.

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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 URO-902 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 FDA may impose restrictions that limit the scope of any approved label and affect our market acceptance.*

The FDA has substantial discretion in the product label review and approval process and may disagree that our studies support the differentiated claims we propose. Even if we are successful in demonstrating that our product offers a differentiated profile compared to current therapies, the FDA may restrict us from mentioning such claims in the U.S. label, which could potentially adversely affect product differentiation.

Further, the FDA could institute a “class” label for all products in the same market, which could require us to include warnings or other information on the label of our product that may not be specifically applicable to our product. For example, while the results of the ambulatory blood pressure study of vibegron demonstrated that vibegron does not have an effect on daytime systolic ambulatory blood pressure compared to placebo, the FDA may nevertheless require a safety warning for blood pressure for all drugs in this class. If the FDA were to institute such a “class” label requiring a blood pressure warning, it would adversely impact our ability to differentiate vibegron from mirabegron, which did not achieve the same positive blood pressure results as vibegron. If we are unable to differentiate our products and compete effectively, our ability to successfully commercialize vibegron and our other product candidates, our business, operating results, prospects or financial condition may be harmed.
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. Prior to obtaining approval to commercialize a product candidate, we must demonstrate acceptable stability under various conduct and for commercially viable lengths of time. Given the timing for completion of validation, it is possible that we could experience delays in FDA approval and/or delays in the commercial launch of vibegron solely as a result of the time it takes to demonstrate acceptable stability. 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. 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 non-technical capabilities and 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 third party 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 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; 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 to resolve allegations of non-compliance with these laws, 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, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts 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 the Affordable Care Act, and President Trump has issued executive orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. 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, then President Obama 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, reform government program reimbursement methodologies for drugs, increase manufacturer rebates for certain drugs in Medicare Part D and provide Medicare Part D plans more control over formularies. At the federal level, the Trump administration’s recent budget proposals contain additional drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. The Trump administration also released a “Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. While proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative, administrative and executive measures, including the President’s issuance of future executive orders, to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

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In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation, administrative or executive action. 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 and make it more difficult for us to attain profitability.

**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 November 2019, 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, coverage and reimbursement decisions. Such interviewees represented payors covering over 147 million U.S. commercial and Medicare Part D lives. The payor representatives interviewed expect that vibegron will likely be managed at a preferred or non-preferred branded tier, without restrictions by a majority of payors, allowing 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. The payor research does not warrant this management will take place at launch or prior to product review. There is no assurance that vibegron, if approved, would achieve adequate coverage and reimbursement levels, or that restrictions, including prior authorizations, will not be required by payors. There also is no assurance as to the timeline for obtaining any level of coverage for vibegron; coverage and reimbursement levels may not be achieved at or near launch.

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 clinical and commercial supplies of our current and future product candidates.

We do not have the capabilities to conduct drug formulation or manufacturing and do not 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 URO-902, respectively. Although Merck and ICI have already transferred the manufacturing process of vibegron and URO-902 to us, respectively, we may still need additional assistance if we experience any setbacks with the manufacturing on the larger scale. If Merck or ICI fail to fulfill their respective continuing 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 currently planned clinical trials for the treatment of OAB in men with BPH and abdominal pain due to IBS. Additionally, supplies from our planned commercial manufacturers have become available and may be used in on-going and future clinical studies. We also expect that the URO-902 drug substance transferred to us under our license agreement with ICI will be sufficient for us to complete our Phase 2a study if materials continue to meet all specifications. We have recently contracted with a third-party vendor for the manufacturing of URO-902 for future preclinical studies and clinical trials, but the vendor has not yet manufactured any URO-902. We intend to contract with third-party vendors for commercialization if and when URO-902 receives marketing approval.

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 prior to FDA approval of our NDA for vibegron. We are currently contracted with one contract manufacturer for our supply of vibegron. Such contract manufacturer has begun commercial manufacturing of vibegron. If the completion of commercial manufacturing is delayed, FDA approval of vibegron may be delayed as well. Any such delays in the approval process would impact our expected timing for the commercial launch for vibegron, if approved, and could harm our business, operating results and prospects.

Further, if we are not able to identify additional contract manufacturers for the commercial supply of vibegron and are not able to produce a sufficient commercial supply of vibegron to support its commercial launch, it may jeopardize our ability to successfully commercialize vibegron and generate any revenue. Also, if additional contract manufacturers are identified but are ultimately not approved by the FDA, we would have unnecessarily incurred additional manufacturing costs. This may be costly, and our investment would be lost if we could not utilize these additional contract manufacturers in the future.

In addition, 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:

- 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 and cost to identify and partner with 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 URO-902, 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 URO-902. If supply from a third-party manufacturing facility is interrupted, there could be a significant disruption in supply of URO-902.

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, including their ability to work during the COVID-19 pandemic. 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, including effects due to the COVID-19 pandemic, 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 URO-902, uses of vibegron and URO-902, or other aspects related to vibegron, URO-902 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, enforceability or commercial value, 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
simply 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; (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.

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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. Also, if competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

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 URO-902, the Biologics Price Competition and Innovation Act of 2009, or 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 URO-902 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, use of a patented or proprietary DNA delivery-related technology to manufacture and commercialize URO-902. 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 parties 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, 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, 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. Our determination of the expiration date of any patent in the United States or abroad that we consider 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 is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

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.

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.

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 counter claims 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 defending 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 party 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 may have an adverse effect 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
If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. 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 lawfully obtained or independently developed by a competitor, we would be unable to prevent such use. The cost to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as 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 used 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.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. 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 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 used 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 a 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 Ownership of Our Common Shares**

An active public market for our common shares may not be sustained or be liquid enough for you to sell your shares quickly or at market price.

Prior to the listing of our common shares on Nasdaq in connection with our IPO in October 2018, no public market for our common shares existed. If an active trading market for our common shares is not sustained, you may not be able to sell your shares quickly or at or above 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.

In addition, our common shares are held by a relatively small number of holders. Sumitovant owns approximately 75% of our outstanding common shares as of June 18, 2020. Moreover, our officers and directors have the right to acquire our common 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 has been and is likely to continue to be highly volatile. The market price of our common shares has been and is likely to continue 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 or ultimate completion of our clinical trials;
- results of clinical trials of our product candidates or those of our competitors;
- any delay in future NDA filings or similar applications for vibegron and any other product candidates and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority’s review of our submitted NDA for vibegron or future NDA submissions or similar applications, 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;
- sales of a substantial number 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 officers who are subject to beneficial ownership reporting requirements under Section 16 of the Exchange Act;
• sales of our common shares by us or our shareholders in the future, including sales by us through our “at-the-market” equity offering program described below;
• 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;
• global health concerns, such as the COVID-19 pandemic; 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 and global health concerns, such as the COVID-19 pandemic, may negatively affect the market price of our common shares, regardless of our actual operating performance.

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

As of December 27, 2019, following the closing of the Sumitomo Transaction, Sumitovant controls a majority of the voting power of our outstanding common shares. As a result, we are a “controlled company” within the meaning of applicable Nasdaq listing rules. Under these rules, a company is a “controlled company” if more than 50% of the voting power for the election of its directors is held by an individual, group or another company. In addition, Sumitovant has the right to designate two directors to our board of directors, each of whom have three votes on all matters presented to the board. Together, the Sumitovant designated directors can control all matters presented to our board of directors for a vote. For so long as the Sumitovant designated directors control all such matters presented, we will be a “controlled company” and may elect not to comply with certain corporate governance requirements in accordance with the Nasdaq listing rules, including the requirements:

• that a majority of the board of directors consists of independent directors;
• that we annually evaluate the performance 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 have elected to use certain of these exemptions, 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 as those afforded to shareholders of companies that are not exempt from such Nasdaq corporate governance requirements.
Sumitovant owns a significant percentage of our common shares and is our primary lender and will be able to exert significant control over matters subject to shareholder approval.

Sumitovant beneficially owns approximately 75% of the voting power of our outstanding common shares as of June 18, 2020. This majority ownership position, in combination with acting as our primary lender, gives Sumitovant the ability to exert substantial influence and control over us and our operations. For example, Sumitovant and its lone shareholder, Sumitomo, will 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.

Sumitovant and Sumitomo’s ability to control such decisions is subject to the terms of the investor rights agreement we entered into with Sumitovant and Sumitomo on December 27, 2019, or the Investor Rights Agreement. The Investor Rights Agreement provides that for so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of our directors, any transaction that would increase Sumitomo’s beneficial ownership to over 80% of our outstanding voting power must be approved by the holders of a majority of our outstanding voting shares that are not beneficially owned by Sumitovant or its affiliates, or the Minority Shares. In addition, the Audit Committee, or the Audit Committee, must approve any transaction that would increase Sumitomo’s beneficial ownership to over 76% of our outstanding voting power (if occurring prior to December 27, 2021) and any other related person transactions between Sumitomo or certain of its affiliates and us, consistent with our existing related person transactions policy.

As a strategic investor, Sumitovant’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 our other shareholders may not agree or that may not be in the best interests of our other shareholders. For example, Sumitovant may oppose a merger, amalgamation, sale of assets or other major corporate transaction involving one of its competitors for reasons independent of its ownership of our common shares. As a result of Sumitovant’s voting power, it has the ability to block matters submitted for shareholder approval. Further, Sumitovant 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 Sumitovant, or to Sumitovant’s business model, that could impact Sumitovant’s interests in a way that may not coincide with our corporate interests or the interests of other shareholders. Any such changes may diminish, or eliminate entirely, any benefits we expect to derive from our affiliation with Sumitovant. So long as Sumitovant or a successor to Sumitovant continues to own a significant amount of our equity, it will continue to be able to strongly influence and effectively control our decisions.

**Sumitovant has the right to appoint two directors to our board of directors, each of whom has three votes.**

Sumitovant is entitled to appoint two directors to our board of directors, each of whom has three votes on all matters presented to the board of directors. All other directors have one vote on all matters presented to the board of directors. While the directors appointed by Sumitovant are obligated to act in accordance with their fiduciary duty, they may have equity or other interests in Sumitovant and, accordingly, their interests may be aligned with Sumitovant’s interests, which may not always coincide with our corporate interests or the interests of our other shareholders. The two directors appointed by Sumitovant and who currently serve on our board of directors, acting together, are able to determine the outcome of all matters presented to the board of directors.

**Any shareholder or group of shareholders who own a majority of our Minority Shares can control the approval of certain transactions with Sumitovant and the elections of our independent directors.**

Pursuant to the Investor Rights Agreement, for so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of our directors, the holders of a majority of our Minority Shares, must approve any of the following actions before they can be taken:

- removal of any of our independent directors who comprise our Audit Committee;
- removal of Mr. Pierre Legault as our lead independent director; and
- any transaction that would increase Sumitomo’s beneficial ownership to over 80% of our outstanding voting power.

In addition, during the same period, the Investor Rights Agreement requires Sumitovant to vote its common shares in connection with the election of our independent directors in direct proportion to how the Minority Shares are voted.

As a result, any investor or group of investors who acquire a majority of our Minority Shares will have the right to control the election and terms of our independent directors and the approval of any transactions that would increase Sumitomo’s beneficial ownership above 80%. The interests of the holders of the majority of the Minority Shares may not always coincide with our corporate interests or the interests of our other shareholders, and such holder may exercise their voting and other rights in a manner with which our other shareholders may not agree or that may not
be in the best interests of our other shareholders. For example, such holders of a majority of the Minority Shares could refuse to approve a covered transaction with Sumitomo, even if our board of directors and the Audit Committee has approved such transaction, or block the removal of an independent director serving on our Audit Committee, even if the remainder of our shareholders desire to remove such director.

If any investor or group of investors acquire a majority of our Minority Shares, our other shareholders may not have access to information about such investors beyond any information such investors would be required to file with the SEC.

**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 holders of our Minority Shares, on the one hand, and Sumitovant and its sole shareholder, Sumitomo, on the other hand. Certain of our directors have indirect equity interests in Sumitovant and, accordingly, their interests may be aligned with Sumitovant’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 access to such information regarding our directors’ equity interest in Sumitovant, Sumitomo or their respective affiliates, which may change at any time through acquisition, disposition, dilution, or otherwise. Any change in our directors’ equity interest in Sumitovant or Sumitomo could impact the interests of those holders.

We are party to various related party agreements with Sumitovant and its affiliates, including the Sumitomo Loan Agreement, the Investor Rights Agreement, and the Information Sharing Agreement (as described in Note 14[C] below), and we may enter into other related party agreements with Sumitovant or its affiliates in the future. These entities and their shareholders, including certain of our directors and employees, may have interests which differ from our interests or those of the holders of our Minority Shares. Any material transaction between us and Sumitovant or its affiliates is subject to our related party transaction policy, which requires prior approval of such transaction by our audit committee. Because Sumitomo beneficially owns more than 10% of the voting interests of Roivant Sciences Ltd., or RSL, Sumitomo is considered a “principal owner” of RSL under applicable accounting standards. For so long as Sumitomo maintains a 10% or more ownership stake in RSL, transactions between us and RSL will be deemed related party transactions. The Investor Rights Agreement also requires that any related person transactions between us and Sumitomo or its affiliates must be approved by the Audit Committee, consistent with our related person transactions policy, for so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of our directors.

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.

**The Sumitomo Transaction may cause disruptions that could have an adverse effect on our business and stock price.**

The Sumitomo Transaction closed on December 27, 2019. Accordingly, Sumitovant now controls a majority of the voting power of our outstanding common shares. A number of factors could adversely affect our business or our stock price following the closing of the Sumitomo Transaction as we begin working with Sumitovant and undergo certain transitions following the closing, including:

- Sumitovant now controls certain matters requiring our shareholders’ approval, including the election of non-independent directors and approval of transactions that are not related person transactions.
- Sumitovant may implement changes to our business or take other corporate actions that our other shareholders may not view as beneficial.
- The anticipated benefits of our affiliation with Sumitomo may not occur or may occur in a less pronounced way than currently expected.
- The vesting of equity awards under the 2017 Plan accelerated upon the closing of the Sumitomo Transaction in accordance with its terms, which could adversely affect the market price of our common shares in the event that the holders of those equity awards elect to exercise their vested awards and sell the underlying common shares.
- The change in ownership of a majority of our outstanding common shares creates uncertainty for our employees, which could make it difficult to attract and retain qualified management and commercial, scientific and clinical personnel.
In connection with the closing of the Sumitomo Transaction and the Sumitomo Loan Agreement, we agreed to abide by certain covenants, and the restrictions imposed by these covenants on our operations could impair our management’s ability to respond to changing circumstances and exploit business opportunities that may arise in the future.

We were a party to a number of services agreements with RSL and its affiliates, and the transition of the services obtained under those agreements from RSL to Sumitovant may cause disruptions to our normal operations.

The Sumitomo Transaction may increase the risk of litigation, which could distract management and negatively impact our business.

We are now party to the Sumitomo Loan Agreement, which restricts us from taking certain actions without the consent of Sumitomo, thereby giving Sumitomo and Sumitovant additional control over our business.

While Sumitomo or Sumitovant also owns or is the majority shareholder of certain business service providers, we may not realize the benefits of this broader commercial network and may not enter into arrangements with these other providers.

In addition to these risks, the Sumitomo Transaction may result in unanticipated risks or other unintended consequences that could have an adverse effect on our business and stock price.

If securities or industry analysts cease to 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 depends, 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.

If we fail to meet the listing standards of Nasdaq, our common shares may be delisted, which could have a material adverse effect on the liquidity of our common shares.

Our common shares are currently listed on Nasdaq. The Nasdaq Stock Market LLC has requirements that a company must meet in order to remain listed on Nasdaq. For example, we are required to maintain minimum levels of shareholders’ equity, market values of our common shares, or bid prices. We are also required to meet certain minimum corporate governance requirements, including related to a majority independent board of directors and independent board committees, although we are exempt from many of these requirements because we are a controlled company. Under Nasdaq rules, even though we are a controlled company, we are not exempt from the requirement that we have three independent members of our Audit Committee, however. As a result of the removal of James Robinson from the Audit Committee pursuant to his appointment as our Principal Executive Officer, we no longer complied with the audit committee composition requirements set forth in Rule 5605(c)(1) of the Nasdaq listing rules, or Rule 5605(c)(1), and we utilized the cure period set forth in Rule 5605(c)(4)(B) of the Nasdaq listing rules, or Rule 5605(c)(4)(B), while we conducted our search. This noncompliance had no immediate effect on the listing or trading of our shares on Nasdaq. Pursuant to Rule 5605(c)(4)(B), we had until the earlier of our next annual meeting of shareholders or March 23, 2021 (the date that is one year from the event that caused our noncompliance) to comply with this requirement, except that if our annual meeting of shareholders occurs no later than 180 days following our noncompliance, we have 180 days to regain compliance. On May 20, 2020, we appointed James Hindman to our board of directors and a member of our Audit Committee. As such, we are now in compliance with Rule 5601(c)(1) and were within the cure period set forth in Rule 5605(c)(4)(B).

If we are unable to meet applicable Nasdaq listing requirements in the future, including following any applicable cure period, our common shares could be delisted. If our common shares were delisted, the liquidity of our common shares would be materially adversely affected and the market price of our common shares could decrease.

We do not anticipate paying any cash dividends on our common shares in the foreseeable future.

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. Additionally, we are subject to Bermuda legal constraints that may affect our ability to pay dividends on our common shares and make other payments.
In addition, the terms of our Sumitomo Loan Agreement restrict our ability to pay dividends to limited circumstances. As a result, investors in our common shares may only receive a return if the market price of our common shares increases.

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

Sales of a substantial number of our common shares in the public market, or the perception by investors that our shareholders intend to sell substantial amounts of our common shares in the public market, could depress the market price of our common shares even if our business is doing well. A decrease in our share price could in turn impair our ability to raise capital through the sale of additional equity securities.

All of the common shares sold in our IPO, as well as shares issued upon the exercise of options granted to persons other than our officers and directors and shares held by our non-affiliated shareholders, are freely transferable without restrictions or further registration under the Securities Act. If our major shareholders, including Sumitovant, or any of our executive officers or directors were to sell a substantial portion of our common shares, or if the market perceived that Sumitovant or any of our executive officers or directors intends to sell our common shares, it could negatively affect our common share price and could cause our share price to fall.

As of March 31, 2020, there were an aggregate of 5,731,759 common shares subject to outstanding options, stock appreciation rights, and restricted stock units. We have filed 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, including these outstanding options, stock appreciation rights, restricted stock units and any equity awards we may grant in the future. Accordingly, these shares may be freely sold in the public market upon issuance as permitted by any applicable vesting requirements, subject to the contractual restrictions described above. Sales of these common shares may 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. We have filed a registration statement on Form S-3 under the Securities Act to register the offer and sale of up to an aggregate of $200.0 million of our securities, which includes $50.0 million of our common shares under our “at-the-market” equity offering program described below. 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.

In November 2019, we entered into an “at-the-market” sales agreement with Jefferies LLC, or Jefferies, pursuant to which we may sell from time to time, common shares having an aggregate offering price of up to $50.0 million through Jefferies, acting as our agent. As of June 18, 2020, we have not sold any common shares pursuant to this “at-the-market” equity offering program. Whether we choose to effect future sales under the “at-the-market” equity offering program will depend on a number of factors, including, among others, market conditions and the trading price of our common shares relative to other sources of capital. The issuance from time to time of common shares through our “at-the-market” equity offering program or in any other equity offering, or the perception that such sales may occur, could have the effect of depressing the market price of our common shares.

**We have incurred, and will continue to 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” and no longer qualify as a “non-accelerated filer,” we will incur significant legal, accounting and other expenses. 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. For as long as we are an emerging growth company and a non-accelerated filer, we will not be required to comply with certain requirements applicable to other public companies, including an auditor attestation of the effectiveness of our internal control over financial reporting, and may be permitted to provide reduced disclosures under applicable SEC rules after we no longer qualify as an emerging growth company or a non-accelerated filer as long as we then qualify as a smaller reporting company under applicable SEC rules. Our legal and financial compliance costs will increase once we are no longer able to benefit from the exemptions and reduced disclosure requirements currently available to us as an emerging growth company and non-accelerated filer. 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 are 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 current fiscal year beginning April 1, 2019. This assessment needs 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 control 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, or such time as we no longer qualify as a non-accelerated filer, whichever occurs later. At such time as we are required to obtain an auditor attestation of our internal control over financial reporting, 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 are required to disclose significant changes made in our internal controls procedures on a quarterly basis.

We have completed the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. Our compliance with Section 404 has required us to incur substantial legal, accounting and other compliance expense and expend significant management efforts. We currently do not have an internal audit group, but we have engaged consultants with appropriate public company experience and technical accounting knowledge to assist in compiling 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 control over financial reporting in the future. Any failure to maintain effective internal control 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 control 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 control 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 control 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 a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting 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) that is March 31, 2024, (b) on which we have total annual gross revenue of at least $1.07 billion or (c) on 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” and/or a “non-accelerated filer,” which would allow us to take advantage of many of the same exemptions and reduced disclosure obligations, including with respect to the exemption from compliance with the auditor attestation requirements of Section 404 and reduced executive compensation disclosure in 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 shareholders 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. As we are incorporated under the laws of Bermuda and all or a substantial portion of our assets are located outside the United States, a shareholder may need to effect service of process upon us in Bermuda. 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; and (5) no new admissible evidence relevant to the action is submitted prior to the rendering of the judgment by the courts of Bermuda. 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.

**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 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.

**Legislation enacted in Bermuda in response to the European Union’s review of harmful tax competition could be harmful to our business.**

During 2017, the European Union Economic and Financial Affairs Council, or ECOFIN, released a list of non-cooperative jurisdictions for tax purposes. The stated aim of this list, and accompanying report, was to promote good governance worldwide in order to maximize efforts to prevent tax fraud and tax evasion. In an effort to remain off this list, Bermuda committed to address concerns relating to economic substance by December 31, 2018. In accordance with that commitment, Bermuda enacted legislation that requires certain entities in Bermuda engaged in “relevant activities” to maintain a substantial economic presence in Bermuda and to satisfy economic substance requirements. In June 2019, Bermuda exempted entities which are resident for tax purposes outside of Bermuda (and which are not resident in a jurisdiction listed by the EU as non-cooperative for tax purposes) from satisfying these economic substance requirements. The Company would be exempt as it is regarded as resident in the U.K. for tax purposes.

To the extent the Company ceases to be exempt from the economic substance requirements and is required to increase its substance in Bermuda to satisfy such requirements, it could result in additional costs that could adversely affect the Company’s financial condition or results of operations. If the Company were required to satisfy economic substance requirements in Bermuda but failed to do so, it could face automatic disclosure to competent authorities in the EU of the information filed by the Company with the Bermuda Registrar of Companies in connection with the economic substance requirements and may also face financial penalties, restriction or regulation of our business activities and/or may be struck off as a registered entity in Bermuda.
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 and subject to U.K.’s controlled foreign company rules, 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.

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 Sumitovant, our majority 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 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 arm’s 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 taxing 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. In addition, our effective tax rate and the availability of any tax holidays could be adversely affected if we do not obtain favorable tax rulings from certain taxing authorities. 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 taxing 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. We continue to assess the impact of such changes in tax laws and interpretations on our business and may determine that changes to our structure, practice, tax positions or the manner in which we conduct our business are necessary in light of such changes and developments in the tax laws of the jurisdictions in which we operate. 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 taxing authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm’s 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 taxing 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 consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Changes in our 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 taxing 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 taxing 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 combined voting power 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 combined voting power or value of all outstanding stock of such non-U.S. corporation) 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.

We believe that we and our non-U.S. subsidiaries were classified as CFCs in the prior taxable year that ended on March 31, 2020. For U.S. holders who hold 10% or more of the combined voting power 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, or the IRS. 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.
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 average quarterly 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 a PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income generally includes dividends, interest, 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 certain distributions by us and the proceeds of sales or other dispositions of our common shares. In addition, special information reporting may be required.

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. Our status may also depend, in part, on how quickly we utilize the cash on hand and cash from future financings, including the cash proceeds from the Sumitomo Loan Agreement, in our business and whether we earned or earn primarily passive income (such as interest income) in the prior, current or future taxable years. With respect to the prior taxable year that ended on March 31, 2020, the current taxable year and foreseeable future taxable years, we believe that we were not a PFIC and presently do not anticipate that we will be a PFIC based upon the expected value of our assets, including any goodwill, and the expected nature and composition of our income and assets. However, our status as a PFIC is a fact-intensive determination made on an annual basis and we cannot provide any assurances regarding our PFIC status for the prior, current or future taxable years. Our U.S. counsel expresses no opinion with respect to our PFIC status for our prior, 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.

We have implemented structures and arrangements intended to mitigate the possibility that we will be classified as a PFIC. There can be no assurance that the IRS will not successfully challenge these structures and arrangements, which may result in an adverse impact on the determination of whether we were or are classified as a PFIC in the prior, current and future taxable years. In addition, recently proposed U.S. Treasury Regulations, of which we are continuing to assess the impact, may also adversely affect the treatment of these structures and arrangements with respect to our PFIC status.

The tax consequences that would apply if we are classified as a PFIC may 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.

Item 1B. Unresolved Staff Comments.
Not applicable.

Item 2. Properties.
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 5281 California Avenue, Suites 100 and 250, Irvine, California 92617 and 324 Blackwell Street Bay 11, Suite 1104, Durham, North Carolina 27701.

Our wholly owned subsidiary, USI, entered into a lease agreement in November 2018 for 21,489 square feet of office space located in Irvine, California for clinical research and development operations, commercial operations, and administrative functions that expires seven years from the lease commencement date with an option to terminate after five years. The lease commenced in June 2019. In April 2020, USI amended the lease agreement to include an additional 6,865 square feet of office space located in Irvine, California. USI also entered into a sublease agreement with our affiliate, RSI, in June 2019 for 2,784 square feet of office space located in Durham, North Carolina for clinical research and development and other activities carried out by our personnel. The lease expires in July 2025.
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 in the future, from where we would plan to conduct business development, intellectual property management, commercial preparation and clinical research and development activities.

We believe that our leased facilities are in good condition and are well maintained and that our current arrangements will be sufficient to meet our needs for the foreseeable future and that any required additional space will be available on commercially reasonable terms to meet space requirements if they arise.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings related to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results, or financial condition.

Item 4. Mine Safety Disclosures.

Not applicable.
PART II

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

Market Information for Common Shares
In October 2018, we completed our initial public offering, or IPO, and our common shares began trading on the Nasdaq Global Select Market, or Nasdaq, under the symbol “UROV” on September 27, 2018. Prior to that date, there was no established public trading market for our common shares.

Shareholders
American Stock Transfer & Trust Company is the transfer agent and registrar for our common shares. As of the close of business on June 18, 2020, we had two shareholders of record. The actual number of shareholders is greater than this number of record shareholders and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. The number of shareholders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividend Policy
We have never declared or paid cash dividends on our common shares. We anticipate that we will retain all of our future earnings, if any, for use in the expansion and operation 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 a number of factors, 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 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) that the realizable value of its assets would thereby be less than its liabilities. 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. Furthermore, our ability to pay cash dividends is currently restricted by the terms of the Sumitomo Loan Agreement.

Recent Sales of Unregistered Equity Securities
None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers
None.

Under SEC rules and regulations, because we qualify as a “smaller reporting company”, we are not required to provide the information required by this item in this report.
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition, results of operations, and cash flows should be read in conjunction with the audited consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or elsewhere in this Annual Report on Form 10-K, 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 “Risk Factors” set forth in this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. In addition, refer to the section of this Annual Report on Form 10-K titled “Cautionary Note Regarding Forward-Looking Statements.”

Overview

We are a clinical-stage biopharmaceutical company focused on developing and commercializing innovative therapies for urologic conditions. Our goal is to be a leading urology company by developing, commercializing and acquiring innovative therapies. Our lead product candidate, vibegron, is an oral, once-daily, small molecule that was observed to be a highly selective agonist of the human beta-3 adrenergic receptor in in vitro assays. Vibegron is currently being developed for three potential indications: overactive bladder, or OAB, the treatment of OAB in men with benign prostatic hyperplasia, or BPH, and the treatment of abdominal pain due to irritable bowel syndrome, or IBS. Our second product candidate, URO-902, is a novel gene therapy that we are developing for patients with OAB who have failed oral pharmacological therapy. Vibegron was licensed to us in February 2017 by Merck Sharp & Dohme Corp., or Merck, and URO-902 was licensed to us in August 2018 by Ion Channel Innovations, LLC, or ICI. Additional information regarding our business and product candidates is included in Part I. Item 1. “Business” of this Annual Report on Form 10-K.

We were incorporated in January 2016, and our operations to date have consisted of organizing and staffing our company, identifying and in-licensing our product candidates, including acquiring the rights to vibegron and URO-902, preparing for and advancing the clinical development of our product candidates and preparing for the potential commercialization of vibegron.

Fiscal Year Ended March 31, 2020 and Recent Clinical and Business Highlights

The following summarizes our fiscal year ended March 31, 2020 and recent clinical and business highlights:

**Vibegron for Treatment of OAB**

- In December 2019, we submitted a new drug application, or NDA, to the FDA seeking approval of once-daily 75mg vibegron for the treatment of patients with OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency. The FDA accepted our NDA in March 2020. Our NDA has been assigned a Prescription Drug User Fee Act, or PDUFA, goal date of December 26, 2020.
- In September 2019, we reported positive long-term data from the double-blind extension of our pivotal Phase 3 EMPOWUR trial of vibegron in adults with OAB. Among the 52-week EMPOWUR vibegron treatment group, the reduction in micturitions at week 52 was 2.4 episodes per day from a baseline of 11.32 episodes and the reduction in urgency episodes was 3.4 episodes per day from a baseline of 8.0 episodes. Vibegron demonstrated sustained efficacy for urge urinary incontinence as the reduction in urge urinary incontinence was 2.2 episodes at week 52 from a baseline of 3.18 per day. In addition, a total of 61% of patients on vibegron achieved at least a 75% reduction in their daily urge urinary incontinence episodes from baseline at week 52 and 41% of patients on vibegron became “dry” which is defined as having no urge urinary incontinence episodes at week 52. This long-term data followed positive top-line results we reported in March 2019 from the pivotal Phase 3 EMPOWUR trial with over 1,500 patients, with vibegron 75 mg meeting both co-primary efficacy endpoints and all seven key secondary endpoints. Onset of action for the co-primary endpoints was observed as early as week two, the first timepoint measured, and statistically significant efficacy was maintained at all timepoints measured through the end of the study.
In August 2019, we completed the ambulatory blood pressure study for vibegron. The purpose of the study was to rule out an effect of vibegron relative to placebo on daytime systolic blood pressure. Vibegron achieved its primary endpoint demonstrating that vibegron does not have an effect on daytime systolic ambulatory blood pressure compared to placebo (where no effect was defined as a change from baseline of less than 3.5mm Hg compared to placebo within a 90% confidence interval). For mean ambulatory daytime systolic blood pressure, there was no statistically significant or clinically relevant difference for vibegron compared to placebo.

**Vibegron for Treatment of OAB in Men with BPH**
- In October 2019, part two of the Phase 3 COURAGE trial assessing efficacy and safety in all patients, and testing 75 mg of vibegron versus placebo, began enrollment. The primary efficacy consists of the co-primary efficacy endpoints, including change from baseline in the average number of micturitions per 24 hours and change from baseline in the average number of urgency episodes per 24 hours. The primary efficacy timepoint is Week 12 after treatment.
- We expect to receive top-line data from the Phase 3 COURAGE trial in the second half of 2021.

**Vibegron for Treatment of Abdominal Pain Due to IBS**
- We continue to enroll patients in our Phase 2a double-blind, placebo-controlled study in women with abdominal pain due to IBS with predominant diarrhea, or IBS-D, or mixed episodes of diarrhea and constipation, or IBS-M. The trial is expected to enroll approximately 200 patients in the United States.
- We expect to complete enrollment in the summer of 2020 and receive top-line data from the Phase 2a clinical trial in the fourth calendar quarter of 2020.

**URO-902**
- In December 2019, we enrolled our first patient in the placebo-controlled, randomized, multicenter proof-of-concept Phase 2a clinical trial to evaluate the safety and efficacy of URO-902 for the treatment of OAB in 78 female patients who have not responded to oral pharmacological therapies. The Phase 2a trial is expected to enroll patients in two cohorts: the first cohort will receive either a single administration of 24 mg of URO-902 or matching placebo, and the second cohort will receive 48 mg of URO-902 or matching placebo into the bladder wall. Patients will be followed for up to 48 weeks after initial administration. The key efficacy endpoints for this Phase 2a clinical trial include reductions per day in micturitions, urgency episodes and UUI episodes.
- We expect to receive the week 12 primary efficacy and safety top-line data for both cohorts in the Phase 2a clinical trial in the second half of 2021 and full trial data after the completion of the 48-week post-treatment period in 2022.

**Sale of RSL’s Interest in the Company**
In October 2019, Roivant Sciences Ltd., or RSL, and certain of its affiliates entered into a definitive agreement, or the Sumitomo Transaction Agreement, with Sumitomo pursuant to which, among other things, Sumitomo agreed to acquire all of RSL’s ownership interest in the Company. In connection with the Sumitomo Transaction Agreement, we entered into a letter agreement with Sumitomo, or the Sumitomo Letter Agreement, pursuant to which, among other things, (i) Sumitomo committed to provide us with a low-interest, interest-only, five-year term loan facility with no principal repayments required to be made by us until the end of the term; and (ii) the parties agreed to enter into an investor rights agreement that would provide Sumitomo with customary registration and information rights and provide our minority shareholders certain protections outlined therein.

On December 27, 2019, Sumitomo and RSL announced the closing of the transactions contemplated by the Sumitomo Transaction Agreement, or the Sumitomo Transaction, pursuant to which all of our common shares held by RSL were contributed to Sumitovant Biopharma Ltd., a wholly-owned subsidiary of RSL at the time of such contribution, or Sumitovant, and subsequent to such contribution, Sumitomo acquired all issued and outstanding equity securities of Sumitovant. As of March 31, 2020, Sumitovant directly, and Sumitomo indirectly, owns approximately 75% of our outstanding common shares. As a result of the transfer of these common shares, RSL no longer beneficially owns any of our common shares.
Sumitomo Loan Agreement

On December 27, 2019, we entered into a $300 million unsecured revolving debt facility with Sumitomo, as lender, or the Sumitomo Loan Agreement. Sumitomo funded an initial amount of $87.5 million on December 30, 2019 under the terms of the Sumitomo Loan Agreement. In April 2020, Sumitomo funded an additional amount of $41.0 million. Additional funds may be drawn down by us no more than once in any calendar quarter, subject to the funding requests that are made in accordance with our board approved operating budget. Loans under the Sumitomo Loan Agreement, or the Loans, bear a variable interest rate per annum equal to the London Inter-bank Offered Rate, or LIBOR, plus a margin of 3% payable on the last day of each calendar quarter. The Loans mature and are payable in full on the five-year anniversary of the closing date of the Sumitomo Loan Agreement or December 27, 2024.

Investor Rights Agreement

On December 27, 2019, we entered into an investor rights agreement with Sumitomo and Sumitovant, or the Investor Rights Agreement. Pursuant to the Investor Rights Agreement, among other things, we agreed to comply with any demands by Sumitovant to register for sale, under the Securities Act of 1933, as amended, any common shares of the Company beneficially owned by Sumitovant that have an anticipated aggregate net offering price of at least $5 million, subject to certain customary exceptions and the right of the Company to refuse any demand for registration if we already effected two registrations for Sumitovant in the year preceding such demand. In addition, we agreed to periodically provide Sumitovant with (i) certain financial statements, projections, capitalization summaries and other information customarily provided to significant investors in publicly-traded companies and (ii) access to our books, records, facilities and employees during our normal business hours as Sumitovant may reasonably request.

Moreover, the Investor Rights Agreement also contains certain protections for our minority shareholders for so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of our directors, or Total Voting Power. These protections include, among other things: (i) a requirement for a minimum of three independent directors on our Board of Directors, or the Board (each of whom cannot be removed by Sumitomo or certain of its affiliates without the approval of a majority of the minority shareholders); (ii) a requirement that the audit committee of the Board, or the Audit Committee, be comprised solely of independent directors; (iii) the appointment of Mr. Pierre Legault as our lead independent director; (iv) a requirement that any transaction proposed by Sumitomo or certain of its affiliates that would increase Sumitomo’s beneficial ownership to over 76% of the Total Voting Power be approved by the Audit Committee (if occurring prior to December 27, 2021) and, if such transaction would increase Sumitomo’s beneficial ownership to over 80% of the Total Voting Power, a majority of our minority shareholders must vote on such matter; and (v) a requirement that any related person transactions between Sumitomo or certain of its affiliates and us be approved by the Audit Committee, consistent with our existing Related Person Transactions Policy.

Pursuant to the Investor Rights Agreement, we also agreed that so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the Total Voting Power, we will inform Sumitovant before issuing any new common shares and allow Sumitovant to (i) participate in such issuance up to its pro rata share (unless such issuance is in connection with the acquisition of a business or its assets) or (ii) make sufficient open market purchases of our securities to ensure that Sumitomo’s beneficial ownership percentage does not decline as a result of such issuance.

Information Sharing and Cooperation Agreement

On May 21, 2020, we entered into an information sharing and cooperation agreement, or the Sumitovant Cooperation Agreement, with Sumitovant. The Sumitovant Cooperation Agreement, among other things, obligates us to deliver to Sumitovant drafts of (i) our quarterly and annual financial statements and (ii) the discussion and analysis by our management of the Company’s financial condition and the results of our operations for such fiscal periods, prior to the applicable deadlines for filing such information with the SEC. We also agreed to coordinate with Sumitovant before releasing earnings results or any interim financial guidance and to notify Sumitovant before issuing any other material press releases.
In addition, the Sumitovant Cooperation Agreement requires us to give Sumitovant’s auditors access to our auditors and our books and records to facilitate the completion of Sumitovant’s own internal audit and their review of our financial statements and internal accounting controls and operations. We also agreed to provide Sumitovant any documents or materials relating to our business and access to our senior management to discuss any matters, in each case as Sumitovant may reasonably request. To the extent we provide Sumitovant any information in response to such a request, Sumitovant may not (i) disclose such information to certain of its affiliates or (ii) use such information in a manner it deems, in good faith, to be detrimental to the Company or our shareholders. In addition, both parties agreed to hold any information they receive from the other party in the strictest confidence, subject to customary exceptions for information that becomes public, that has been independently developed, or that is otherwise received on a non-confidential basis from a third party.

Moreover, the Sumitovant Cooperation Agreement provides that we must adopt and maintain policies to address our obligations with respect to financial reporting, audits, internal controls, record keeping, taxes, and other applicable laws. In addition, the Board must have a compliance oversight committee, or the Compliance Committee, that oversees a compliance program designed to ensure we comply with our obligations under applicable laws, or the Compliance Program. The Compliance Committee, in turn, is required to (i) appoint a member of our senior management to administer the Compliance Program and (ii) cause the implementation of internal reporting procedures and training to support the Compliance Program. The Sumitovant Cooperation Agreement also requires us to comply in all material respects with applicable laws.

**Market Access Services Agreement**

On June 17, 2020, Urovant Sciences GmbH, or USG, entered into a market access services agreement, or the Market Access Services Agreement, with Sunovion Pharmaceuticals, Inc., or Sunovion, a wholly-owned subsidiary of Sumitomo. Pursuant to the Market Access Services Agreement, among other things, USG appointed Sunovion as the exclusive distributor of vibegron in the United States, including all of its territories and possessions.

Sunovion, in turn, has agreed to provide certain market access services with respect to the distribution and sale of vibegron, including, among other things: (i) adding vibegron to Sunovion’s agreements with its third party logistics providers; (ii) adding vibegron to certain of Sunovion’s contracts with wholesalers, group purchasing organizations and integrated delivery networks; (iii) facilitating USG’s entry into new contracts with certain health organizations regarding vibegron; (iv) managing the validation, processing and payment of rebates, chargebacks, and certain administrative, distribution and service fees related to vibegron; (v) providing USG with price reporting metrics and other information required for it to comply with applicable government price reporting requirements; (vi) coordinating with USG and any applicable wholesalers to address any recalls, investigations, or product holds; and (vii) providing certain other ancillary support services to facilitate the foregoing.

In order to facilitate Sunovion’s provision of these services, USG agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by USG, solely to enable Sunovion to perform the contemplated services; (ii) provide Sunovion periodic reports of sales projections and volume requirements, as well as such other information as Sunovion reasonably requests or may need to perform the services; (iii) comply with the provisions of any agreements between Sunovion and third parties pursuant to which vibegron will be distributed or sold; (iv) cooperate with certain investigations related to orders and audits of USG’s quality systems; and (v) promptly notify Sunovion in the event vibegron is recalled.

As consideration for the services, USG will pay Sunovion an agreed-upon monthly service charge for each of the first two years of the agreement term. After the second year of the agreement term, the monthly service charges will be determined by the parties. In addition, USG also agreed to (x) reimburse Sunovion for any pass-through expenses it incurs while providing the services and (y) establish an escrow fund for use by Sunovion when managing any rebates, chargebacks and similar fees.

The Market Access Services Agreement also contains customary representations and warranties by the parties and customary provisions related to confidentiality, indemnification and insurance. The initial term of the Market Access Services Agreement is three years. Thereafter, the term will be automatically extended for one-year periods, unless either party provides notice of its intent to terminate the agreement at least nine (9) months prior to the expiration of the applicable term. Either party may also terminate the agreement prior to the end of its term in the event of an uncured material breach by the other party or if such other party becomes insolvent or undergoes a change of control. Finally, USG may also terminate the Market Access Services Agreement if Sunovion fails to satisfy certain market access milestones or upon payment of a break-up fee.

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Appointment of New Principal Executive Officer and Changes to Board of Directors

On March 23, 2020, following the resignation of Keith Katkin as our Principal Executive Officer and member of the Board, the Board appointed James Robinson to serve as our Principal Executive Officer. Mr. Robinson has served as a member of the Board since March 2019 and will continue to serve on the Board.

On March 23, 2020, we, Sumitomo and Sumitovant executed a waiver of the requirements of Section 4.1(a) of the Investor Rights Agreement, solely with respect to the reduction of the number of independent directors serving on the Board as a result of the appointment of Mr. Robinson as our Principal Executive Officer, until September 19, 2020. The remaining terms of the Investor Rights Agreement remained in full force and effect. On May 20, 2020, James Hindman was appointed to the Company’s Board of Directors and a member of the Audit Committee and, as a result, the Company’s Board of Directors and Audit Committee has three independent directors. Therefore, the Company is in compliance with Section 4.1(a) of the Investor Rights Agreement.

Corporate Financing

- We raised aggregate gross cash proceeds of $117.5 million from debt financing transactions, including $87.5 million from the Sumitomo Loan Agreement, during the year ended March 31, 2020. In April 2020, we borrowed an additional $41.0 million under the Sumitomo Loan Agreement.

- In January 2020, we terminated the Hercules Loan Agreement in connection with, and as a requirement under, the Sumitomo Loan Agreement. Our obligations under the Hercules Loan Agreement of $48.2 million were repaid in full in January 2020.

Impact of COVID-19

In December 2019, an outbreak of a novel strain of coronavirus, or COVID-19, was identified. Due to the rapid and global spread of the virus, in March 2020, the World Health Organization categorized the novel COVID-19 as a pandemic, and it continues to spread throughout the United States and other countries across the world. To limit the spread of COVID-19, governments have taken various actions including the issuance of stay-at-home orders and social distancing guidelines and causing some businesses to suspend operations. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, and has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. To date, our operations have not been significantly impacted by the COVID-19 pandemic other than, for vibegron, from March 19, 2020 to April 27, 2020, we temporarily halted the screening of new subjects into our Phase 3 COURAGE trial and Phase 2a trial for abdominal pain due to IBS. For URO-902, from March 19, 2020 to May 4, 2020, we temporarily halted the screening of new subjects in our Phase 2a trial due to the COVID-19 pandemic. Subjects that were in the run-in phase or already enrolled in our ongoing studies continued with treatment pursuant to the clinical trial protocol and treatments were not halted or delayed. Such disruption is not expected to have a material adverse impact on our clinical trial plans and timelines.

Our priorities during the COVID-19 pandemic are protecting the health and safety of our employees while continuing our mission to develop and commercialize innovative therapies for urological conditions. Beginning the week of March 16, 2020, substantially all of our workforce began working from home and we curtailed employee travel. The effects of the stay-at-home orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. We have adopted remote working tools to minimize the disruption to the achievement of our goals and objectives. As stay-at-home orders have started to be lifted, we may continue to require employees to work from home for a period of time after the order is lifted to protect the health and safety of employees. We continue to follow and monitor recommended actions of government and health authorities to protect our employees and will gradually resume normal operations once it is prudent to do so, and in compliance with all Federal, State, and local laws.

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Further, the COVID-19 pandemic may negatively affect our supply chain, our ability to obtain approval of vibegron from the FDA and our pre-launch commercial readiness activities. We rely exclusively on third-party manufacturers to manufacture vibegron and URO-902 and our key third-party suppliers and manufacturers have been able to broadly maintain operations. To date, we have not experienced any significant disruption in our current supply chain for our clinical trials and as we prepare for the commercial launch of vibegron, if approved, or any negative impact or delay in our pre-launch commercial readiness activities or timelines. While we currently do not anticipate any interruptions in our manufacturing process or our pre-launch commercial readiness activities, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our third-party suppliers and contract manufacturing partners’ ability to supply and/or manufacture our products and our ability to conduct our pre-launch commercial readiness activities.

Our clinical trials may also be affected in the future by the COVID-19 pandemic. Site initiation and patient enrollment may be delayed due to prioritization of healthcare resources toward the COVID-19 pandemic. The COVID-19 pandemic may delay enrollment in our clinical trials, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services.

The ultimate impact of the COVID-19 pandemic is highly uncertain and we do not yet know the full extent of potential delays or impacts on our business, our financial results, our clinical trials, our supply chains, our pre-launch commercial readiness activities, end user demand for our products, if approved, healthcare systems or the global economy as a whole. The extent to which COVID-19 impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. As such, it is uncertain as to the full magnitude that the pandemic will have on our financial condition, liquidity, and future results of operations.

Financial History

We have incurred, and expect to continue to incur, significant operating losses and negative cash flows as we continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of vibegron. To date, we have not generated any revenue, and we do not expect to generate revenue unless and until we successfully complete development and obtain regulatory approval for at least one of our product candidates.

We have funded our operations primarily from the issuance and sale of our common shares, from the Sumitomo Loan Agreement and from the term loans we had pursuant to the Hercules Loan Agreement. Additional information about our sources of funding is included under “—Liquidity and Capital Resources—Sources of Liquidity” below.

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 vibegron, URO-902 or any future product candidate alone or in collaboration with third parties, we may generate revenue from vibegron, URO-902 or any such future product candidate.

Research and Development Expenses

Our research and development expenses to date have been primarily attributed to the license of rights to vibegron and URO-902, the initiation and ongoing activities related to our clinical programs and the increase in our personnel. Research and development expenses include program-specific costs, as well as costs that are not allocated to a specific program.

Program-specific costs include:

- direct third-party costs such as expenses incurred under agreements with clinical research organizations, or 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 attributable to the development of our product candidates.
Unallocated costs primarily include:

- employee-related expenses, such as salaries, share-based compensation, benefits and travel expense for our research and development personnel; and
- other expenses, which include the costs of consultants who assist with research and development activities not specific to a program.

Research and development expenses also include in-process research and development expense related to our acquisition of the rights to our product candidates, vibegron and URO-902, from Merck and ICI, respectively.

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. It is difficult to determine with certainty the duration and completion costs of any clinical trial we may conduct. We expect our overall research and development expenses to continue to be a significant area of spend over the next several years as we advance the clinical development of vibegron and URO-902. With the completion of the Phase 3 EMPOWUR study and submission of our NDA seeking approval of vibegron for the treatment of patients with OAB, development costs for vibegron for OAB will decrease but are expected to be partially offset by increases in development costs of vibegron for other indications, particularly if the programs are successful, as well as increases in other areas, such as regulatory, pharmacovigilance, and medical affairs.

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; the efficacy and safety profile of the product candidate; and any impact as a result of the COVID-19 pandemic.

In addition, the probability of success for vibegron, URO-902 and any other product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our programs or when and to what extent we will generate revenue from commercialization and sale of any of our product candidates. Our research and development activities may be subject to change from time to time as we evaluate our priorities and available resources.

**General and Administrative Expenses**

General and administrative expenses consist primarily of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for general and administrative personnel, professional fees for legal, consulting, accounting, auditing and tax services, commercial readiness costs, insurance, facilities and information technology costs, and general overhead.

We anticipate that our general and administrative expenses will increase in the future to support anticipated organizational growth, commercial readiness, commercial launch if our product candidates are approved, and increased costs of continuing to operate as a public company. These increases will likely include increased costs related to the hiring of additional personnel, professional fees and general overhead. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of The Nasdaq Global Select Market, or Nasdaq, and the SEC, insurance and investor relations costs. We expect to incur increased costs associated with establishing sales, marketing, and commercialization functions in advance of potential future regulatory approvals and commercialization of our product candidates. 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 and funding commercial activities.
### Results of Operations

The following table sets forth our results of operations for the years ended March 31, 2020 and 2019 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
</tr>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>$92,437</td>
</tr>
<tr>
<td>General and administrative</td>
<td>46,299</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>138,736</td>
</tr>
<tr>
<td><strong>Other income (expense):</strong></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net</td>
<td>(3,581)</td>
</tr>
<tr>
<td>Loss on extinguishment of long-term debt</td>
<td>(4,093)</td>
</tr>
<tr>
<td>Loss on disposal of property and equipment</td>
<td>(236)</td>
</tr>
<tr>
<td>Other expense, net</td>
<td>(34)</td>
</tr>
<tr>
<td>Loss before provision for income taxes</td>
<td>(146,680)</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>65</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(146,745)</td>
</tr>
</tbody>
</table>

### Research and Development Expenses

For the years ended March 31, 2020 and 2019, our research and development expenses consisted of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
</tr>
<tr>
<td><strong>Program-specific costs:</strong></td>
<td></td>
</tr>
<tr>
<td>Vibegron</td>
<td>$65,453</td>
</tr>
<tr>
<td>URO-902</td>
<td>3,498</td>
</tr>
<tr>
<td><strong>License fees:</strong></td>
<td>10,000</td>
</tr>
<tr>
<td><strong>Unallocated costs:</strong></td>
<td></td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>3,609</td>
</tr>
<tr>
<td>Personnel expenses</td>
<td>7,219</td>
</tr>
<tr>
<td>Services Agreements</td>
<td>—</td>
</tr>
<tr>
<td>Other expense</td>
<td>2,658</td>
</tr>
<tr>
<td><strong>Total research and development expenses</strong></td>
<td>$92,437</td>
</tr>
</tbody>
</table>

Research and development expenses increased by $0.2 million, to $92.4 million, for the year ended March 31, 2020 compared to $92.2 million for the year ended March 31, 2019. The increase in research and development expenses is primarily due to the following:

- milestone payments of $10.0 million and $2.5 million pursuant to the license agreement with Merck and collaboration agreement with Kyorin, respectively;
- an increase of $5.8 million in chemistry, manufacturing and controls costs as a result of sourcing and preparing for the manufacturing of validation batches of vibegron;
- the PDUFA fee of $2.9 million in connection with the submission of our NDA seeking approval of vibegron for the treatment of OAB;
- an increase of $2.3 million in share-based compensation due to the acceleration of vesting of certain stock options and restricted stock units as a result of the sale of RSL’s interest in the Company to Sumitomo;
- an increase of $1.8 million in personnel-related costs due to increased headcount;
- an increase of $1.6 million in other program-specific third-party research and development costs to support the continuation of our clinical programs and the submission of our NDA filing for vibegron; and
These increased expenses were partially offset by decreases primarily attributed to the following:

- an increase of $1.1 million in other unallocated research and development costs.

These increased expenses were partially offset by decreases primarily attributed to the following:

- a decrease of $25.0 million in CRO costs primarily due to the completion of the Phase 3 EMPOWUR study; and
- a decrease of $2.2 million in costs billed under the service agreements with RSI and RSG.

**General and Administrative Expenses**

General and administrative expenses increased by $27.7 million, to $46.3 million, for the year ended March 31, 2020 compared to $18.6 million for the year ended March 31, 2019. The increase in general and administrative expenses is primarily due to the following:

- an increase of $14.7 million in share-based compensation expense for stock options and restricted stock units granted to employees and board members due to the acceleration of vesting of certain stock options and restricted stock units as a result of the sale of RSL’s interest in the Company to Sumitomo and increased fair value of certain stock options modified and reclassified to liabilities;
- an increase of $6.0 million in personnel-related costs due to increased headcount;
- an increase of $4.4 million in general overhead and corporate expenses due to costs associated with operating as a public company and larger office facilities to accommodate our increased headcount;
- an increase of $2.3 million in market research and other commercial readiness costs; and
- an increase of $1.8 million in legal and other professional and consulting fees due to costs associated with operating as a public company.

These increased expenses were partially offset by a $1.5 million decrease in share-based compensation expense allocated to us by RSL and costs billed under the services agreements with RSI and RSG.

**Interest Expense, Net**

Interest expense, net consists of interest expense related to the Hercules Loan Agreement and Sumitomo Loan Agreement as well as the associated non-cash amortization of debt discount and issuance costs, partially offset by interest income earned on interest bearing cash deposit accounts. Interest expense, net, increased by $3.3 million, to $3.6 million, for the year ended March 31, 2020 compared to $0.3 million for the year ended March 31, 2019 primarily due to the Company entering into the Hercules Loan Agreement in February 2019.

**Loss on Extinguishment of Long-Term Debt**

The loss on extinguishment of long-term debt consists of the difference between the carrying value of the term loans pursuant to the Hercules Loan Agreement on the date of termination and the outstanding obligations paid in full of $48.2 million. The difference of $4.1 million primarily consists of the remaining unamortized debt discount and issuance costs on the termination date of $3.2 million and a prepayment charge of $0.9 million pursuant to the Hercules Loan Agreement being terminated prior to the one-year anniversary of its execution.

**Liquidity and Capital Resources**

**Sources of Liquidity**

In October 2018, we completed our IPO, in which we sold 10,297,813 common shares, including 297,813 common shares pursuant to the partial exercise of the underwriters’ over-allotment option to purchase additional shares, at a public offering price of $14.00 per common share. The net proceeds to us were approximately $132.9 million, after deducting $10.1 million in underwriting discounts and commissions and $1.2 million in offering expenses.

In February 2019, we entered into the Hercules Loan Agreement in the amount of $100.0 million. A first tranche of $15.0 million was funded in February 2019, a second tranche of $30.0 million was funded in September 2019. In January 2020, we terminated the Hercules Loan Agreement in connection with, and as a requirement under, the Sumitomo Loan Agreement and repaid in full our remaining obligations under the Hercules Loan Agreement as of the date of termination totaling $48.2 million.
In November 2019, we filed a registration statement on Form S-3 under the Securities Act of 1933 to register the offer and sale of up to an aggregate of $200.0 million of our securities, which includes our $50.0 million “at-the-market” equity offering program. As of March 31, 2020, we had $50.0 million of capacity available to us under our “at-the-market” equity offering program.

In December 2019, we entered into the Sumitomo Loan Agreement in the amount of $300.0 million. Sumitomo funded an initial amount of $87.5 million in December 2019 and an additional amount of $41.0 million in April 2020. Additional funds totaling $171.5 million as of June 19, 2020 may be drawn down by us no more than once in any calendar quarter, subject to certain terms and conditions.

As of March 31, 2020, we had $50.0 million of capacity available to us under our “at-the-market” equity offering program.

In December 2019, we entered into the Sumitomo Loan Agreement in the amount of $300.0 million. Sumitomo funded an initial amount of $87.5 million in December 2019 and an additional amount of $41.0 million in April 2020. Additional funds totaling $171.5 million as of June 19, 2020 may be drawn down by us no more than once in any calendar quarter, subject to certain terms and conditions.

As of March 31, 2020, we had an accumulated deficit of $322.3 million and a cash balance of $51.4 million, as compared to $175.5 million and $85.4 million, respectively, as of March 31, 2019. Prior to our IPO, the Hercules Loan Agreement and the Sumitomo Loan Agreement, all operations had been financed through capital contributions or short-term advances from RSL or its affiliates.

Capital Requirements
For the years ended March 31, 2020 and 2019, we had a net loss of $146.7 million and $111.3 million, respectively, and we have never generated any revenue.

We expect to continue to incur significant operating losses and negative cash flows 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 and negative cash flows 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 and commercialization efforts. We anticipate that our capital requirements will increase substantially as we:

- establish a sales, marketing and distribution infrastructure;
- advance our Phase 3 COURAGE trial of vibegron for the treatment of OAB in men with BPH;
- advance the clinical development of vibegron for the treatment of abdominal pain due to IBS beyond our ongoing Phase 2a trial;
- advance the clinical development of URO-902 for the treatment of OAB in patients who have not responded to oral pharmacological therapies beyond our ongoing Phase 2a trial;
- expand our chemistry, manufacturing, and control and other manufacturing related activities, including scale up external manufacturing capabilities to commercialize any drug candidates for which we may obtain regulatory approval;
- 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;
- service debt obligations and payment of interest associated with the Sumitomo Loan Agreement; and
- continue to operate as a public company.
Our primary use of cash is to fund the development of vibegron for the treatment of OAB, advance our Phase 3 COURAGE trial for vibegron for the treatment of OAB in men with BPH, advance our Phase 2a clinical trial for vibegron in patients with abdominal pain due to IBS, advance our Phase 2a clinical trial for URO-902 for the treatment of OAB in patients who have not responded to oral pharmacological therapies, and to fund our commercial readiness and general and administrative costs. We expect our operating expenses to continue to increase in the future as we expand our operations to continue to develop our product candidates and prepare for the potential future regulatory approvals and commercialization of vibegron. Based on anticipated spend and timing of expenditure assumptions, we currently believe that our existing cash, together with the draw down under the Sumitomo Loan Agreement of $41.0 million in April 2020 and the financing commitment from Sumitomo of $171.5 million which is available to us if future funding requests are in accordance with our board approved operating budget, will be sufficient to fund our committed operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this Annual Report on Form 10-K. This estimate is based on our current assumptions, including assumptions relating to the timing of regulatory approval and subsequent launch of vibegron for OAB and our ability to manage the amount and timing of our spend. Our current assumptions may prove to be wrong and we could use our available capital resources sooner than we currently expect. Changes may occur that would consume our available capital faster than anticipated, including the length and severity of the COVID-19 pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities and the impact on commercialization efforts due to the COVID-19 pandemic. We will need additional funding to complete the clinical development of, and seek regulatory approval for, vibegron for the treatment of OAB in men with BPH and abdominal pain due to IBS, URO-902, and commercially launch vibegron or URO-902, if approved. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, as well as may be limited pursuant to the terms of the Sumitomo Loan Agreement and Sumitomo’s ability to exert substantial influence and control over us due to Sumitomo’s majority ownership of our outstanding common shares. As such, adequate additional funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

Until such time, if ever, as we can generate substantial product revenue from sales of vibegron, URO-902 or any future product candidate, we expect to finance our cash needs through a combination of the remaining financing commitment available to us from the Sumitomo Loan Agreement, equity offerings, debt financings and potential collaboration, license or development agreements. 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. Our agreement with Sumitomo involves, and 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.

In addition, 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. If we are unable to raise capital, when needed, in sufficient amounts or on terms acceptable to us, or if the current financing commitment of $171.5 million available to us under the Sumitomo Loan Agreement is no longer available to us despite our future funding requests being in accordance with our board approved operating budget, we may have to significantly delay or scale back our operations to reduce working capital requirements beginning in the fourth calendar quarter of 2020, including but not limited to actions such as reducing personnel-related costs, curtailment of our pre-commercial launch efforts, development activities and other discretionary expenditures that are within our control. Additionally, we may have to discontinue the development or commercialization of vibegron or URO-902, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or potentially discontinue operations and substantial uncertainty would exist with respect to our ability to continue as a going concern. We will prioritize necessary and appropriate steps to enable the continued operations of our business and preservation of the value of our assets beyond the next twelve months. These reductions in expenditures, if required, may have an adverse impact on our ability to achieve certain of our planned objectives in fiscal years 2020 and 2021. Any of these actions could materially harm our business, results of operations and future prospects.
Cash Flows

The following table sets forth a summary of our cash flows for the years ended March 31, 2020 and 2019 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>(102,084)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(769)</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>68,937</td>
</tr>
</tbody>
</table>

Operating Activities

For the year ended March 31, 2020, $102.1 million of cash was used in operating activities. This was primarily attributable to a net loss of $146.7 million. This amount was partially offset by $20.5 million in share-based compensation expense from stock options and restricted stock units granted to employees and board members as a result of the acceleration of vesting of certain stock options and restricted stock units due to the Sumitomo Transaction and increased fair value of certain stock options modified and reclassified to liabilities, an increase of $11.9 million in accounts payable and accrued expenses primarily due to the accruals for clinical trial and drug supply costs, a decrease of $6.6 million in prepaid expenses and other current assets primarily due to the expense of amounts paid in advance of services performed by our CRO for our Phase 3 EMPOWUR study, $4.1 million in loss on extinguishment of long-term debt for the termination of the Hercules Loan Agreement in January 2020, $0.6 million in non-cash operating lease costs, $0.2 million from the loss on disposal of property and equipment upon our move to a larger office space in Irvine, California, and $0.7 million for the amortization of the debt discount and issuance costs from the Hercules Loan Agreement and Sumitomo Loan Agreement.

For the year ended March 31, 2019, $109.0 million of cash was used in operating activities. This was primarily attributable to a net loss of $111.3 million, an increase of $7.5 million in prepaid expenses and other current assets and a decrease of $1.5 million in amounts due to RSL. These amounts were partially offset by an increase of $6.7 million in accounts payable and accrued expenses, $3.4 million in share-based compensation expense from stock options and restricted stock units granted to employees, board members and consultants, and $0.6 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.

Investing Activities

For the years ended March 31, 2020 and 2019, $0.8 million and $0.6 million of cash was used in investing activities, respectively, all for the purchase of property and equipment.

Financing Activities

For the year ended March 31, 2020, cash provided by financing activities of $68.9 million was primarily attributable to proceeds of $87.5 million from the Sumitomo Loan Agreement, proceeds of $30.0 million from the Hercules Loan Agreement, proceeds of $0.8 million from the exercise of stock options, and capital contributions from RSL of $0.3 million, offset by the repayment and redemption fees associated with the Hercules Loan Agreement of $47.9 million, payment of stock options and restricted stock units tax withholding on net settlement of $0.9 million, debt financing costs in connection with the Hercules Loan Agreement and Sumitomo Loan Agreement of $0.6 million, and deferred offering costs in connection with our “at-the-market” equity offering program of $0.2 million.

For the year ended March 31, 2019, cash provided by financing activities of $188.6 million was primarily attributable to the net proceeds of $132.9 million from our IPO, capital contributions from RSL of $41.6 million, and net proceeds of $14.1 million from the debt financing with Hercules.

Contractual Obligations and Commitments

We enter into agreements in the normal course of business with vendors for services and products for operating purposes such as CROs for clinical trials, 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.
The following table provides information with respect to our contractual obligations as of March 31, 2020 and the effect such obligations are expected to have on our liquidity and cash flows in future years (in thousands):

<table>
<thead>
<tr>
<th>Contractual obligations</th>
<th>Payments due by period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td>Long-term debt obligation, including interest</td>
<td>$106,234</td>
</tr>
<tr>
<td>Operating lease obligations</td>
<td>4,972</td>
</tr>
<tr>
<td></td>
<td>$111,206</td>
</tr>
</tbody>
</table>

**Long-Term Debt Obligation – Related Party**

Long-term debt obligation reflects our obligation to pay interest on the outstanding principal amount as of March 31, 2020 of $87.5 million under the Sumitomo Loan Agreement and to make the principal repayment at maturity. Our long-term debt obligation under the Sumitomo Loan Agreement bears interest at a LIBOR variable rate plus a margin of 3% per annum. The related interest on the aggregate principal amounts outstanding to Sumitomo included in the above table was estimated using the interest rate in effect at March 31, 2020. See Note 5[B], “Long-term debt,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further discussion of the Sumitomo Loan Agreement.

**Operating Lease Obligations**

Operating lease obligations include future rent payments under one office lease in Irvine, California and one office lease in Durham, North Carolina. The Irvine lease is for 21,489 square feet of office space pursuant to a lease agreement which commenced in June 2019 and expires in May 2026, with the option to extend the lease term for an additional five years. The Durham lease is for 2,784 square feet of office space pursuant to a sublease agreement with our affiliate, RSI, that expires in July 2025 with no option to extend the lease term. The minimum lease payments included in the table above do not include any related common area maintenance charges or real estate taxes. In addition, the operating lease obligations included in the table above do not include potential rent payments during the optional lease renewal term.

In April 2020, we entered into an amendment to our Irvine office lease to add 6,865 square feet of office space. The lease term for the additional office space is concurrent with the existing Irvine lease and expires in May 2026. The total rental payment obligation under the new office lease is $1.3 million. The lease commenced in May 2020.

**License and Collaboration Agreements**

We received an exclusive license to develop, manufacture and commercialize vibegron worldwide, excluding Japan, China, 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. During the year ended March 31, 2020, we made a regulatory milestone payment of $10.0 million to Merck upon acceptance of our NDA submission by the FDA. We cannot, at this time, estimate the timing or likelihood of achieving the remaining milestones or generating future product sales which result in royalty payments to be made under this agreement. Therefore, such payments are not included in the table above. See Note 3[A], “License agreements,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further discussion of 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, solely as it relates to any of our rights or obligations in China, to RSG. 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 Note 6[H], “Related party transactions,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K 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. In December 2019, we achieved a certain regulatory milestone pursuant to the Kyorin Agreement and, as a result, recorded a milestone payment of $2.5 million during the year ended March 31, 2020. The remaining obligation under this agreement of $8.0 million would be due upon achievement of a regulatory milestone by us in the United States, subject to certain specific conditions which we believe are not probable to occur; therefore, such payment is not included in the table above. See Note 11[B], “Commitments and contingencies,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding our collaboration agreement with Kyorin.

We received an exclusive license to develop, manufacture and commercialize URO-902 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 $0.25 million to ICI during the year ended 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. We cannot, at this time, estimate the timing or likelihood of achieving these milestones or generating future product sales which result in royalty payments to be made under this agreement. Therefore, such payments are not included in the table above. See Note 3[B], “License agreements,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further discussion of our license agreement with ICI.

Supply Agreement
As of March 31, 2020, 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. See Note 11[A], “Commitments and contingencies,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding our enzyme supply agreement.

Uncertain Tax Positions
We provide for uncertain tax positions when such tax positions do not meet the recognition thresholds or measurement criteria as set forth in Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 740. As of March 31, 2020 and 2019, we had unrecognized tax benefits of $1.2 million and $0.7 million, respectively. We are not able to reasonably estimate the timing of future tax payments related to these obligations. Therefore, such amounts are not included in the table above.

Off-Balance Sheet Arrangements
During the periods presented, we did not have nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Jumpstart Our Business Startups Act
We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under this act, an emerging growth company can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. However, we intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended. 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.

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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 consolidated 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 consolidated 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 consolidated 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 to determine which costs are charged to research and development and general and administrative expense, as well as assumptions used to estimate the fair value of common share and option awards. 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 audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, 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 and stock appreciation rights, or SARs, granted to employees, directors and consultants 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. For SARs, we estimate fair value using a binominal lattice 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 estimated 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.

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

**Expected term.** Our expected term represents the period that the share-based awards are expected to be outstanding. Since we have limited option exercise history, we have generally elected to estimate the expected life of an award based upon the SEC approved “simplified method” (based on the mid-point between the vesting date and the end of the contractual term) noted under the provisions of Staff Accounting Bulletin, or SAB, No. 107 with the continued use of this method extended under the provisions of SAB No. 110. For share-based awards granted to non-employees, the expected term represents the contractual term of the award.

**Expected volatility.** Because we do not have an extended trading history for our common shares, 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. Beginning in the third quarter of fiscal year 2019, we began including our own historical volatility with the historical volatility of our peer group of companies as part of the weighted-average measure of expected volatility.

As part of the valuation of share-based compensation under the Black-Scholes option-pricing model, it is necessary for us to utilize the fair value of our common shares on the grant date. Prior to our IPO, we were required to periodically estimate the fair value of our common shares when issuing options and in computing our estimated share-based compensation expense. Given the absence of a public trading market prior to the completion of our IPO,
and in accordance with the American Institute of Certified Public Accountants’ Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, we exercised reasonable judgment and considered numerous objective and subjective factors to determine our best estimate of the fair value of our common shares. The estimation of the fair value of the common shares considered factors including the following: the estimated present value of our future cash flows; our business, financial condition and results of operations; our forecasted operating performance; the illiquid nature of our 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. In connection with our IPO, we reassessed the fair value of our options. Subsequent to our IPO, we utilize the closing market price of our common shares on the grant date when estimating the fair value of share-based payment awards.

Share-based compensation expense associated with time-vesting restricted stock units is based on the fair value of our common shares on the grant date, which equals the closing market price of our common shares on the grant date. We recognize the share-based compensation expense related to these awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

We have made an entity-wide accounting policy election to account for pre-vesting award forfeitures when they occur.

Research and Development Expense and Accruals

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. The estimate of the work completed is developed through discussions with internal personnel and external service 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 our 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.

We consider regulatory approval of product candidates to be uncertain and products manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized, but rather expensed as research and development expenses when 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 agreements of vibegron from Merck and URO-902 from ICI based on the applicable guidance in ASC 805, Business Combinations, and have determined that the in-process research and development, or IPR&D, assets licensed did not meet the definition of a business and thus the transactions were not considered a business combination. We then evaluated, pursuant to ASC 730, Research and Development, whether the IPR&D assets had an alternative future use and concluded they did not. As a result, we recorded the upfront license payment of $25.0 million under the Merck agreement and the $0.25 million upfront license payment under the ICI agreement as research and development expense upon entry into the license agreements. Further, we recorded the regulatory milestone payment of $10.0 million pursuant to the Merck agreement upon acceptance of our NDA by the FDA in March 2020 as research and development expense.

Leases

Prior to April 1, 2019, we recognized our leases in accordance with ASC 840, Leases, and all of our leases were classified as operating leases. Rent expense was recognized on a straight-line basis over the terms of the leases and, accordingly, we recorded the cumulative difference between cash rent payments and the recognition of rent expense as a deferred rent liability. When an operating lease included lease incentives, such as rent abatements or leasehold improvement allowances, or required fixed escalations of the minimum lease payments, the aggregate rental expense, including such incentives or increases, was recognized on a straight-line basis over the lease term.
Effective April 1, 2019, we adopted Accounting Standards Update, or ASU, No. 2016-02, Leases (Topic 842), or ASC 842, using the modified retrospective method, which provides a method for recording existing leases at adoption using the effective date as its date of initial application. We also applied the practical expedient which allows companies to not recast comparative financial periods presented. As a result of the adoption of ASC 842 on April 1, 2019, we have changed our accounting policy for leases. We consider the lease accounting policy under ASC 842 to be critical because the adoption has a material impact in our consolidated financial statements and requires us to make judgments, estimates, and assumptions.

ASC 842 requires leases to be accounted for using a right-of-use model, which recognizes that, at the date of commencement, a lessee has a financial obligation to make lease payments to the lessor for the right to use the underlying asset during the lease term. The lessee recognizes a corresponding right-of-use asset related to this right.

We apply judgment in determining whether a contract contains a lease and if a lease is classified as an operating lease or a finance lease. We determine the lease term as the non-cancelable term of the lease, which may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. We apply judgment in evaluating whether it is reasonably certain whether or not to exercise the option to renew or terminate the lease and estimate the lease term applicable to lease contracts. That is, we consider all relevant factors that create an economic incentive to exercise a renewal or termination. After the commencement date, we reassess the lease term if there is a significant event or change in circumstance that is within our control and affects our ability to exercise or not to exercise the option to renew or terminate.

Right of use assets and liabilities are recognized at the commencement date based on the present value of the lease payments over the term. As our leases do not provide an implicit rate, the incremental borrowing rate is used based on the information available at commencement date in determining the present value of lease payments. We make estimates in determining the incremental borrowing rates.

Recent Accounting Pronouncements

For information regarding recently issued accounting pronouncements and the expected impact on our audited consolidated financial statements, see Note 2, “Summary of significant accounting policies,” to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Under SEC rules and regulations, because we qualify as a “smaller reporting company,” we are not required to provide the information required by this item in this report.

Item 8. Financial Statements and Supplementary Data.

All consolidated financial statements and schedules required to be filed hereunder are listed in the Index to Consolidated Financial Statements and are incorporated herein by reference.


None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

Under the supervision of our principal executive officer and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020, the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2020 at the reasonable assurance level.
Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of a company’s principal executive and principal financial officers, and effected by its board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Our internal control over financial reporting includes those policies and procedures that:

• pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company;
• provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
• provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we assessed the effectiveness of our internal control over financial reporting as of March 31, 2020. In making this assessment, our management used the criteria in the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on its assessment, our management has concluded that, as of March 31, 2020, our internal control over financial reporting is effective based on those criteria.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for “emerging growth companies” and because we qualify as a “non-accelerated filer” (i.e., we do not qualify as either an “accelerated filer” or a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act).

Changes in Internal Control over Financial Reporting

No changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.
PART III

We intend to file a definitive proxy statement for our 2020 Annual General Meeting of Shareholders, or the 2020 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after March 31, 2020. Accordingly, certain information required by Part III has been omitted pursuant to General Instruction G(3) to Form 10-K. Only those sections of the 2020 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our 2020 Proxy Statement under the captions “Election of Directors,” “Information Regarding Board of Directors and Corporate Governance,” “Executive Officers” and, if applicable, “Delinquent Section 16(a) Reports” and is incorporated herein by reference.

Code of Conduct

We have adopted a Code of Business Conduct and Ethics, or Code of Conduct, that applies to all of our directors, officers and employees, including our principal executive officer and principal financial and accounting officer. The Code of Conduct is posted on our website located at www.urovant.com. We intend to disclose any material future amendments to, or waivers of, provisions of the Code of Conduct on our website within four business days following the date of the amendment or waiver to the extent required by applicable rules of the SEC or Nasdaq.

Item 11. Executive Compensation.

The information required by this item will be contained in our 2020 Proxy Statement under the captions “Information Regarding Board of Directors and Corporate Governance,” “Executive Compensation” and “Director Compensation” and is incorporated herein by reference.


The information required by this item will be contained in our 2020 Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be contained in our 2020 Proxy Statement under the captions “Transactions with Related Persons” and “Information Regarding the Board of Directors and Corporate Governance” and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be contained in our 2020 Proxy Statement under the captions “Ratification of Selection of Independent Registered Public Accounting Firm, Appointment of Auditor for Statutory Purposes and Authorization for the Board to set Auditor Remuneration” and is incorporated herein by reference.

(a) Documents filed as part of this Annual Report on Form 10-K:

(1) Financial Statements. Our audited consolidated financial statements and the Report of Independent Registered Public Accounting Firm are included herein on the pages indicated:

<table>
<thead>
<tr>
<th>Financial Statement</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report of Independent Registered Public Accounting Firm</td>
<td>F-2</td>
</tr>
<tr>
<td>Consolidated Balance Sheets as of March 31, 2020 and 2019</td>
<td>F-3</td>
</tr>
<tr>
<td>Consolidated Statements of Operations for the Years Ended March 31, 2020 and 2019</td>
<td>F-4</td>
</tr>
<tr>
<td>Consolidated Statements of Comprehensive Loss for the Years Ended March 31, 2020 and 2019</td>
<td>F-5</td>
</tr>
<tr>
<td>Consolidated Statements of Shareholders’ Equity (Deficit) for the Years Ended March 31, 2020 and 2019</td>
<td>F-6</td>
</tr>
<tr>
<td>Consolidated Statements of Cash Flows for the Years Ended March 31, 2020 and 2019</td>
<td>F-7</td>
</tr>
<tr>
<td>Notes to Consolidated Financial Statements</td>
<td>F-8</td>
</tr>
</tbody>
</table>

(2) Financial Statement Schedules. All financial statement schedules are omitted because they are not applicable or the required information is included in the audited consolidated financial statements or notes thereto.
<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description</th>
<th>Form</th>
<th>File No.</th>
<th>Exhibit</th>
<th>Filing Date</th>
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<tr>
<td>3.1</td>
<td>Certificate of Incorporation.</td>
<td>S-1</td>
<td>333-226169</td>
<td>3.1</td>
<td>7/13/18</td>
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<td>3.2</td>
<td>Memorandum of Association.</td>
<td>S-1</td>
<td>333-226169</td>
<td>3.2</td>
<td>7/13/18</td>
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<tr>
<td>3.3</td>
<td>Second Amended and Restated Bye-laws.</td>
<td>10-Q</td>
<td>001-38667</td>
<td>3.3</td>
<td>2/13/20</td>
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<tr>
<td>4.1</td>
<td>Warrant Agreement, dated February 20, 2019, issued to Hercules Capital, Inc.</td>
<td>8-K</td>
<td>001-38667</td>
<td>4.1</td>
<td>2/22/19</td>
</tr>
<tr>
<td>4.2</td>
<td>Warrant Agreement, dated September 20, 2019, issued to Hercules Capital, Inc.</td>
<td>8-K</td>
<td>001-38667</td>
<td>4.1</td>
<td>9/25/19</td>
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<td>4.3</td>
<td>Description of Share Capital.</td>
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<tr>
<td>10.3*</td>
<td>China IP Purchase Agreement, effective as of June 12, 2017, by and between Urovant Sciences GmbH and Roivant Sciences GmbH, as amended on May 22, 2018.</td>
<td>S-1</td>
<td>333-226169</td>
<td>10.3</td>
<td>7/13/18</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>
<td>S-1</td>
<td>333-226169</td>
<td>10.4</td>
<td>7/13/18</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>
<td>S-1/A</td>
<td>333-226169</td>
<td>10.5</td>
<td>9/10/18</td>
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<td>10.6</td>
<td>Amended and Restated Services Agreement, effective as of July 9, 2018, by and among Roivant Sciences, Inc., Urovant Sciences GmbH, Urovant Sciences, Inc. and the Registrant.</td>
<td>S-1</td>
<td>333-226169</td>
<td>10.6</td>
<td>7/13/18</td>
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<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>
<td>S-1</td>
<td>333-226169</td>
<td>10.7</td>
<td>7/13/18</td>
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<tr>
<td>10.8*</td>
<td>Data Sharing Agreement, effective as of May 22, 2018, by and between Urovant Sciences GmbH and Datavant, Inc.</td>
<td>S-1</td>
<td>333-226169</td>
<td>10.10</td>
<td>7/13/18</td>
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<td>10.9+</td>
<td>License Agreement, dated August 24, 2018, by and between Urovant Sciences GmbH and Ion Channel Innovations, LLC.</td>
<td>S-1/A</td>
<td>333-226169</td>
<td>10.11</td>
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<tr>
<td>10.10+</td>
<td>Form of Indemnification Agreement with directors and executive officers.</td>
<td>8-K</td>
<td>001-38667</td>
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<td>10.11+</td>
<td>2017 Equity Incentive Plan, as amended and restated.</td>
<td>8-K</td>
<td>001-38667</td>
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<td>10.12+</td>
<td>2019 Employee Stock Purchase Plan.</td>
<td>8-K</td>
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<tr>
<td>10.13+</td>
<td>Forms of Option Grant Notice and Option Agreement under the 2017 Equity Incentive Plan, as amended and restated.</td>
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<td>10.14+</td>
<td>Form of Early Exercise Stock Purchase Agreement under the 2017 Equity Incentive Plan, as amended and restated.</td>
<td>S-1/A</td>
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<td>10.15+</td>
<td>Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2017 Equity Incentive Plan, as amended and restated.</td>
<td>10-Q</td>
<td>001-38667</td>
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<td>10.18+</td>
<td>Employment Agreement, dated October 28, 2019, by and between Ajay Bansal and Urovant Sciences, Inc.</td>
<td>8-K</td>
<td>001-38667</td>
<td>10.2</td>
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<td>10.21+</td>
<td>Employment Agreement, dated September 13, 2018, by and between Bryan E. Smith and Urovant Sciences, Inc.</td>
<td>S-1/A</td>
<td>333-226169</td>
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<td>10.22+</td>
<td>Employment Agreement, dated June 1, 2020, by and between Walt Johnston and Urovant Sciences, Inc.</td>
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<tr>
<td>10.23+</td>
<td>Letter Agreement, dated October 31, 2019, by and between Sumitomo Dainippon Pharma Co., Ltd. and Urovant Sciences Ltd.</td>
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<td>001-38667</td>
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<td>10.24</td>
<td>Loan Agreement, dated December 27, 2019, by and between Sumitomo Dainippon Pharma Co., Ltd. and Urovant Sciences Ltd.</td>
<td>8-K</td>
<td>001-38667</td>
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<td>10.25</td>
<td>Investor Rights Agreement, dated December 27, 2019, by and among Sumitomo Dainippon Pharma Co., Ltd., Urovant Sciences Ltd., and Sumitovant Biopharma Ltd.</td>
<td>8-K</td>
<td>001-38667</td>
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<td>10.26</td>
<td>Information Sharing and Cooperation Agreement, dated as of May 21, 2020, by and between Sumitovant Biopharma Ltd. and the Registrant.</td>
<td>8-K</td>
<td>001-38667</td>
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<tr>
<td>10.27</td>
<td>Open Market Sale Agreement, dated November 8, 2019, by and between the Company and Jefferies LLC.</td>
<td>S-3</td>
<td>333-234620</td>
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<td>10.28</td>
<td>Sublease Agreement between Roivant Sciences, Inc. and Urovant Sciences, Inc. dated June 10, 2019.</td>
<td>10-Q</td>
<td>001-38667</td>
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<td>21.1</td>
<td>Subsidiaries of the Registrant.</td>
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<td>23.1</td>
<td>Consent of Ernst &amp; Young LLP, independent registered public accounting firm.</td>
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<td>24.1</td>
<td>Power of Attorney (included on signature page)</td>
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<td>31.1</td>
<td>Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</td>
<td>X</td>
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<td>31.2</td>
<td>Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</td>
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<td>32.1**</td>
<td>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</td>
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<td>32.2**</td>
<td>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</td>
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<td></td>
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</tr>
</tbody>
</table>
+ Indicates management contract or compensatory plan.

* Confidential treatment has been granted for portions omitted from this exhibit (indicated by asterisks) and those portions have been separately filed with the SEC.

** These certifications are being furnished solely to accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Exchange Act, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. Form 10-K Summary

None.
SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

UROVANT SCIENCES LTD.

Date: June 19, 2020

By: /s/ James Robinson
James Robinson
Principal Executive Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James Robinson and Ajay Bansal, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, 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 sign this Annual Report on Form 10-K of Urovant Sciences Ltd., and any or all amendments (including post-effective amendments) thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ James Robinson</td>
<td>Principal Executive Officer and Director</td>
<td>June 19, 2020</td>
</tr>
<tr>
<td>James Robinson</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Ajay Bansal</td>
<td>Principal Financial Officer (Urovant’s authorized representative in the United States)</td>
<td>June 19, 2020</td>
</tr>
<tr>
<td>Ajay Bansal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Christine G. Ocampo</td>
<td>Principal Accounting Officer</td>
<td>June 19, 2020</td>
</tr>
<tr>
<td>Christine G. Ocampo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Myrtle S. Potter</td>
<td>Director</td>
<td>June 19, 2020</td>
</tr>
<tr>
<td>Myrtle S. Potter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Sef P. Kurstjens</td>
<td>Director</td>
<td>June 19, 2020</td>
</tr>
<tr>
<td>Sef P. Kurstjens, M.D., Ph.D.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Pierre Legault</td>
<td>Director</td>
<td>June 19, 2020</td>
</tr>
<tr>
<td>Pierre Legault</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ Shigeyuki Nishinaka</td>
<td>Director</td>
<td>June 19, 2020</td>
</tr>
<tr>
<td>Dr. Shigeyuki Nishinaka</td>
<td></td>
<td></td>
</tr>
<tr>
<td>/s/ James Hindman</td>
<td>Director</td>
<td>June 19, 2020</td>
</tr>
<tr>
<td>James Hindman</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Consolidated Statements of Comprehensive Loss for the Years Ended March 31, 2020 and 2019  F-5
Consolidated Statements of Shareholders’ Equity (Deficit) for the Years Ended March 31, 2020 and 2019  F-6
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To the Shareholders 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, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, shareholders’ equity (deficit) and cash flows for each of the two years in the period ended March 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2020, in conformity with U.S. generally accepted accounting principles.

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.

Irvine, California

June 19, 2020

F-2
## UROVANT SCIENCES LTD.
### Consolidated Balance Sheets
**(in thousands, except share and per share data)**

#### March 31, 2020 | March 31, 2019
---|---
**Assets** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | }
<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating expenses:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development(1)</td>
<td>$92,437</td>
<td>$92,198</td>
</tr>
<tr>
<td>General and administrative(2)</td>
<td>46,299</td>
<td>18,585</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>138,736</td>
<td>110,783</td>
</tr>
<tr>
<td><strong>Other expense:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interest expense, net(3)</td>
<td>(3,581)</td>
<td>(259)</td>
</tr>
<tr>
<td>Loss on extinguishment of long-term debt</td>
<td>(4,093)</td>
<td>—</td>
</tr>
<tr>
<td>Loss on disposal of property and equipment</td>
<td>(236)</td>
<td>—</td>
</tr>
<tr>
<td>Other expense, net</td>
<td>(34)</td>
<td>(257)</td>
</tr>
<tr>
<td><strong>Loss before provision for income taxes</strong></td>
<td>(146,680)</td>
<td>(111,299)</td>
</tr>
<tr>
<td><strong>Provision for income taxes</strong></td>
<td>65</td>
<td>47</td>
</tr>
<tr>
<td>Net loss</td>
<td>$146,745</td>
<td>$111,346</td>
</tr>
<tr>
<td><strong>Net loss per common share—basic and diluted</strong></td>
<td>$4.82</td>
<td>$4.43</td>
</tr>
<tr>
<td>Weighted average common shares outstanding—basic and diluted</td>
<td>30,416,641</td>
<td>25,145,211</td>
</tr>
</tbody>
</table>

(1) Includes $0 and $2,251 of costs allocated from Roivant Sciences Ltd. during the years ended March 31, 2020 and 2019, respectively. Also includes share-based compensation expense (see Note 9[C]).

(2) Includes $213 and $1,692 of costs allocated from Roivant Sciences Ltd. during the years ended March 31, 2020 and 2019, respectively. Also includes share-based compensation expense (see Note 9[C]).

(3) Includes $1,108 of interest expense from related-party long-term debt with Sumitomo Dainippon Pharma Co., Ltd. during the year ended March 31, 2020 (see Note 5[B]).

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

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### UROVANT SCIENCES LTD.
#### Consolidated Statements of Comprehensive Loss
#### (in thousands)

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
</tr>
<tr>
<td>Net loss</td>
<td>$(146,745)</td>
</tr>
<tr>
<td>Other comprehensive income:</td>
<td></td>
</tr>
<tr>
<td>Foreign currency translation adjustment</td>
<td>183</td>
</tr>
<tr>
<td>Total other comprehensive income</td>
<td>183</td>
</tr>
<tr>
<td>Comprehensive loss</td>
<td>$(146,562)</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
<table>
<thead>
<tr>
<th>Common Shares</th>
<th>Shareholder</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Deficit</th>
<th>Accumulated Other Comprehensive Income</th>
<th>Total Shareholders' Equity (Deficit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shares</td>
<td>Amount</td>
<td>Subscribed (1)</td>
<td>(1,310)</td>
<td>72,562</td>
<td>(64,185)</td>
</tr>
<tr>
<td>Balance at March 31, 2018</td>
<td>20,025,098</td>
<td>$ 1</td>
<td>—</td>
<td>$ 7,074</td>
<td>$ 7,074</td>
</tr>
<tr>
<td>Capital contributions from RSI and RSG</td>
<td>—</td>
<td>—</td>
<td>1,310</td>
<td>40,321</td>
<td>—</td>
</tr>
<tr>
<td>Share-based compensation expense</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>3,398</td>
<td>—</td>
</tr>
<tr>
<td>Capital contribution from RSI and RSG - share-based compensation expense</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>580</td>
<td>—</td>
</tr>
<tr>
<td>Issuance of common shares in initial public offering, net of commissions and offering costs of $11.3 million</td>
<td>10,297,813</td>
<td>—</td>
<td>—</td>
<td>132,932</td>
<td>—</td>
</tr>
<tr>
<td>Warrants issued with long-term debt</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>240</td>
<td>—</td>
</tr>
<tr>
<td>Foreign currency translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(111,346)</td>
</tr>
<tr>
<td>Balance at March 31, 2019</td>
<td>30,322,911</td>
<td>$ 1</td>
<td>(1)</td>
<td>—</td>
<td>250,032</td>
</tr>
<tr>
<td>Capital contributions from RSI and RSG</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>251</td>
</tr>
<tr>
<td>Share-based compensation expense</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>15,859</td>
</tr>
<tr>
<td>Capital contribution from Sumitovant - share-based compensation expense</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>1,351</td>
</tr>
<tr>
<td>Capital contribution from RSI and RSG - share-based compensation expense</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>111</td>
</tr>
<tr>
<td>Share-based compensation expense reclassified to liabilities</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(4,074)</td>
</tr>
<tr>
<td>Exercise of stock options, net of tax withholding</td>
<td>302,526</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(87)</td>
</tr>
<tr>
<td>Vesting of restricted stock units, net of tax withholding</td>
<td>9,821</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(63)</td>
</tr>
<tr>
<td>Warrants issued with long-term debt</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>438</td>
</tr>
<tr>
<td>Foreign currency translation adjustment</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Balance at March 31, 2020</td>
<td>30,635,258</td>
<td>$ 1</td>
<td>(1)</td>
<td>—</td>
<td>263,818</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these consolidated financial statements.
## UROVANT SCIENCES LTD.
### Consolidated Statements of Cash Flows
(in thousands)

#### Year Ended March 31, 2020

<table>
<thead>
<tr>
<th>Cash Flows from Operating Activities:</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss</td>
<td>$(146,745)</td>
<td>$(111,346)</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>246</td>
<td>180</td>
</tr>
<tr>
<td>Share-based compensation expense</td>
<td>20,483</td>
<td>3,978</td>
</tr>
<tr>
<td>Amortization of debt discount and issuance costs</td>
<td>675</td>
<td>92</td>
</tr>
<tr>
<td>Non-cash operating lease cost</td>
<td>640</td>
<td>—</td>
</tr>
<tr>
<td>Loss on extinguishment of long-term debt</td>
<td>4,093</td>
<td>—</td>
</tr>
<tr>
<td>Loss on disposal of property and equipment</td>
<td>236</td>
<td>—</td>
</tr>
<tr>
<td>Unrealized foreign currency translation adjustment</td>
<td>183</td>
<td>262</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>6,590</td>
<td>(7,462)</td>
</tr>
<tr>
<td>Other assets</td>
<td>79</td>
<td>(4)</td>
</tr>
<tr>
<td>Due from Sumitovant Biopharma Ltd.</td>
<td>(172)</td>
<td>—</td>
</tr>
<tr>
<td>Due to Roivant Sciences Ltd.</td>
<td>16</td>
<td>(1,467)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>(336)</td>
<td>1,092</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>12,266</td>
<td>5,639</td>
</tr>
<tr>
<td>Operating lease liabilities</td>
<td>(338)</td>
<td>—</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>(102,084)</td>
<td>(109,036)</td>
</tr>
</tbody>
</table>

#### Cash Flows from Investing Activities:

<table>
<thead>
<tr>
<th>Cash flows from investing activities:</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchases of property and equipment</td>
<td>(769)</td>
<td>(593)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(769)</td>
<td>(593)</td>
</tr>
</tbody>
</table>

#### Cash Flows from Financing Activities:

<table>
<thead>
<tr>
<th>Cash Flows from financing activities:</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proceeds from capital contributions from Roivant Sciences Ltd.</td>
<td>251</td>
<td>41,631</td>
</tr>
<tr>
<td>Proceeds from exercise of stock options</td>
<td>796</td>
<td>—</td>
</tr>
<tr>
<td>Payment of stock options and restricted stock units tax withholding on net settlement</td>
<td>(946)</td>
<td>—</td>
</tr>
<tr>
<td>Debt financing costs paid</td>
<td>(645)</td>
<td>(931)</td>
</tr>
<tr>
<td>Repayment of long-term debt and redemption fees</td>
<td>(47,654)</td>
<td>—</td>
</tr>
<tr>
<td>Cash proceeds from third-party debt financing</td>
<td>30,000</td>
<td>15,000</td>
</tr>
<tr>
<td>Cash proceeds from related-party debt financing</td>
<td>87,500</td>
<td>—</td>
</tr>
<tr>
<td>Deferred offering costs paid</td>
<td>(165)</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from issuance of common shares in initial public offering, net of offering costs</td>
<td>—</td>
<td>132,931</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>68,937</td>
<td>188,631</td>
</tr>
<tr>
<td>Net change in cash and restricted cash</td>
<td>(33,916)</td>
<td>79,002</td>
</tr>
<tr>
<td>Cash and restricted cash—beginning of year</td>
<td>86,196</td>
<td>7,194</td>
</tr>
<tr>
<td>Cash and restricted cash—end of year</td>
<td>$ 52,280</td>
<td>$ 86,196</td>
</tr>
</tbody>
</table>

#### Non-cash Financing Activities:

<table>
<thead>
<tr>
<th>Non-cash financing activities:</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warrants issued with long-term debt</td>
<td>$ 438</td>
<td>$ 240</td>
</tr>
<tr>
<td>Reclassification of share-based compensation expense from additional paid-in capital to liabilities</td>
<td>$ 4,074</td>
<td>—</td>
</tr>
<tr>
<td>Deferred financing costs included in accounts payable and accrued expenses</td>
<td>$ —</td>
<td>$ 387</td>
</tr>
</tbody>
</table>

#### Supplemental disclosure of cash paid:

<table>
<thead>
<tr>
<th>Supplemental disclosure of cash paid:</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income taxes</td>
<td>$ 65</td>
<td>$ 178</td>
</tr>
<tr>
<td>Interest</td>
<td>$ 3,081</td>
<td>$ 169</td>
</tr>
</tbody>
</table>

The accompanying notes are an integral part of these 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 lead 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 abdominal pain due to irritable bowel syndrome. The Company’s second product candidate, URO-902, is a gene therapy that the Company is developing for patients with OAB who have failed oral pharmacological therapy. There are no currently available U.S. Food and Drug Administration (“FDA”) approved gene therapy treatments for OAB. The Company was founded on January 27, 2016 as a Bermuda Exempted Limited Company and a wholly owned subsidiary of Roivant Sciences Ltd. (“RSL”). 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, (3) UroVant Sciences, Inc. (“USI”), a Delaware corporation based in the United States of America, and in March 2019 incorporated as its wholly owned subsidiaries (4) UroVant Treasury Holdings, Inc. (“UTH”), a Delaware corporation based in the United States of America, and (5) UroVant Sciences Treasury, Inc. (“UST”), a Delaware corporation based in the United States of America.

On December 27, 2019, Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo”) and RSL announced the closing of the transactions between Sumitomo and RSL and certain of its affiliates contemplated by the definitive transaction agreement entered into on October 31, 2019 (the “Sumitomo Transaction”), pursuant to which all of the Company’s common shares held by RSL were contributed to Sumitovant Biopharma Ltd., a wholly-owned subsidiary of RSL at the time of such contribution (“Sumitovant”), and subsequent to such contribution, Sumitomo acquired all issued and outstanding equity securities of Sumitovant (see Note 6[A]).

Since its inception, the Company has devoted substantially all of its efforts to organizing and staffing the Company, acquiring its product candidates, vibegron and URO-902, and preparing for and advancing vibegron and URO-902 into clinical development. Vibegron was licensed from Merck Sharp & Dohme Corp. (“Merck”), a subsidiary of Merck & Co., in February 2017. URO-902 was licensed from Ion Channel Innovations, LLC (“ICI”) in August 2018. 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 historically been capitalized with funding from its initial public offering, which was completed in October 2018, and debt financings. Certain other costs of conducting the Company’s operations prior to the Company’s initial public offering were paid by RSL, inclusive of its wholly owned subsidiaries, and were subsequently reimbursed by the Company including amounts pursuant to services agreements with Roivant Sciences, Inc. (“RSI”) and Roivant Sciences GmbH (“RSG”).

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. Since inception, the Company has incurred and expects to continue to incur significant and increasing operating losses and negative cash flows for at least the next several years. To date, 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 one of its product candidates. At March 31, 2020, the Company reported cash of $51.4 million and a shareholders’ deficit of $58.0 million. The Company currently believes its existing cash, together with the draw down under the Sumitomo Loan Agreement of $41.0 million in April 2020 and the financing commitment from Sumitomo of $171.5 million, which is available to the Company based on funding requests in accordance with the Company’s board approved operating budget (see Notes 5[B] and 14[B]), will be sufficient to fund its committed operating expenses and capital expenditure requirements for at least the next 12 months from the date of issuance of these consolidated financial statements. This estimate is based on the Company’s current assumptions, including assumptions relating to the timing of regulatory approval and subsequent launch of vibegron for OAB and its ability to manage the amount and timing of its spend. The Company’s available capital may also be consumed faster than anticipated due to other events, including the length and severity of the global novel coronavirus disease (“COVID-19”) pandemic and measures taken to control the spread of COVID-19, as well as changes in and progress of our development activities and the

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impact of commercialization efforts due to the COVID-19 pandemic. The Company will seek to obtain additional capital as needed through equity financings, debt or other financing arrangements, but given the impact of COVID-19 on the U.S. and global financial markets and any limitations on future financing arrangements pursuant to the terms of the Sumitomo Loan Agreement, as well as Sumitomo’s ability to exert substantial influence and control over the Company due to Sumitomo’s majority ownership of the Company’s outstanding common shares, the Company may be unable to access further equity or debt financing when needed. As such, there can be no assurance that the Company will be able to raise additional capital 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. The Company’s agreement with Sumitomo involves, and any agreements for future debt or preferred equity financings, if available, may involve, covenants limiting or restricting the Company’s ability to take specific actions, such as incurring additional debt, incurring capital expenditures or declaring dividends. If the Company is unable to obtain such additional financing, as needed, in sufficient amounts or on terms acceptable to the Company, or if the current financing commitment of $171.5 million available to the Company under the Sumitomo Loan Agreement is no longer available to the Company despite its future funding requests being in accordance with its board approved operating budget, the Company may have to significantly delay or scale back its operations to reduce working capital requirements beginning in the fourth calendar quarter of 2020 and substantial uncertainty would exist with respect to the Company’s ability to continue as a going concern. The Company will prioritize necessary and appropriate steps to enable the continued operations of the business and preservation of the value of its assets beyond the next twelve months, including but not limited to actions such as reduced personnel-related costs, curtailment of the Company’s pre-commercial launch efforts, development activities and other discretionary expenditures that are within the Company’s control. These reductions in expenditures, if required, may have an adverse impact on the Company’s ability to achieve certain of the Company’s planned objectives in fiscal years 2020 and 2021.

The Company’s future operations are highly dependent on a combination of factors, including (1) the success of its research and development programs; (2) regulatory approval and market acceptance of vibegron, URO-902 or any future product candidate; (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) the timely and successful completion of any additional financing.

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, USI, UTH, and UST, USL’s wholly owned subsidiaries. USL has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

[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, costs, and expenses including the evaluation of the Company’s ability to continue as a going concern, as well as share-based compensation expenses, research and development expenses and accruals, 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 may differ from these estimates under different assumptions or conditions and such differences may be material.
[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, including the need to successfully commercialize and gain market acceptance of its product candidates, the need to obtain marketing approval for its product candidates, risks of failure or unsatisfactory results of nonclinical studies and clinical trials, the need to obtain additional financing to fund the future development and commercialization of its product candidates, dependence on key products, third-party service providers such as contract research organizations and contract manufacturing organizations, protection of intellectual property rights, compliance with government regulations, and the ability to make milestone, royalty or other payments due under any license, collaboration or supply agreements.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. Due to the COVID-19 pandemic, there has been uncertainty and disruption in the global economy and financial markets. Through June 19, 2020, the date of issuance of this Annual Report on Form 10-K, the Company’s results of operations and cash flows have not been significantly impacted by the COVID-19 outbreak. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company’s assets or liabilities as of June 19, 2020.

[D] Cash, cash equivalents and restricted cash:

Cash includes cash deposits in banks. The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents. The Company maintains cash deposits in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities to maintain liquidity and preservation of capital. The Company has not experienced any credit losses related to these financial instruments and does not believe that it is exposed to any significant credit risk related to these instruments.

Restricted cash consists of legally restricted non-interest-bearing deposit accounts held as compensating balances against the Company’s corporate credit card program and irrevocable standby letters of credit connected to its office leases (see Note 12). Restricted cash classified as a current asset consists of the restricted deposit account relating to the Company’s corporate credit card agreement. Restricted cash classified as a long-term asset consists of the restricted deposit account related to the irrevocable standby letters of credit.

Cash as reported in the consolidated statements of cash flows includes the aggregate amounts of cash and restricted cash as presented on the consolidated balance sheets. Cash as reported in the consolidated statements of cash flows consists of (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2020</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash</td>
<td>51,414</td>
<td>85,353</td>
</tr>
<tr>
<td>Restricted cash</td>
<td>866</td>
<td>843</td>
</tr>
<tr>
<td>Cash and restricted cash</td>
<td>52,280</td>
<td>86,196</td>
</tr>
</tbody>
</table>

[E] Property and equipment:

Property and equipment, consisting of computers, office 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 is 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.
Deferred offering costs consist of qualified legal, accounting, and other direct costs related to the Company’s efforts to raise capital through a public or private sale of the Company’s capital stock. These costs are deferred until the completion of the applicable offering, at which time such costs are reclassified to additional paid-in-capital as a reduction of the proceeds. The Company’s initial public offering costs were reclassified to additional paid-in-capital upon the closing of the Company’s initial public offering on October 1, 2018.

Debt issuance costs include the costs of debt financings undertaken by the Company, including legal fees, accounting fees, and other direct costs of the financing. Debt issuance costs related to a recognized debt liability are presented in the consolidated balance sheets as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts, and are amortized to interest expense over the term of the related debt using the effective interest method. Further, debt discounts created as a result of the allocation of proceeds received from a debt issuance to warrants issued in conjunction with the debt issuance are amortized to interest expense under the effective interest method over the life of the recognized debt liability.

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 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, restricted cash, accounts payable, accrued expenses, amounts due to and from RSL and Sumitovant, share-based compensation liabilities, and debt obligations. The carrying value of the Company’s debt obligations approximates fair value based on current interest rates for similar types of borrowings and is included in Level 2 of the fair value hierarchy. The share-based compensation liabilities are remeasured at fair value on a recurring basis and are included in Level 3 of the fair value hierarchy. The remaining financial instruments are stated at their respective historical carrying amounts, which approximates fair value due to their short-term nature.

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 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, unless the Company has determined that any such reasonably possible losses will not have a material impact on the Company’s results of operations, financial condition or cash flows.
Research and development expenses primarily consist of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for research and development personnel, expenses from third parties who conduct research and development activities on behalf of the Company, the intellectual property and research and development materials acquired from Merck and ICI (see Note 3) and certain costs charged by RSI and RSG under their services agreements with the Company (see Note 6[G]). 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 service 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.

The Company considers regulatory approval of product candidates to be uncertain and products manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, the manufacturing costs for product candidates incurred prior to regulatory approval are not capitalized, but rather expensed as research and development expenses when 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.

In accordance with ASC 842, as adopted by the Company on April 1, 2019, the Company determines if an arrangement is a lease at inception. Operating lease right-of-use (“ROU”) assets represent the Company’s right to use an underlying asset during the lease term, and operating lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Operating leases are included in ROU assets, current operating lease liabilities, and long-term operating lease liabilities on our consolidated balance sheet.

Operating lease ROU assets and lease liabilities are initially recognized based on the present value of the future minimum lease payments over the lease term at commencement date using the Company’s incremental borrowing rate applicable to the lease asset, unless the implicit rate is readily determinable. Operating lease ROU assets also include any lease payments made at or before lease commencement and exclude any lease incentives received. The Company determines the lease term as the noncancellable period of the lease, and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the consolidated balance sheet. The Company’s leases do not contain any residual value guarantees. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

The Company accounts for lease and non-lease components as a single lease component for all its facilities leases.

Prior to April 1, 2019, at the inception of a lease, the Company evaluated the lease agreement to determine whether the lease was an operating or capital lease. For operating leases, the Company recognized rent expense on a straight-line basis over the lease term and recorded the difference between cash rent payments and the recognition of rent expense as a deferred liability. Where lease agreements contained rent escalation clauses, rent abatements and/or concessions, such as rent holidays and tenant improvement allowances, the Company applied them in the determination of straight-line rent expense over the lease term.

Certain lease agreements also required the Company to make additional payments for taxes, insurance, and other operating expenses incurred during the lease period, which were expensed as incurred.
[L] Pushdown accounting:
In November 2014, the FASB issued ASU No. 2014-17, Business Combinations (Topic 805): Pushdown Accounting, (“ASU No. 2014-17”). ASU No. 2014-17 provides an acquired entity with an option to apply pushdown accounting in its separate financial statements upon occurrence of an event in which an acquirer obtains control of the acquired entity. An acquired entity may elect the option to apply pushdown accounting in the reporting period in which the change-in-control event occurs. If pushdown accounting is applied to an individual change-in-control event, that election is irrevocable. The Company elected not to apply pushdown accounting in its consolidated financial statements upon the change-in-control of the Company on December 27, 2019 (see Note 6[A]).

[M] 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.

[N] Share-based compensation:
The Company records share-based compensation expenses for awards of stock options, stock appreciation rights (“SARs”) and restricted stock units (“RSUs”) under ASC 718, Share-based compensation (“ASC 718”). For awards to non-employees for periods prior to the adoption of ASU 2018-07, Compensation-Stock Compensation: Improvements to Non-employee Share-Based Payment Accounting, on April 1, 2019, the Company had applied ASC 505-50, Equity – Equity-based payments to non-employees (“ASC 505-50”). ASC 718 establishes guidance for the recognition of expenses arising from the issuance of share-based compensation awards at their fair value at the grant date.

The Company recognizes share-based compensation expense related to stock options and SARs granted to employees, directors and consultants based on the estimated fair value of the awards on the date of grant. The Company estimates 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. For SARs, the Company estimates fair value using a binomial lattice model (see Note 10 for assumptions utilized). 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, the Company determines the fair value of awards as of the grant date using a Monte Carlo simulation model.

The Black-Scholes option-pricing model requires the use of subjective assumptions, which determine the fair value of share-based awards. These assumptions include:
Expected term. The Company’s expected term represents the period that the share-based awards are expected to be outstanding. 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” (based on the mid-point between the vesting date and the end of the contractual term) 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. For share-based awards granted to non-employees, the expected term represents the contractual term of the award.

Expected volatility. Because the Company does not have an extended trading history for its common shares, the expected volatility was estimated using weighted-average measures of implied volatility and the historical volatility of its peer group of companies for a period equal to the expected life of the stock options. The Company’s peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty. Beginning in the third quarter of the year ended March 31, 2020, the Company began including its own historical volatility with the historical volatility of its peer group of companies as part of the weighted-average measure of expected volatility.

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

Expected dividend. The Company has never paid, and does not anticipate paying, cash dividends on its common shares. Therefore, the expected dividend yield was assumed to be zero.

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. Prior to the Company’s initial public offering, it was required to periodically estimate the fair value of its common shares when issuing options and in computing its estimated share-based compensation expense. Given the absence of a public trading market prior to the completion of its initial public offering, 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. In connection with the Company’s initial public offering, the Company reassessed the fair value of its options. Subsequent to the Company’s initial public offering, the Company utilizes the closing market price of its common shares on the grant date when estimating the fair value of share-based payment awards under the Black-Scholes option-pricing model.

Share-based compensation expense associated with time-vesting restricted stock units is based on the fair value of the Company’s common shares on the grant date, which equals the closing market price of the Company’s common shares on the grant date. The Company recognizes the share-based compensation expense related to these awards on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

The Company has made an entity-wide accounting policy election to account for pre-vesting award forfeitures when they occur.

[O] 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 shareholders’ equity (deficit) 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 shareholders’ equity (deficit). Foreign exchange transaction gains and losses realized and unrealized are included in other income (expense) in the Company’s consolidated results of operations.
[P] Net loss per common share:

Basic net loss per common share is computed by dividing net loss applicable to common shareholders 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 shareholders by the diluted weighted-average number of common shares outstanding during the period calculated in accordance with the treasury stock method. In periods in which the Company reports a net loss, all common share equivalents are deemed anti-dilutive such that basic net loss per common share and diluted net loss per common share are equivalent. Potentially dilutive common shares have been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company’s net loss. There are no reconciling items used to calculate the weighted-average number of total common shares outstanding for basic and diluted net loss per common share data.

At March 31, 2020 and 2019, potentially dilutive securities were as follows:

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2020</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Options</td>
<td>4,134,100</td>
<td>4,058,866</td>
</tr>
<tr>
<td>Restricted stock units (unvested)</td>
<td>751,927</td>
<td>5,000</td>
</tr>
<tr>
<td>Stock appreciation rights</td>
<td>845,732</td>
<td>—</td>
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<tr>
<td>Warrants</td>
<td>99,777</td>
<td>33,259</td>
</tr>
<tr>
<td>Total</td>
<td>5,831,536</td>
<td>4,097,125</td>
</tr>
</tbody>
</table>

[Q] Recently adopted accounting standards:

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), (“ASU No. 2016-02”) a comprehensive new lease standard that amended various aspects of existing accounting guidance for leases. The core principle of ASU No. 2016-02 requires lessees to present the assets and liabilities that arise from leases on their consolidated balance sheets. ASU No. 2016-02 was effective for annual periods beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2018. The Company adopted this standard, codified as ASC 842, on April 1, 2019 using the optional modified retrospective transition method and applied the transition package of practical expedients allowed by the standard. Comparative periods were not restated. Upon adoption, on April 1, 2019, the Company recorded a $0.2 million increase in operating lease right-of-use assets and a $0.2 million increase in operating lease liabilities. The adoption of the standard did not materially impact the Company’s consolidated results of operations and cash flows and did not have an impact on the Company’s beginning accumulated deficit balance.

ASU No. 2016-02 provided a number of optional practical expedients in transition. For leases that commenced prior to April 1, 2019, the Company elected the following package of practical expedients when assessing the transition impact: (1) not to reassess whether any expired or existing contracts are or contain leases; (2) not to reassess the lease classification for any expired or existing leases; and (3) not to reassess initial direct costs for any existing leases. The Company also elected to: (1) use the total lease term in its initial incremental borrowing rate calculation; (2) combine its lease and non-lease components and account for them as a single lease component for its facilities leases; and (3) not apply the use of hindsight in determining the lease term when considering lessee options to extend or terminate the lease and to purchase the underlying asset. For additional information regarding the Company’s leases, see Note 12.

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. 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 adoption of ASU No. 2018-07 on April 1, 2019 did not have a material impact on the Company’s consolidated financial position, results of operations and related disclosures.
In July 2018, the FASB issued ASU No. 2018-09, *Codification Improvements* ("ASU No. 2018-09"), to make changes to a variety of topics to clarify, correct errors in, or make minor improvements to the ASC. Certain items of the amendments in ASU No. 2018-09 will be effective for the Company in annual periods beginning after December 15, 2018. The adoption of ASU No. 2018-19 on April 1, 2019 did not have a material impact on the Company's consolidated financial position, results of operations and related disclosures.

**R** Recently issued accounting standards:

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* ("ASU No. 2016-13") which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost.

ASU No. 2016-13 replaces the existing incurred loss impairment model with an expected loss model that requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses on available-for-sale debt securities to be recorded through an allowance for credit losses instead of as a reduction in the amortized cost basis of the securities. ASU No. 2016-13 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted, including adoption in any interim period. The Company does not expect the adoption to have a material impact on the Company’s consolidated financial position, results of operations, and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820) Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement,* ("ASU No. 2018-13") which provides guidance that removes, modifies and adds to the disclosure requirements related to fair value measurements. The guidance removes the requirements to disclose the amount and reasons for transfers between Level 1 and Level 2 assets, the policy for timing and transfers between levels and the valuation process for Level 3 fair value measurements. The guidance modifies disclosure requirements for investments in certain entities that calculate net asset value and clarifies the purpose of the measurement uncertainty disclosure. The guidance adds requirements to disclose changes in unrealized gains or losses included in other comprehensive income for recurring Level 3 fair value measurements and to disclose the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The Company does not expect the adoption to have a material impact on the Company’s consolidated financial position, results of operations, and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes,* ("ASU No. 2019-12"). The amendments of this update simplify the accounting for income taxes by removing certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new standard also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently assessing the impact the adoption of this standard will have on its consolidated financial position, results of operations, and related disclosures.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting,* ("ASU No. 2020-04") that provides temporary optional guidance to ease the potential burden in accounting for or recognizing the effects of reference rate reform on financial reporting. The new guidance provides expedients and exceptions for applying U.S. GAAP to contract modifications and hedging relationships affected by reference rate reform if certain criteria are met. The amendments apply only to contracts and hedging relationships that reference London Inter-bank Offered Rate ("LIBOR") or another reference rate that is expected to be discontinued due to reference rate reform. This new guidance is effective prospectively beginning on March 12, 2020 through December 31, 2022. As of March 31, 2020, the Company has not modified its contract that will be impacted by reference rate reform. The Company will continue to assess the impact the adoption of this standard will have on its consolidated financial position, results of operations, and related disclosures when its contract impacted by reference rate reform is modified.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants, and the SEC did not, or are not believed by management to, have a material impact on the Company’s present or future consolidated financial position, results of operations or cash flows.
Note 3—License agreements

[A] Merck 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:

- An initial one-time, non-refundable, non-creditable payment of $25.0 million;
- 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 sub-teem 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, Vietnam and China (see Note 6[H]).

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 developed independently all clinical processes and procedures for its clinical trials using internal and external resources.

The Company evaluated the in-license agreement of vibegron from Merck based on the applicable guidance in ASC 805, Business Combinations, (“ASC 805”), and determined that the in-process research and development (“IPR&D”) asset 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, (“ASC 730”), 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 $25.0 million as research and development expense. Upon acceptance of the Company’s New Drug Application (“NDA”) submission by the FDA in March 2020, the Company triggered a regulatory milestone payment of $10.0 million and recorded the payment to Merck as research and development expense in the accompanying consolidated statement of operations during the year ended March 31, 2020 as the IPR&D asset did not have an alternative future use in accordance with ASC 730. There were no amounts due to or paid to Merck for the year ended March 31, 2019.

[B] ICI agreement:
On August 24, 2018, the Company’s wholly owned subsidiary, USG, entered into an exclusive license agreement with ICI (the “ICI Agreement”) for the development and commercialization of URO-902 in exchange for the following consideration:

- An initial one-time, non-refundable, non-creditable payment of $0.25 million;
- Up to an aggregate of $35.0 million upon the achievement of certain development and regulatory milestones;
- Up to an aggregate of $60.0 million upon the achievement of certain annual sales-based milestones; and
- An escalating mid-to-high single-digit royalty on annual net sales of licensed products made by the Company, its affiliates or its sublicensees, subject to certain reductions as set forth in the ICI Agreement. The Company’s 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.

The exclusive license under the ICI Agreement extends to all countries and territories worldwide.
For the consideration above, the Company received certain research and development historical records. The Company did not receive any material inventory of URO-902, did not hire, or receive, any ICI employees working on URO-902, and did not receive any research, clinical or manufacturing equipment. Additionally, the Company did not assume from ICI any contracts, licenses or agreements between ICI and any third party with respect to URO-902. The Company developed independently all clinical processes and procedures for its clinical trials using internal and external resources.

The Company evaluated the in-license agreement of URO-902 from ICI based on the applicable guidance in ASC 805 and has determined that the IPR&D asset 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 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 $0.25 million as research and development expense in the accompanying consolidated statement of operations for the year ended March 31, 2019. There were no amounts due to or paid to ICI for the year ended March 31, 2020.

Note 4—Accrued expenses

Accrued expenses at March 31, 2020 and 2019 consist of the following (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2020</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development expenses</td>
<td>$13,728</td>
<td>$4,993</td>
</tr>
<tr>
<td>Compensation-related expenses</td>
<td>6,296</td>
<td>3,398</td>
</tr>
<tr>
<td>Professional services expenses</td>
<td>433</td>
<td>821</td>
</tr>
<tr>
<td>Other general and administrative expenses</td>
<td>1,299</td>
<td>665</td>
</tr>
<tr>
<td><strong>Total accrued expenses</strong></td>
<td><strong>$21,756</strong></td>
<td><strong>$9,877</strong></td>
</tr>
</tbody>
</table>

Note 5—Long-term debt

[A] Hercules Capital:

On February 20, 2019, the Company and its subsidiaries, UHL, USG (collectively with the Company and UHL, the “Borrowers”) and USI (collectively with the Borrowers, the “Loan Parties”) entered into a secured debt financing agreement (the “Hercules Loan Agreement”) with Hercules Capital, Inc. (“Hercules”), as agent and lender in the amount of $100 million (the “Term Loans”). A first tranche of $15 million, or net cash proceeds of $14.1 million, was funded upon execution of the Loan Agreement, and a second tranche of $30 million was funded in September 2019. The Company terminated the Hercules Loan Agreement in January 2020, as described in further detail below.

The Term Loans bore a variable interest rate equal to the greater of (i) 10.15% or (ii) the lesser of (x) the prime rate as reported in The Wall Street Journal plus 4.65% and (y) 12.15%. The Company was obligated to make monthly payments of accrued interest for the first 12 months from closing (the “Interest-only Period”), followed by monthly installments of principal and interest through the maturity date. Pursuant to the terms of the Hercules Loan Agreement, the end of the Interest-only Period was extended from April 1, 2020 to October 1, 2020 as a result of the achievement of a clinical milestone.

The Term Loans were scheduled to mature 36 months from closing and included an option for the Loan Parties to extend the maturity date up to 18 months subject to the achievement of certain defined milestones. Pursuant to the terms of the Hercules Loan Agreement, the Term Loan Maturity Date (as defined in the Hercules Loan Agreement) was extended from March 1, 2022 to March 1, 2023 as a result of the achievement of a clinical milestone. The Loan Parties had the option to prepay the Term Loans and the prepayment of the Term Loans was subject to, in some circumstances, a prepayment charge equal to 2% in the first 12 months from closing, 1% in the second 12 months, and 0% thereafter. Upon repayment of the Term Loans, the Company was obligated to pay an end of term charge in an amount equal to 4.25% of the amount of the Term Loans actually advanced.

On January 2, 2020, the Company terminated the Hercules Loan Agreement in connection with and as a requirement under the $300 million unsecured revolving debt financing agreement the Company entered into on December 27, 2019 with Sumitomo, as lender (the “Sumitomo Loan Agreement”) (see Note 6[B]). On December 26, 2019, Hercules delivered a limited waiver of the mandatory prepayment provisions under the Hercules Loan Agreement to permit the Company’s entry into the Sumitomo Loan Agreement, so long as the obligations under the Hercules Loan Agreement were repaid by January 7, 2020. The Company’s obligations under the Hercules Loan Agreement were repaid in full on January 2, 2020, using the financing the Company obtained pursuant to the Sumitomo Loan Agreement. Prepayment of the Hercules Loan Agreement prior to the one-year anniversary of its execution required the Company to pay a prepayment charge of $0.9 million, which is included in loss on extinguishment of long-term debt in the accompanying consolidated statement of operations for the year ended March 31, 2020. In addition, the Company was obligated to pay an end of term charge of $1.9 million.
The Company’s obligations under the Hercules Loan Agreement were fully and unconditionally guaranteed by the subsidiaries of the Borrowers, including USI. The Loan Parties’ obligations under the Hercules Loan Agreement were secured by a first priority security interest on substantially all of their personal property, other than intellectual property, and subject to certain other exceptions. The Hercules Loan Agreement contained certain representations and warranties, affirmative covenants, negative covenants and conditions that were customarily required for similar financings. The agreement also contained a minimum cash covenant that required the Loan Parties to hold certain minimum cash balances in the event that either certain milestones were not achieved or the market capitalization of the Company was below a certain threshold for certain periods of time. Such minimum cash covenant ceased to apply if the Company achieved certain clinical development and financial milestones as set forth in the Hercules Loan Agreement. The Hercules Loan Agreement also contained customary events of default (subject, in certain instances, to specified grace periods). If any event of default occurred, the principal, premium, if any, interest and any other monetary obligations on all the then outstanding amounts under the Term Loans would have become due and payable immediately. Upon the occurrence of an event of default, a default interest rate of an additional 5% would have been applied to the outstanding principal balance, and Hercules could have declared all outstanding obligations immediately due and payable (subject, in certain instances, to specified grace periods) and take such other actions as set forth in the Hercules Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations under the Hercules Loan Agreement would have automatically become due and payable. The Company was in compliance with the covenants under the Hercules Loan Agreement at the date of loan termination.

In connection with each funding of the Term Loans, the Company was required to issue to Hercules a warrant (the “Warrants”) to purchase a number of common shares equal to 2% of the principal amount of the relevant Term Loan funded divided by the exercise price, which was based on the closing price of the Company’s common shares on the business day immediately prior to the relevant Term Loan funding (or for the first and second tranches only at the lower of (i) $9.02 per share or (ii) the closing price of the Company’s common shares on the business day immediately prior to the relevant Term Loan funding). The Warrants may be exercised on a cashless basis, and are immediately exercisable through the seventh anniversary of the applicable funding date. The number of common shares for which each Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrants.

In connection with the first tranche of the Term Loans, the Company issued a Warrant to Hercules, exercisable for an aggregate of 33,259 of the Company’s common shares at an exercise price of $9.02 per share. Concurrent with the funding of the second tranche, the Company issued a Warrant to Hercules exercisable for an aggregate of 66,518 of the Company’s common shares at an exercise price of $9.02 per share. The Company accounted for the Warrants as equity instruments since they were indexed to the Company’s common shares and met the criteria for classification in shareholders’ equity. The relative fair value of the Warrants related to the first and second tranche funding was approximately $0.2 million and $0.4 million, respectively, and were treated as a discount to the Term Loans. This amount was being amortized to interest expense using the effective interest method over the life of the Term Loans. The Company estimated the fair value of the Warrants using the Black-Scholes option-pricing model based on the following key assumptions:

| Exercise price | $9.02 | $9.02 |
| Common share price on date of issuance | $10.50 | $10.12 |
| Expected volatility | 69.6% | 65.9% |
| Contractual term, in years | 7.00 | 7.00 |
| Risk-free interest rate | 2.55% | 1.68% |
| Expected dividend yield | —% | —% |

The Company recorded the first tranche of the Term Loans at a discount of $1.8 million, including the proceeds allocated to the related Warrant, and incurred financing costs of $0.4 million relating to the Hercules Loan Agreement which were recorded as an offset to long-term debt on the Company’s consolidated balance sheets. The Company recorded the second tranche of the Terms Loans at a discount of $1.7 million, including the proceeds allocated to the related Warrant. The debt discount and deferred financing costs were being amortized over the term of the debt using the effective interest method, and were included in interest expense in the Company’s consolidated statements of operations. During the years ended March 31, 2020 and 2019, interest expense included $0.7 million and $0.1 million, respectively, of amortized debt discount and issuance costs related to the Term Loans. As a result of the repayment of the obligations under the Hercules Loan Agreement on January 2, 2020, the remaining unamortized debt discount and issuance costs on the date of loan termination of $3.2 million were amortized in full and included in loss on extinguishment of long-term debt in the accompanying consolidated statement of operations during the year ended March 31, 2020.

F-19
Outstanding debt obligations to Hercules Capital, Inc. were as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2020</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal amount</td>
<td>$</td>
<td>$ 15,000</td>
</tr>
<tr>
<td>End of term charge</td>
<td></td>
<td>638</td>
</tr>
<tr>
<td>Less: unamortized debt and issuance costs</td>
<td></td>
<td>(2,104)</td>
</tr>
<tr>
<td>Loan payable less unamortized debt discount and issuance costs</td>
<td></td>
<td>13,534</td>
</tr>
<tr>
<td>Less: current maturities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term debt, net of unamortized debt discount and issuance costs</td>
<td>$</td>
<td>$ 13,534</td>
</tr>
</tbody>
</table>

(B) Sumitomo:

On December 27, 2019, the Company entered into the Sumitomo Loan Agreement which provides the Company with a $300 million unsecured revolving debt facility with Sumitomo. Sumitomo funded an initial amount of $87.5 million on December 30, 2019 under the terms of the Sumitomo Loan Agreement. In April 2020, Sumitomo funded an additional amount of $41.0 million (see Note 14[B]). Additional funds may be drawn down by the Company, upon request, no more than once in any calendar quarter, subject to the funding requests that are made are in accordance with our board approved operating budget.

Loans under the Sumitomo Loan Agreement (“Loans”) bear a variable interest rate per annum equal to LIBOR plus a margin of 3% payable on the last day of each calendar quarter. If LIBOR becomes unavailable in the future, the Company and Sumitomo will negotiate in good faith to select an alternative interest rate and, if applicable as a result of such alternative interest rate, margin adjustment that is consistent with industry accepted successor rates for determining a LIBOR replacement. The interest rate on the Loans was 4.45% at March 31, 2020. The Loans mature and are payable in full on the five-year anniversary of the closing date of the Sumitomo Loan Agreement or December 27, 2024.

The Company’s obligations under the Sumitomo Loan Agreement are fully and unconditionally guaranteed by each of the Company’s direct and indirect subsidiaries. The Sumitomo Loan Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that are customarily required for similar financings. The Sumitomo Loan Agreement required that, within ten business days of funding, a portion of the proceeds of the Loans shall be used to repay in full all outstanding obligations under the Hercules Loan Agreement. The Hercules Loan Agreement was repaid in full on January 2, 2020 (see Note 5[A]).

The Sumitomo Loan Agreement also contains customary events of default (subject, in certain instances, to specified grace periods). If any event of default occurs, the principal, premium, if any, interest and any other monetary obligations on all the then outstanding amounts under the Loans may become due and payable immediately. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding principal balance, and Sumitomo may declare all outstanding obligations immediately due and payable (subject, in certain instances, to specified grace periods) and take such other actions as set forth in the Sumitomo Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations under the Sumitomo Loan Agreement would automatically become due and payable. The Company is in compliance with the covenants pursuant to the Sumitomo Loan Agreement as of March 31, 2020.

The Company incurred financing costs of $0.3 million relating to the Sumitomo Loan Agreement which are recorded as an offset to related-party long-term debt on the Company’s consolidated balance sheet. The deferred financing costs are being amortized over the term of the debt using the effective interest method, and are included in interest expense in the Company’s consolidated statement of operations.

Outstanding debt obligations to Sumitomo are as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal amount</td>
<td>$ 87,500</td>
</tr>
<tr>
<td>Less: unamortized debt issuance costs</td>
<td>(248)</td>
</tr>
<tr>
<td>Related-party loan payable less unamortized debt issuance costs</td>
<td>$ 87,252</td>
</tr>
<tr>
<td>Less: current maturities</td>
<td></td>
</tr>
<tr>
<td>Related-party long-term debt, net of unamortized debt issuance costs</td>
<td>$ 87,252</td>
</tr>
</tbody>
</table>

F-20
Annual maturities of related-party long-term debt outstanding, excluding interest, as of March 31, 2020 are as follows (in thousands):  

<table>
<thead>
<tr>
<th>Years Ending March 31</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>$—</td>
</tr>
<tr>
<td>2022</td>
<td>$—</td>
</tr>
<tr>
<td>2023</td>
<td>$—</td>
</tr>
<tr>
<td>2024</td>
<td>$—</td>
</tr>
<tr>
<td>2025</td>
<td>$87,500</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$87,500</td>
</tr>
</tbody>
</table>

**Note 6—Related party transactions**

[A] **Sumitomo and RSL transaction:**  
On December 27, 2019, the Sumitomo Transaction occurred and, as a result, all of the Company’s outstanding common shares held directly or indirectly by RSL were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo, resulting in Sumitovant directly, and Sumitomo indirectly, owning 22,860,013 of the Company’s outstanding common shares, representing approximately 74.9% of the Company’s common shares outstanding on December 27, 2019. As a result of the transfer of these common shares, Roivant no longer beneficially owns any common shares of the Company.

[B] **Sumitomo loan agreement:**  
See Note 5[B] for information regarding the Sumitomo Loan Agreement.

[C] **Sumitovant share purchase agreement:**  
See Note 9[B] for information regarding the share purchase agreement between Sumitovant and certain employees of the Company.

[D] **Investor rights agreement – Sumitomo and Sumitovant:**
On December 27, 2019, the Company entered into an investor rights agreement with Sumitomo and Sumitovant (the “Investor Rights Agreement”). Pursuant to the Investor Rights Agreement, among other things, the Company agreed to comply with any demands by Sumitovant to register for sale, under the Securities Act of 1933, as amended, any common shares of the Company beneficially owned by Sumitovant that have an anticipated aggregate net offering price of at least $5 million, subject to certain customary exceptions and the right of the Company to refuse any demand for registration if the Company already effected two registrations for Sumitovant in the year preceding such demand. In addition, the Company agreed to periodically provide Sumitovant with (i) certain financial statements, projections, capitalization summaries and other information customarily provided to significant investors in publicly-traded companies and (ii) access to the Company’s books, records, facilities and employees during the Company’s normal business hours as Sumitovant may reasonably request.

Moreover, the Investor Rights Agreement also contains certain protections for the Company’s minority shareholders for so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of the Company’s directors (the “Total Voting Power”). These protections include, among other things: (i) a requirement for a minimum of three independent directors on the Company’s Board of Directors (the “Board”) (each of whom cannot be removed by Sumitomo or certain of its affiliates without the approval of a majority of the minority shareholders); (ii) a requirement that the audit committee of the Board (the “Audit Committee”) be comprised solely of independent directors; (iii) the appointment of Mr. Pierre Legault as the Company’s lead independent director; (iv) a requirement that any transaction proposed by Sumitomo or certain of its affiliates that would increase Sumitomo’s beneficial ownership to over 76% of the Total Voting Power be approved by the Audit Committee (if occurring prior to December 27, 2021) and, if such transaction would increase Sumitomo’s beneficial ownership to over 80% of the Total Voting Power, a majority of the Company’s minority shareholders must vote on such matter; and (v) a requirement that any related person transactions between Sumitomo or certain of its affiliates and the Company be approved by the Audit Committee, consistent with the Company’s existing Related Person Transactions Policy.
Pursuant to the Investor Rights Agreement, the Company also agreed that so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the Total Voting Power, the Company will inform Sumitovant before issuing any new common shares and allow Sumitovant to (i) participate in such issuance up to its pro rata share (unless such issuance is in connection with the acquisition of a business or its assets) or (ii) make sufficient open market purchases of the Company’s securities to ensure that Sumitomo’s beneficial ownership percentage does not decline as a result of such issuance.

On March 23, 2020, as a result of the appointment of Mr. James Robinson as our Principal Executive Officer, the Board determined that Mr. Robinson no longer qualified as an independent director of the Company pursuant to the listing rules of The Nasdaq Stock Market LLC and Rule 10A-3 under the Securities Exchange Act of 1934, as amended. Consequently, the Company’s Board had only two independent directors as of March 31, 2020. On March 23, 2020, the Company, Sumitovant and Sumitomo executed a waiver of the requirements of Section 4.1(a) of the Investor Rights Agreement, solely with respect to the reduction of the number of independent directors serving on the Board as a result of Mr. Robinson’s appointment as our Principal Executive Officer, until September 19, 2020. The remaining terms of the Investor Rights Agreement remain in full force and effect. On May 20, 2020, James Hindman was appointed to the Company’s Board and a member of the Audit Committee and, as a result, the Company’s Board and Audit Committee has three independent directors. Therefore, the Company is in compliance with Section 4.1(a) of the Investor Rights Agreement.

No amounts have been paid or received under the Investor Rights Agreement; however, the Company believes this agreement is material to its business and operations.

[E] Information sharing agreement – Sumitovant

See Note 14[C] for information regarding the information sharing and cooperation agreement with Sumitovant.

[F] Market access services agreement – Sunovion

See Note 14[D] for information regarding the market access services agreement with Sunovion Pharmaceuticals, Inc. (“Sunovion”), a wholly-owned subsidiary of Sumitomo.

[G] Services agreements – Roivant:

In May 2017, the Company entered into a services agreement with RSI effective January 17, 2017, as amended and restated on July 9, 2018, under which RSI agreed to provide certain administrative and research and development services to the Company during its formative period. Under this services agreement, the Company pays or reimburses 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 predetermined 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 are billed back to the Company 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, 2020 and 2019, 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.

In May 2017, USG entered into a separate services agreement with RSG effective as of January 17, 2017, as amended and restated 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 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 90 days’ written notice.
Under the RSI and RSG services agreements, for the years ended March 31, 2020 and 2019, the Company incurred expenses of $0.2 million and $3.4 million, respectively, inclusive of the mark-up. Based upon the service performed under the services agreements, amounts included in research and development expenses totaled $0 and $2.2 million, and amounts included in general and administrative expenses totaled $0.2 million and $1.2 million during the years ended March 31, 2020 and 2019, respectively.

[H] China intellectual property purchase agreement – Roivant:

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 $1.8 million plus applicable Swiss VAT and was determined based on an independent third-party valuation. 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 $1.8 million as a deemed capital contribution from its parent, RSL. In July 2017, the Company received payment of $0.5 million under such agreement and the remaining consideration due of $1.3 million was classified within equity as a shareholder receivable in the consolidated balance sheet as of March 31, 2018. The remaining consideration of $1.3 million was received in October 2018.

[I] Information sharing and cooperation agreement – Roivant:

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) obligated 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) required the Company to supply certain material information to RSL to assist it in preparing any future SEC filings; and (3) required the Company to implement and observe certain policies and procedures related to applicable laws and regulations. The 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.

In addition, the Cooperation Agreement included an automatic termination provision that would be triggered upon the later to occur of such time as when (1) RSL holds less than 25% of the aggregate voting rights attached to the Company’s common shares and (2) RSL is no longer required to consolidate the Company’s financial results in accordance with U.S. GAAP. On December 27, 2019, RSL consummated the Sumitomo Transaction, pursuant to which RSL divested all of the Company’s common shares it previously held. As a result of the consummation of the Sumitomo Transaction, both of the preconditions to the automatic termination of the Cooperation Agreement have occurred, and the Cooperation Agreement terminated pursuant to its terms.

No amounts were paid or received under this agreement prior to its termination.

[J] Data sharing agreement – Roivant:

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.

[K] Operating lease – Roivant:

In June 2019, the Company entered into a sublease agreement with its affiliate, RSI, for 2,784 square feet of office space located in Durham, North Carolina that expires in July 2025. The sublease has scheduled rent increases each year and the total sublease payment obligations under the agreement are $0.6 million. See Note 12 for more details on the sublease.

[L] Share-based compensation expense allocated to the Company – Roivant:

See Note 9[C] for information regarding share-based compensation expense allocated to the Company based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.

Note 7—Shareholders’ equity (deficit)

[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, 2020, the Company had 267,001,308 shares authorized with a par value of $0.000037453 per share.

[B] Transactions:

Initial public offering

On September 26, 2018, the Company’s registration statement on Form S-1 relating to its initial public offering of its common shares was declared effective by the SEC. In the initial public offering, which closed on October 1, 2018, the Company issued and sold 10,000,000 common shares at a price to the public of $14.00 per share. On October 18, 2018, the Company issued and sold an additional 297,813 common shares at the public offering price of $14.00 per share pursuant to the partial exercise of the underwriters’ over-allotment option in the initial public offering. The Company’s sole shareholder prior to the initial public offering, RSL, purchased 2,678,571 shares in the initial public offering at the public offering price of $14.00. The aggregate net proceeds to the Company from the initial public offering, inclusive of the proceeds from the partial over-allotment exercise, were $132.9 million after deducting underwriting discounts and commissions of $10.1 million and offering related expenses of $1.2 million.

Capital contributions

For the years ended March 31, 2020 and 2019, RSL made capital contributions of $0.3 million and $40.3 million, respectively.

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 $1.8 million of which $0.5 million was received during the year ended March 31, 2018 and the remaining $1.3 million during the year ended March 31, 2019. As RSG and USG were under common control, the consideration of $1.8 million was recorded as a capital contribution from the Company’s former parent, RSL (see Note 6[H]).

[C] At-the-market equity offering program:

In November 2019, the Company entered into a sales agreement (the “Sales Agreement”) with Jefferies LLC (“Jefferies”) to sell its common shares having an aggregate offering price of up to $50 million from time to time through an “at-the-market” equity offering program under which Jefferies acts as the Company’s agent. During the
year ended March 31, 2020, no shares were issued and sold under the Sales Agreement. As of March 31, 2020, the Company had $50 million of capacity available to it under its “at-the-market” equity offering program.

[D] Hercules warrants:
During the years ended March 31, 2020 and 2019, the Company issued warrants to purchase 66,518 and 33,259 common shares, respectively, to Hercules in connection with the Term Loans (see Note 5[A]). The warrants have an expiration term of seven years and an exercise price of $9.02 per share.

Note 8—Income taxes
The loss before income taxes and the related tax provision are as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31,</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
<td>2019</td>
<td></td>
</tr>
<tr>
<td>Loss before income taxes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>($14,742)</td>
<td>($1,437)</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>(117,644)</td>
<td>(107,905)</td>
<td></td>
</tr>
<tr>
<td>Bermuda</td>
<td>(13,832)</td>
<td>(1,924)</td>
<td></td>
</tr>
<tr>
<td>Other(1)</td>
<td>(462)</td>
<td>(33)</td>
<td></td>
</tr>
<tr>
<td>Total loss before income taxes</td>
<td>$ (146,680)</td>
<td>$ (111,299)</td>
<td></td>
</tr>
<tr>
<td>Current taxes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>64</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Bermuda</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Other(1)</td>
<td>1</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Total current tax expense</td>
<td>65</td>
<td>47</td>
<td></td>
</tr>
<tr>
<td>Deferred taxes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Bermuda</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Other(1)</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Total deferred tax expense</td>
<td>—</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Total income tax provision</td>
<td>$ 65</td>
<td>$ 47</td>
<td></td>
</tr>
</tbody>
</table>

(1) Primarily United States state and United Kingdom activity.

As of March 31, 2020 and 2019, the Company had an aggregate income tax receivable of $0.1 million from various federal, state, and local jurisdictions which is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets.

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 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Year Ended March 31,</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
<td>2019</td>
</tr>
<tr>
<td>Income tax provision at Bermuda statutory rate</td>
<td>$ —</td>
<td>—</td>
</tr>
<tr>
<td>Foreign rate differential(2)</td>
<td>(26,218)</td>
<td>17.88</td>
</tr>
<tr>
<td>Other</td>
<td>21</td>
<td>(0.01)</td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>26,262</td>
<td>(17.91)</td>
</tr>
<tr>
<td>Total income tax provision</td>
<td>$ 65</td>
<td>(0.04) %</td>
</tr>
</tbody>
</table>

(2) Mainly related to current tax on United States operations including permanent and temporary differences (e.g. research and development credits, etc.) as well as operations in Switzerland and the United Kingdom at rates different than the Bermuda rate.

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The Company’s effective tax rate for the years ended March 31, 2020 and 2019 was (0.04)% driven by the Company’s jurisdictional earnings by location and a valuation allowance that eliminates the Company’s global net deferred tax assets.

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, 2020 and 2019 are as follows (in thousands):

<table>
<thead>
<tr>
<th>Deferred tax assets:</th>
<th>March 31, 2020</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research tax credits</td>
<td>$6,791</td>
<td>$4,081</td>
</tr>
<tr>
<td>Intangibles</td>
<td>4,895</td>
<td>3,041</td>
</tr>
<tr>
<td>Net operating losses</td>
<td>35,077</td>
<td>18,052</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>4,815</td>
<td>805</td>
</tr>
<tr>
<td>Other</td>
<td>1,429</td>
<td>5</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>$53,007</td>
<td>$25,984</td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>(52,035)</td>
<td>(25,773)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deferred tax liabilities:</th>
<th>March 31, 2020</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depreciation</td>
<td>(248)</td>
<td>(155)</td>
</tr>
<tr>
<td>Other</td>
<td>(724)</td>
<td>(56)</td>
</tr>
<tr>
<td><strong>Total deferred tax assets</strong></td>
<td>$—</td>
<td>$—</td>
</tr>
</tbody>
</table>

During the year ended March 31, 2020, the Company recognized deferred tax assets and deferred tax liabilities associated with operating lease liabilities and right-of-use assets, respectively, in accordance with ASC 842. The Company also derecognized existing deferred rent liabilities, but consistent with its adoption of ASC 842 and the optional transition method, there has been no change to the prior year deferred tax assets related to deferred rent liabilities.

The Company’s adoption of ASC 842 is more fully described in Note 2(Q).

On March 18, 2020, the Families First Coronavirus Response Act (the “FFCR Act”) and on March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferral of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. Specifically, the CARES Act lifts certain deduction limitations originally imposed by the Tax Cuts and Jobs Act of 2017 (the “2017 Tax Act”). Under the 2017 Tax Act, federal net operating losses (“NOLs”) generated after 2017 could not be carried back and utilization was limited to 80% of taxable income. The CARES Act allows for a five-year carryback of federal NOLs generated in 2018 through 2020 and eliminates the 80% taxable income limitation by allowing corporate entities to fully utilize NOL carryforwards to offset taxable income in 2018 through 2020. Also, the CARES Act generally allows taxpayers to deduct interest up to 50% of adjusted taxable income (30% limit under the 2017 Tax Act) for tax years 2019 and 2020. Additionally, the CARES Act raises the corporate charitable deduction limit to 25% of taxable income and provides a technical correction to the 2017 Tax Act to generally provide qualified improvement property a 15-year cost-recovery period and allow 100% bonus depreciation. The enactment of the FFCR Act and CARES Act did not result in any material adjustments to the Company’s income tax provision for the year ended March 31, 2020, or to the Company’s U.S. federal and state net deferred tax assets as of March 31, 2020; however, the Company continues to examine the impacts the FFCR Act and CARES Act may have on its business, results of operations, financial condition and liquidity.

The Company has NOLs in Switzerland, the United Kingdom and the United States in the amount of $251.7 million, $11.5 million, and $0.3 million, respectively. The NOLs in Switzerland will begin to expire in fiscal year 2024. The NOLs in the United Kingdom and the United States can be carried forward indefinitely with an annual usage limitation.

As of March 31, 2020, the Company has research and development (“R&D”) credit carryforwards in the United States in the amount of $8.0 million which will begin to expire in fiscal year 2037. Pursuant to Section 382 and Section 383 of the Internal Revenue Code (“IRC”), use of the Company’s R&D credit carryforwards in the United States may be limited if the Company experiences a cumulative change in ownership of greater than 50% in a rolling
three-year period. Upon consummation of the Sumitomo Transaction on December 27, 2019, a change in ownership of greater than 50% of the Company occurred. As a result, the Company’s R&D credit carryforwards as of December 27, 2019 may be limited pursuant to IRC Section 382 and IRC Section 383.

The Company has not yet completed an analysis under IRC Section 382 or IRC Section 383 to determine whether a limitation on its R&D credit carryforwards has been triggered or the extent of such limitation. Upon completion of such IRC Section 382 and IRC Section 383 analysis, it may be determined that the R&D credit carryforwards in the United States as of the date of the Sumitomo Transaction are limited or unable to be utilized prior to their expiration. The Company expects to complete such analysis prior to the filing of its March 31, 2020 income tax return.

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 $52.0 million and $25.8 million as of March 31, 2020 and 2019, 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, 2020 and 2019, the Company recorded an increase to its valuation allowance of $26.2 million and $18.7 million, 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 provides for uncertain tax positions when such tax positions do not meet the recognition thresholds or measurement criteria as set forth in ASC 740. As of March 31, 2020 and 2019, the Company had unrecognized tax benefits of $1.2 million and $0.7 million, respectively.

The Company’s gross unrecognized tax benefits as of March 31, 2020 and 2019, and the changes in those balances are as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2020</th>
<th>March 31, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross unrecognized tax benefits at beginning of year</td>
<td>$739</td>
<td>$100</td>
</tr>
<tr>
<td>Increases for tax positions for current year</td>
<td>486</td>
<td>621</td>
</tr>
<tr>
<td>Increase for tax positions of prior years</td>
<td>2</td>
<td>18</td>
</tr>
<tr>
<td>Reductions due to lapse of applicable statute of limitations</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Gross unrecognized tax benefits at year end</td>
<td>$1,227</td>
<td>$739</td>
</tr>
</tbody>
</table>

The Company is subject to tax and files 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 2017 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.

The Company believes its reserve for unrecognized tax benefits and contingent tax issues is adequate with respect to all open years. Notwithstanding the foregoing, the Company could adjust its provision for income taxes and contingent tax liability based on future developments.

Note 9—Share-based compensation

Equity Incentive Plan:

On June 1, 2017, the Company adopted its 2017 Equity Incentive Plan (the “2017 Plan”), under which 2,002,509 common shares were initially reserved for grant. On June 15, 2018, the Board approved an increase in the common shares reserved for grant under the 2017 Plan of 1,068,006 common shares. The 2017 Plan was approved by the
Company’s shareholders in September 2018. In connection with the Company’s initial public offering, the 2017 Plan was amended effective upon the execution of the underwriting agreement related to the offering. All references herein to the Company’s 2017 Plan will be deemed to refer to the 2017 Plan, as amended and restated, unless the context otherwise requires.

In September 2019, the shareholders of the Company approved an amendment to the 2017 Plan to increase the number of common shares reserved for issuance under the 2017 Plan by 3,000,000 common shares.

Share-based awards under the 2017 Plan are subject to terms and conditions established by the Compensation Committee of the Board. The 2017 Plan provides for the grant of incentive options within the meaning of Section 422 of the IRC to the Company’s employees and its parent and subsidiary corporations’ employees, and for the grant of nonstatutory options, restricted share awards, restricted share unit awards, share appreciation rights, performance share awards and other forms of share compensation to its employees, including officers, consultants and directors. The 2017 Plan also provides for the grant of performance cash awards to the Company’s employees, consultants and directors. The Company’s policy is to issue new common shares upon the exercise of stock options, conversion of share units or purchase of restricted shares.

Pursuant to the “evergreen” provision contained in the 2017 Plan, the number of common shares reserved for issuance under the 2017 Plan automatically increases on November 1 of each year, commencing on November 1, 2018 and ending on November 1, 2028, in an amount equal to 4% of the total number of the Company’s common shares outstanding on the last day of the preceding month, or by a lesser number of common shares as may be determined by the Company’s Board prior to any such increase date. On November 1, 2019 and 2018, the number of common shares authorized for issuance increased automatically by 1,215,257 shares and 1,212,916 shares, respectively, in accordance with the evergreen provision of the 2017 Plan.

At March 31, 2020, a total of 2,454,582 common shares were available for future issuance under the 2017 Plan.

2019 Employee Stock Purchase Plan:

In July 2019, the Company’s Board adopted the 2019 Employee Stock Purchase Plan (the “2019 ESPP”). In September 2019, the Company’s shareholders approved the 2019 ESPP. A total of 450,000 shares of common stock are authorized for issuance under the 2019 ESPP. Pursuant to the “evergreen” provision contained in the 2019 ESPP, the number of common shares reserved for issuance under the 2019 ESPP automatically increases on November 1 of each year, commencing on November 1, 2020 and ending on November 1, 2028, in an amount equal to the lesser of (i) 1% of the total number of the Company’s common shares outstanding on March 31st of the preceding calendar year, and (ii) 600,000 shares of common stock. The Company’s Board may approve an increase of a lesser number of common shares prior to any such increase date.

The 2019 ESPP permits eligible employees to purchase common shares at a discount through payroll deductions during defined six month consecutive offering periods beginning on January 1st. The price at which the shares are purchased is equal to the lower of (i) 85% of the fair market value of the common shares on the first day of the offering or (ii) 85% of the fair market value of the common shares on the purchase date. A participant may purchase a maximum of 60,000 shares of common stock during each offering period, not to exceed $25,000 worth of common shares on the offering date during each calendar year, and the maximum number of shares of common stock that can be purchased by all participants during each offering period is 150,000 shares. The Company uses the Black-Scholes option-pricing model, in combination with the discounted employee price, in determining the value of the 2019 ESPP share-based compensation expense to be recognized during each offering period. The weighted-average grant date fair value per share using the Black-Scholes option-pricing model was $5.26 during the year ended March 31, 2020.

As of March 31, 2020, no shares of common stock were issued under the 2019 ESPP and 450,000 shares remain available for future issuance under the 2019 ESPP. At March 31, 2020, the Company had an outstanding liability of $0.2 million, which is included in accrued expenses in the consolidated balance sheet, for employee contributions to the 2019 ESPP for shares pending issuance at the end of the next offering period on June 30, 2020.
Stock options:

The Company estimated the fair value of each stock option on the date of grant using the Black-Scholes option-pricing model applying the range of assumptions in the following table:

<table>
<thead>
<tr>
<th>Year Ended March 31</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>1.39% - 2.33%</td>
<td>2.53% - 3.06%</td>
</tr>
<tr>
<td>Expected term, in years</td>
<td>5.50 - 6.11</td>
<td>6.00 - 6.25</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>62.7% - 70.4%</td>
<td>65.6% - 68.4%</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>—%</td>
<td>—%</td>
</tr>
</tbody>
</table>

The following table presents a summary of stock option activity and data under the Company’s 2017 Plan through March 31, 2020 (in thousands, except share and per share data):

<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, 2018</td>
<td>1,737,838</td>
<td>$3.84</td>
<td>$2.46</td>
<td>9.58</td>
<td>$—</td>
</tr>
<tr>
<td>Granted</td>
<td>2,329,038</td>
<td>$7.79</td>
<td>$4.98</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forfeited</td>
<td>(8,010)</td>
<td>$6.33</td>
<td>$5.72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Options outstanding at March 31, 2019</td>
<td>4,058,866</td>
<td>$6.10</td>
<td>$3.90</td>
<td>9.13</td>
<td>$16,854</td>
</tr>
<tr>
<td>Granted</td>
<td>665,300</td>
<td>$9.54</td>
<td>$5.81</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercised</td>
<td>(457,276)</td>
<td>$4.24</td>
<td>$2.71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forfeited</td>
<td>(132,790)</td>
<td>$6.55</td>
<td>$4.37</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Options outstanding at March 31, 2020</td>
<td>4,134,100</td>
<td>$6.85</td>
<td>$4.24</td>
<td>8.38</td>
<td>$11,337</td>
</tr>
<tr>
<td>Options exercisable at March 31, 2020</td>
<td>3,875,300</td>
<td>$6.58</td>
<td>$4.07</td>
<td>8.29</td>
<td>$11,337</td>
</tr>
</tbody>
</table>

The aggregate intrinsic value is calculated as the difference between the exercise price of all outstanding stock options and the quoted market price of the Company’s common shares at March 31, 2020. As a result of the Sumitomo Transaction (see Note 6[A]), which triggered a change in control as defined in the 2017 Plan, the vesting of options to purchase a total of 2,804,385 common shares accelerated and became exercisable during the year ended March 31, 2020. At March 31, 2020, there were 3,875,300 vested or exercisable options outstanding. During the years ended March 31, 2020 and 2019, the Company granted options to purchase 665,300 common shares and 2,329,038 common shares, respectively, to certain employees and directors of the Company with a weighted-average exercise price and grant date fair value per share of $9.54 and $5.81 and $7.79 and $4.98, respectively, under the 2017 Plan. The aggregate intrinsic value of options exercised during the year ended March 31, 2020 was $3.6 million.

During the year ended March 31, 2020, in connection with the resignation of the Company’s former Principal Executive Officer, fully-vested stock options to purchase 1,416,166 shares of common stock with a weighted-average exercise price of $5.59 per share held by the former Principal Executive Officer were reclassified from equity to liabilities following the modification of the stock options to include a share repurchase feature. The share repurchase feature is in the form of a right of first refusal for Sumitovant to purchase up to 1,416,666 shares underlying the stock options upon exercise by the former Principal Executive Officer pursuant to the same terms and conditions in the Sumitovant share purchase agreement (see Note 9[B]). As a result, during the year ended March 31, 2020, the Company reclassified $4.1 million from additional paid-in capital to share-based compensation liabilities in the accompanying consolidated balance sheet and recorded an additional $3.1 million in share-based compensation expense in the accompanying consolidated statement of operations based on the fair value of the stock options of $7.2 million as of March 31, 2020 (see Note 10). The stock options remain exercisable through October 1, 2021.
Stock appreciation rights ("SARs"):
SARs entitle the holder to receive, upon exercise, an amount of the Company’s common shares or cash (or a combination thereof) determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of the Company’s common stock over the strike price on the exercise date. The SARs are subject to vesting terms similar to the Company’s stock options and restricted stock units.

In March 2020, a total of 845,732 SARs were granted under the 2017 Plan to the Company’s new Principal Executive Officer pursuant to his employment agreement. The SARs vest as to 25% on the one-year anniversary of the grant date with the remaining SARs vesting in 12 equal quarterly installments thereafter, subject to the Principal Executive Officer providing continuous service to the Company through each such vesting date. The SARs can be settled in shares or cash upon exercise, at the sole discretion of the Company’s Board. Due to the current presumption that the SARs will be settled in cash upon exercise, the SARs have been classified as a liability instrument requiring the Company to remeasure the SARs at each reporting period until exercise (see Note 10). The estimated fair value of the SARs granted was $5.2 million at March 31, 2020.

Restricted stock unit ("RSUs"):
A summary of restricted stock unit activity under the Company’s 2017 Plan through March 31, 2020 is as follows:

<table>
<thead>
<tr>
<th>Number of Shares</th>
<th>Weighted Average Grant Date Fair Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unvested balance at March 31, 2018</strong></td>
<td>$</td>
</tr>
<tr>
<td>Granted</td>
<td>5,000</td>
</tr>
<tr>
<td><strong>Unvested balance at March 31, 2019</strong></td>
<td>$</td>
</tr>
<tr>
<td>Granted</td>
<td>5,000</td>
</tr>
<tr>
<td>Vested</td>
<td>761,927</td>
</tr>
<tr>
<td><strong>Unvested balance at March 31, 2020</strong></td>
<td>$</td>
</tr>
<tr>
<td>(15,000)</td>
<td>751,927</td>
</tr>
</tbody>
</table>

The weighted average grant-date fair value of RSUs granted during the years ended March 31, 2020 and 2019 was $13.76 per unit and $7.84 per unit, respectively.

[A] Share-based compensation expense:
Share-based compensation expense was as follows (in thousands):

<table>
<thead>
<tr>
<th>Year Ended March 31,</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Share-based compensation recognized as:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>$3,609</td>
<td>$1,296</td>
</tr>
<tr>
<td>General and administrative</td>
<td>16,874</td>
<td>2,682</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$20,483</td>
<td>$3,978</td>
</tr>
</tbody>
</table>

Share-based compensation expense is included in research and development and general and administrative expenses in the accompanying consolidated statements of operations consistent with the grantee’s salary classification. Share-based compensation expense presented in the table above includes share-based compensation expense allocated to the Company by RSL as described below in Note 9[C], from the reclassification of the former Principal Executive Officer’s stock options to liabilities mentioned above, and from a deemed capital contribution by Sumitovant as described below in Note 9[B].

Of the total share-based compensation expense, amounts recognized for options granted to non-employees were immaterial for all periods presented.

As a result of the Sumitomo Transaction (see Note 6[A]), which triggered a change in control as defined in the 2017 Plan, share-based compensation expense recognized due to the accelerated vesting of stock options and RSUs was $10.3 million during the year ended March 31, 2020. For the years ended March 31, 2020 and 2019, the Company recorded share-based compensation expense related to stock options, RSUs and SARs issued to employees, directors and consultants of $19.0 million and $3.4 million, respectively. This share-based compensation expense is included in general and administrative expenses and research and development expenses in the accompanying consolidated statements of operations.
Total unrecognized share-based compensation expense was approximately $16.6 million at March 31, 2020 and is expected to be recognized over a weighted-average period of 3.70 years.

[B] Share-based compensation — Sumitovant share purchase agreement:

In February 2020, certain employees of the Company elected to cashless exercise outstanding stock options pursuant to the terms of the 2017 Plan and enter into a share purchase agreement with Sumitovant wherein the remaining shares from the employee’s cashless exercise of certain stock options would be sold to Sumitovant at a price per share equal to the closing share price of the Company on the date of exercise. The total number of shares of common stock surrendered for cashless exercise and tax withholdings was 154,750 shares. The number of shares of common stock sold to Sumitovant by the employees was 103,250 shares at a price per share of $13.08 or a total sales price of $1.4 million. As the transaction was deemed a modification of the existing equity award and purchase of shares by the Company’s majority shareholder, Sumitovant, prior to the employee realizing the risks and rewards of share ownership, the Company recorded $1.4 million as a capital contribution from Sumitovant in the accompanying consolidated balance sheet and additional share-based compensation expense in the accompanying consolidated statement of operations during the year ended March 31, 2020.

[C] 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 no share-based compensation expense during the year ended March 31, 2020. For the year ended March 31, 2019, the Company recorded share-based compensation of $0.6 million.

Share-based compensation expense was 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 were valued at fair value on the date of grant and that fair value was 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 were not publicly traded. RSL common share awards and RSL options were 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 was 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 was estimated using the Black-Scholes option-pricing model.

Compensation expense was allocated to the Company over the required service period over which these RSL common share awards and RSL options would vest and was based upon the relative percentage of time utilized by RSL, RSI and RSG employees on Company matters.

RSL RSUs:

In connection with his employment agreement, the Company’s former Principal Executive Officer was granted 66,845 RSUs of the Company’s former parent company, RSL, during the year ended March 31, 2018. The RSUs had a requisite service period of eight years and had no dividend rights. The RSUs were to vest upon the achievement of both a performance and liquidity condition, if both were achieved within the requisite service period. In March 2020, the 66,845 RSUs were cancelled and, in connection with such cancellation, the former Principal Executive Officer received a cash payment of $0.1 million from RSL.

As of the date of cancellation, the performance condition had not been met and was deemed not probable of being met. As a result, the Company did not record any share-based compensation expense for this award as the performance condition was not met but, for the year ended March 31, 2020, the Company recorded the cash payment to the former Principal Executive Officer of $0.1 million as a capital contribution from RSL in the accompanying consolidated balance sheet and share-based compensation expense in the accompanying consolidated statement of operations.

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Note 10—Fair value measurements

As of March 31, 2020, the liabilities measured at fair value on a recurring basis consisted of certain liability classified stock options and SARs (see Note 9), which are included in share-based compensation liabilities in the accompanying consolidated balance sheet. There were no assets measured at fair value on a recurring basis as of March 31, 2020 and there were no assets or liabilities measured at fair value on a recurring basis at March 31, 2019. The following represents the fair value using the hierarchy described in Note 2[H] for the Company’s financial liabilities that are required to be measured at fair value on a recurring basis as of March 31, 2020 (in thousands):

<table>
<thead>
<tr>
<th>Liabilities:</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Total Fair Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Share-based compensation liability - stock options</td>
<td>$ —</td>
<td>$ —</td>
<td>$7,204</td>
<td>$ 7,204</td>
</tr>
<tr>
<td>Share-based compensation liability - SARs</td>
<td>—</td>
<td>—</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Total liabilities</td>
<td>$ —</td>
<td>$ —</td>
<td>$7,236</td>
<td>$ 7,236</td>
</tr>
</tbody>
</table>

The Company measured the share-based compensation liabilities at fair value based on significant inputs not observable in the market, which caused them to be classified as a Level 3 measurement within the fair value hierarchy. The valuation of the share-based compensation liabilities used assumptions and estimates the Company believed would be made by a market participant in making the same valuation.

The stock options liability is marked-to-market each reporting period with the change in fair value recorded as share-based compensation expense on the Company’s consolidated statements of operations until the stock options are exercised and are sold to Sumitovant or the former Principal Executive Officer has held the exercised shares for a period of at least six months. The fair value of the stock options liability is determined at each reporting period by utilizing the Black-Scholes option-pricing model. The fair value of the stock options liability as of March 31, 2020 was calculated using the following significant unobservable inputs:

<table>
<thead>
<tr>
<th>Input</th>
<th>March 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>0.20%</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>—%</td>
</tr>
<tr>
<td>Expected term, in years</td>
<td>1.50</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>76.2%</td>
</tr>
<tr>
<td>Exercise price (per share)</td>
<td>$3.86 - $14.00</td>
</tr>
<tr>
<td>Number of stock options valued</td>
<td>1,416,166</td>
</tr>
</tbody>
</table>

The SARs liability is marked-to-market each reporting period with the change in fair value recorded as share-based compensation expense on the Company’s consolidated statements of operations over the vesting term and until the SARs are exercised. The fair value of the SARs liability is determined at each reporting period by utilizing a binomial lattice model. The fair value of the SARs liability as of March 31, 2020 was calculated using the following significant unobservable inputs:

<table>
<thead>
<tr>
<th>Input</th>
<th>March 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk-free interest rate</td>
<td>0.76%</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>—%</td>
</tr>
<tr>
<td>Expected term, in years</td>
<td>10.00</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>77.0%</td>
</tr>
<tr>
<td>Post-vesting cancellation rate</td>
<td>3.5%</td>
</tr>
<tr>
<td>Exercise ratio</td>
<td>2.8</td>
</tr>
<tr>
<td>Exercise price (per share)</td>
<td>$9.16</td>
</tr>
<tr>
<td>Number of SARs granted</td>
<td>845,732</td>
</tr>
</tbody>
</table>
The table presented below is a summary of changes in the fair value of the Company’s Level 3 valuation for the share-based compensation liabilities for the year ended March 31, 2020 (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Stock Options</th>
<th>SARs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at March 31, 2019</td>
<td>$</td>
<td>$</td>
</tr>
<tr>
<td>Additions</td>
<td>7,204</td>
<td>32</td>
</tr>
<tr>
<td>Change in fair value</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Settlements</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Balance at March 31, 2020</td>
<td>$ 7,204</td>
<td>$ 32</td>
</tr>
</tbody>
</table>

Note 11—Commitments and contingencies

The Company entered into certain commitments under the Merck license agreement (see Note 3[A]), the ICI license agreement (see Note 3[B]), the Codexis enzyme supply agreement (see Note 11[A]), the Kyorin information sharing collaboration agreement (see Note 11[B]) and the services agreements with RSI and RSG (see Note 6[G]).

In addition, the Company has entered into services agreements with third parties for pharmaceutical research and development and manufacturing activities. 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.

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, unless the Company has determined that any such reasonably possible losses will not have a material impact on the Company’s results of operations, financial condition or cash flows.

[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. No milestone payments were made pursuant to this agreement during the years ended March 31, 2020 and 2019.

[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.

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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. In December 2019, the Company achieved a certain regulatory milestone pursuant to the Kyorin Agreement and, as a result, recorded a milestone payment of $2.5 million, which is included in research and development expenses for the year ended March 31, 2020 in the accompanying consolidated statement of operations. No payments were made pursuant to this agreement during the year ended March 31, 2019. The remaining obligation under this agreement of $8.0 million would be due upon achievement of a regulatory milestone by the Company in the United States, subject to certain specific conditions which the Company believes are not probable to occur. 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. The Company indemnifies its 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 the Company could be obligated to make. Historically, the Company has 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 12—Leases
In December 2017, the Company entered into an operating lease agreement for office space which consisted of approximately 8,038 square feet located in Irvine, California. The lease term was 26 months beginning January 2018 through February 2020, with no option to extend the term. In connection with this lease, the Company recognized an operating lease right-of-use asset of $0.2 million and an aggregate operating lease liability of $0.2 million in the accompanying consolidated balance sheet on April 1, 2019. The estimated incremental borrowing rate was 13.4%. This lease and all future obligations under this lease were terminated in June 2019 upon the commencement of the Company’s new office lease agreement and, as a result, the remaining operating lease liability and right-of-use asset on the lease termination date were written off. The net impact to the consolidated statement of operations was not material.

In November 2018, the Company entered into an operating lease for office space in Irvine, California for approximately 21,489 square feet. The lease term for the operating lease is seven years with options to terminate after five years and to extend the lease term for an additional five years which are both not reasonably certain of exercise. Subject to rent abatement for the first through fifth months of the lease, the Company will be required to pay $54,367 per month for rent for the first twelve months of the lease term which will increase at a fixed rate of approximately 3% per year. The lease further provides that the Company is obligated to pay certain variable costs, including common area maintenance expenses. The lease commenced in June 2019 and the Company recognized an operating lease right-of-use asset of $3.0 million and an operating lease liability of $3.0 million. In connection with the lease, the Company maintains a standby letter of credit for the benefit of the landlord in the amount of $0.6 million. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash as of March 31, 2020 and 2019. The remaining lease term is 6.2 years at March 31, 2020 and the estimated incremental borrowing rate applied was 12.4%.

In June 2019, the Company entered into a sublease agreement with its affiliate, RSI, for office space in Durham, North Carolina for approximately 2,784 square feet. The lease term for the operating lease is six years and two months with no option to extend the lease term. The Company will be required to pay $7,192 per month through July 2020 which will increase at a fixed rate of 3% per year. The lease commenced in June 2019 and the Company recognized an operating lease right-of-use asset of $0.4 million and an operating lease liability of $0.4 million. In connection with the lease, the Company maintains a standby letter of credit for the benefit of the landlord in the amount of $0.02 million. The Company secured the letter of credit for the full amount of the letter with cash on deposit, which is reported as restricted cash as of March 31, 2020. The remaining lease term was 5.3 years at March 31, 2020 and the estimated incremental borrowing rate applied was 12.4%.

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Supplemental balance sheet information related to operating leases was as follows (in thousands, except lease term and discount rate):

<table>
<thead>
<tr>
<th>Description</th>
<th>March 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating lease right-of-use assets</td>
<td>$3,135</td>
</tr>
<tr>
<td>Operating lease liabilities, current portion</td>
<td>$351</td>
</tr>
<tr>
<td>Operating lease liabilities, long-term portion</td>
<td>$3,086</td>
</tr>
<tr>
<td>Total lease liabilities</td>
<td>$3,437</td>
</tr>
</tbody>
</table>

Weighted average remaining lease term (years) 6.1 years
Weighted average discount rate 12.4%

Supplemental cash flow information for the year ended March 31, 2020 related to operating leases as follows (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>March 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash paid within cash flows used in operations</td>
<td>$338</td>
</tr>
<tr>
<td>Operating lease right-of-use asset obtained in exchange for operating lease liabilities</td>
<td>$3,414</td>
</tr>
<tr>
<td>Amortization of operating lease right-of-use assets</td>
<td>$279</td>
</tr>
</tbody>
</table>

The undiscounted future lease payments under the lease liabilities as of March 31, 2020 were as follows:

<table>
<thead>
<tr>
<th>Years Ending March 31,</th>
<th>Lease Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>$758</td>
</tr>
<tr>
<td>2022</td>
<td>781</td>
</tr>
<tr>
<td>2023</td>
<td>804</td>
</tr>
<tr>
<td>2024</td>
<td>828</td>
</tr>
<tr>
<td>2025</td>
<td>853</td>
</tr>
<tr>
<td>Thereafter</td>
<td>941</td>
</tr>
<tr>
<td>Total lease payments</td>
<td>4,965</td>
</tr>
<tr>
<td>Less: imputed interest</td>
<td>(1,528)</td>
</tr>
<tr>
<td>Total lease liabilities</td>
<td>$3,437</td>
</tr>
</tbody>
</table>

Operating lease costs for the year ended March 31, 2020 were $0.7 million. Short-term and variable lease costs were not material for the year ended March 31, 2020.

Disclosures related to periods prior to adopting the new lease guidance

Rent expense for the year ended March 31, 2019 was $0.3 million.

Approximate future operating lease obligations (excluding the optional lease renewal term) as of March 31, 2019 were as follows (in thousands):

<table>
<thead>
<tr>
<th>Years Ending March 31,</th>
<th>Operating Leases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>$455</td>
</tr>
<tr>
<td>2021</td>
<td>675</td>
</tr>
<tr>
<td>2022</td>
<td>692</td>
</tr>
<tr>
<td>2023</td>
<td>711</td>
</tr>
<tr>
<td>2024</td>
<td>731</td>
</tr>
<tr>
<td>Thereafter</td>
<td>1,662</td>
</tr>
<tr>
<td>Total minimum operating lease payments</td>
<td>$4,926</td>
</tr>
</tbody>
</table>

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Note 13—Defined contribution plan

Beginning in February 2020, the Company sponsors a defined contribution plan pursuant to Section 401(k) of the IRC that allows eligible participants to contribute up to 90% of their eligible compensation, subject to maximum deferral limits specified by the IRC. Prior to February 2020, the Company’s employees participated in a defined contribution plan sponsored by its former parent company, RSL. The Company provides a discretionary employer matching contribution of $0.50 for every $1.00 contributed by a participating employee up to 6% of the employee’s eligible compensation, with such matching contributions becoming fully vested after two years of service. For the years ended March 31, 2020 and 2019, the Company recorded total expense for discretionary matching contributions of $0.3 million and $0.2 million, respectively.

Note 14—Subsequent events

[A] Operating lease:

In April 2020, the Company entered into an amendment to its Irvine facility operating lease to add approximately 6,865 square feet of office space for a total of approximately 28,354 square feet. The lease term for the additional office space is concurrent with the existing operating lease and expires in May 2026. Subject to rent abatement for the first through fifth months of the additional leased office space, the Company will be required to pay $17,918 per month for rent for the first twelve months of the lease term which will increase at a fixed rate of approximately 3% per year. The lease commenced in May 2020.

Approximate future operating lease obligations for the additional space under the lease agreement are as follows (in thousands):

<table>
<thead>
<tr>
<th>Years Ending March 31</th>
<th>Operating Leases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>$108</td>
</tr>
<tr>
<td>2022</td>
<td>221</td>
</tr>
<tr>
<td>2023</td>
<td>227</td>
</tr>
<tr>
<td>2024</td>
<td>234</td>
</tr>
<tr>
<td>2025</td>
<td>241</td>
</tr>
<tr>
<td>Thereafter</td>
<td>289</td>
</tr>
<tr>
<td>Total minimum operating lease payments</td>
<td>$1,320</td>
</tr>
</tbody>
</table>

[B] Sumitomo loan agreement funding:

In April 2020, the Company received gross proceeds of $41.0 million pursuant to the Sumitomo Loan Agreement (see Note 5[B]). Subsequent to this draw, approximately $171.5 million of borrowing capacity remains available to the Company.

[C] Information sharing and cooperation agreement – Sumitovant

On May 21, 2020, the Company entered into an information sharing and cooperation agreement (the “Sumitovant Cooperation Agreement”) with Sumitovant. The Sumitovant Cooperation Agreement, among other things, obligates the Company to deliver to Sumitovant drafts of (i) the Company’s quarterly and annual financial statements and (ii) the discussion and analysis by the Company’s management of its financial condition and the results of its operations for each fiscal period, prior to the applicable deadlines for filing such information with the SEC. The Company also agreed to coordinate with Sumitovant before releasing earnings results or any interim financial guidance and to notify Sumitovant before issuing any material press releases.

In addition, the Sumitovant Cooperation Agreement requires the Company to give Sumitovant’s auditors access to its auditors and its books and records to facilitate the completion of Sumitovant’s own internal audit and their review of the Company’s financial statements and internal accounting controls and operations. The Company also agreed to provide Sumitovant any documents or materials relating to its business and access to its senior management to discuss any matters, in each case as Sumitovant may reasonably request. To the extent the Company provides Sumitovant any information in response to such a request, Sumitovant may not (i) disclose such information to certain of its affiliates or (ii) use such information in a manner it deems, in good faith, to be detrimental to the Company or its shareholders. In addition, both parties agreed to hold any information they receive from the other party in the strictest confidence, subject to customary exceptions for information that becomes public, that has been independently developed, or that is otherwise received on a non-confidential basis from a third party.

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Moreover, the Sumitovant Cooperation Agreement provides that the Company must adopt and maintain policies to address its obligations with respect to financial reporting, audits, internal controls, record keeping, taxes, and other applicable laws. In addition, the Board of Directors of the Company (the “Board”) must have a compliance oversight committee (the “Compliance Committee”) that oversees a compliance program designed to ensure the Company complies with its obligations under applicable laws (the “Compliance Program”). The Compliance Committee, in turn, is required to (i) appoint a member of the Company’s senior management to administer the Compliance Program and (ii) cause the implementation of internal reporting procedures and training to support the Compliance Program. The Sumitovant Cooperation Agreement also requires the Company to comply in all material respects with applicable laws.

**[D] Market access services agreement – Sunovion**

On June 17, 2020, USG entered into a market access services agreement (the “Market Access Services Agreement”) with Sunovion. Pursuant to the Market Access Services Agreement, among other things, USG appointed Sunovion as the exclusive distributor of vibegron in the United States, including all of its territories and possessions.

Sunovion, in turn, has agreed to provide certain market access services with respect to the distribution and sale of vibegron, including, among other things: (i) adding vibegron to Sunovion’s agreements with its third party logistics providers; (ii) adding vibegron to certain of Sunovion’s contracts with wholesalers, group purchasing organizations and integrated delivery networks; (iii) facilitating USG's entry into new contracts with certain health organizations regarding vibegron; (iv) managing the validation, processing and payment of rebates, chargebacks, and certain administrative, distribution and service fees related to vibegron; (v) providing USG with price reporting metrics and other information required for it to comply with applicable government price reporting requirements; (vi) coordinating with USG and any applicable wholesalers to address any recalls, investigations, or product holds; and (vii) providing certain other ancillary support services to facilitate the foregoing.

In order to facilitate Sunovion’s provision of these services, USG agreed, among other things, to: (i) grant Sunovion a non-exclusive license under all intellectual property owned or controlled by USG, solely to enable Sunovion to perform the contemplated services; (ii) provide Sunovion periodic reports of sales projections and volume requirements, as well as such other information as Sunovion reasonably requests or may need to perform the services; (iii) comply with the provisions of any agreements between Sunovion and third parties pursuant to which vibegron will be distributed or sold; (iv) cooperate with certain investigations related to orders and audits of USG’s quality systems; and (v) promptly notify Sunovion in the event vibegron is recalled.

As consideration for the services, USG will pay Sunovion an agreed-upon monthly service charge for each of the first two years of the agreement term. After the second year of the agreement term, the monthly service charges will be determined by the parties. In addition, USG also agreed to (x) reimburse Sunovion for any pass-through expenses it incurs while providing the services and (y) establish an escrow fund for use by Sunovion when managing any rebates, chargebacks and similar fees.

The Market Access Services Agreement also contains customary representations and warranties by the parties and customary provisions related to confidentiality, indemnification and insurance. The initial term of the Market Access Services Agreement is three years. Thereafter, the term will be automatically extended for one-year periods, unless either party provides notice of its intent to terminate the agreement at least nine (9) months prior to the expiration of the applicable term. Either party may also terminate the agreement prior to the end of its term in the event of an uncured material breach by the other party or if such other party becomes insolvent or undergoes a change of control. Finally, USG may also terminate the Market Access Services Agreement if Sunovion fails to satisfy certain market access milestones or upon payment of a break-up fee.
Description of Share Capital

The following description of our share capital and provisions of our memorandum of association and second amended and restated bye-laws are summaries. You should also refer to the memorandum of association and the second amended and restated bye-laws, or Bye-laws, which are filed as exhibits to our Annual Report on Form 10-K. As used herein, the terms “we,” “us,” “our” and the “Company” refer to Urovant Sciences Ltd. and its wholly owned subsidiaries.

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 5281 California Avenue, Suite 100, Irvine, California 92617 and 324 Blackwell Street Bay 11, Suite 1104, Durham, North Carolina 27701.

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, and 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.

Share capital

Our authorized share capital consists of 267,001,308 common shares, $0.000037453 par value per common share. Pursuant to our Bye-laws, subject to the requirements of The Nasdaq Stock Market LLC, or 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 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 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 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 Companies Act 1981, as amended, or the Companies 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 Bye-laws, each common share is entitled to such dividends as the Board may from time to time declare, 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 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 its common shares by completing a form of transfer in the form set out in our 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 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 board of directors may convene a special general meeting. Under our 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 rights 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 chairs all general meetings at which such individual is present.
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 corporate records.

In addition, pursuant to the investor rights agreement described below, the Company has agreed to periodically provide Sumitovant Biopharma Ltd., or SBL a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., or Sumitomo, who holds approximately 75.0% of our outstanding common shares as of March 31, 2020, with (i) certain financial statements, projections, capitalization summaries and other information customarily provided to significant investors in publicly-traded companies and (ii) access to the Company’s books, records, facilities and employees during the Company’s normal business hours as SBL may reasonably request.

Election and removal of directors

Our Bye-laws 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. Prior to the first date on which Sumitomo, or any parent or wholly-owned subsidiary thereof, ceases to hold at least a majority of the aggregate voting rights attaching to our issued and outstanding shares, Sumitomo is entitled to appoint two directors, or the Sumitomo 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 a Sumitomo Director), will serve a term as determined by our shareholders and each Sumitomo Director will serve a term as determined by Sumitomo. In either case, if no such determination is made, each such director’s term shall last until the next annual meeting of shareholders at which his or her successor is elected or appointed, subject to his or her office being vacated sooner pursuant to our Bye-laws.

A shareholder that, together with shares owned of record by its affiliates, owns at least 5% of the aggregate voting rights of issued and outstanding shares that are entitled to vote at a general meeting and who has held such shares for at least three years, may propose for election as a director (other than a Sumitomo 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 a Sumitomo 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. Prior to the first date on which Sumitomo ceases to hold at least a majority of the aggregate voting rights attaching to our issued and outstanding shares, directors appointed by Sumitomo may be removed, with or without cause, by Sumitomo upon duly executed notice to us. On or after the date on which Sumitomo ceases to hold at least a majority of the aggregate voting rights attaching to 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 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 Bye-laws or Bermuda law that our directors must retire at a certain age.

The compensation of our directors is 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 Sumitomo ceases to hold at least a majority of the aggregate voting rights attaching to our issued and outstanding shares, the chairperson of our board of directors will be a Sumitomo Director designated to us by duly executed notice from Sumitomo. On or after the date on which Sumitomo ceases to hold at least a majority of the aggregate voting rights attaching to 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 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 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 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 the affirmative vote in general meeting of the holders of a majority of the aggregate voting rights of the issued and outstanding shares entitled to vote thereon and voting at the meeting.

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 Bye-laws provide that the approval of the amalgamation or merger agreement shall require the affirmative votes of the holders of at least 66 2/3% of the aggregate voting rights of the issued and outstanding shares entitled to vote thereon and voting at the meeting (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.

**Investor Rights Agreement provisions regarding certain actions**

In December 2019, we entered into an investor rights agreement with Sumitomo and SBL in connection with a transaction whereby all of our common shares previously held by Roivant Sciences Ltd. were contributed to SBL, a wholly owned subsidiary of Roivant at the time of such contribution and, subsequent to such contribution, Sumitomo acquired all issued and outstanding equity securities of SBL. Upon consummation of this transaction, SBL acquired 22,860,013 common shares of the Company, which represented approximately 74.9% of our common shares outstanding on December 27, 2019. The investor rights agreement contains certain protections for the Company’s minority shareholders for so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the total number of votes entitled to be cast at elections of the Company’s directors, or the Total Voting Power. These protections include, among other things: (i) a requirement for a minimum of three independent directors on the Company’s board of directors (each of whom cannot be removed by Sumitomo or certain of its...
affiliates without the approval of a majority of the minority shareholders); (ii) a requirement that our audit committee be comprised solely of independent directors; (iii) the appointment of Mr. Pierre Legault as the Company’s lead independent director; (iv) a requirement that any transaction proposed by Sumitomo or certain of its affiliates that would increase Sumitomo’s beneficial ownership to over 76% of the Total Voting Power be approved by our audit committee (if occurring prior to December 27, 2021) and, if such transaction would increase Sumitomo’s beneficial ownership to over 80% of the Total Voting Power, a majority of the Company’s minority shareholders must vote on such matter; and (v) a requirement that any related person transactions between Sumitomo or certain of its affiliates and the Company be approved by our audit committee, consistent with the Company’s existing Related Person Transactions Policy.

Pursuant to the investor rights agreement, the Company also agreed that so long as Sumitomo or certain of its affiliates beneficially own between 50% and 90% of the Total Voting Power, the Company will inform SBL before issuing any new common shares and allow SBL to (i) participate in such issuance up to its pro rata share (unless such issuance is in connection with the acquisition of a business or its assets) or (ii) make sufficient open market purchases of the Company’s securities to ensure that Sumitomo’s beneficial ownership percentage does not decline as a result of such issuance.

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 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.

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 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 U.S. Securities Exchange Commission, or 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 Bye-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 Bye-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 enquiries 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 Bermudan dollar, and
there are no restrictions on our ability to transfer funds (other than funds denominated in Bermudan 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 our issued and outstanding common shares 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 our filings with the SEC. 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

Pursuant to the investor rights agreement we entered into with Sumitomo and SBL in December 2019, among other things, the Company agreed to comply with any demands by SBL to register for sale, under the Securities Act of 1933, as amended, or the Securities Act, any common shares of the Company beneficially owned by SBL that have an anticipated aggregate net offering price of at least $5 million, subject to certain customary exceptions and the right of the Company to refuse any demand for registration if the Company already effected two registrations for SBL in the year preceding such demand. In addition, if we propose to register the offer and sale of any of our securities under the Securities Act, including for any shareholders other than SBL or its valid transferees, SBL 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. The registration of our common shares pursuant to the exercise of the foregoing registration rights would enable SBL to sell these common shares without restriction under the Securities Act when the applicable registration statement is declared effective. Subject to the terms of the investor rights agreement, we will generally pay the registration expenses, other than underwriting discounts, selling commissions and transfer taxes, of the shares registered pursuant to the foregoing demand and registration rights.

The demand and piggyback registration rights described above will expire upon the earlier of (1) 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 (2) at such time, if any as Sumitomo or any of its controlled affiliates (other than the Company and its subsidiaries) beneficially owns, in the aggregate, less than 10% of our issued and outstanding common shares. In addition, 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, Hercules Capital, Inc., or Hercules, will be entitled to certain “piggyback” registration rights allowing it to include its common shares, including those common shares issuable upon exercises of its warrants, in such registration, subject to certain limitations. As a result, whenever we propose to file a registration statement under the Securities Act that falls within Hercules’ “piggyback” registration rights, Hercules has the right 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, where the registration statement would not include substantially the same information required to offer such securities, or pursuant to which we register up to $150,000,000 of securities in a registered offering or series of offerings declared effective prior to September 30, 2019.

Transfer agent and registrar

A register of holders of the common shares is maintained by Conyers Corporate Services (Bermuda) Limited in Bermuda, and a branch register is maintained in the United States by American Stock Transfer & Trust Company, LLC, which also serves as transfer agent. The transfer agent’s address is 6201 15th Avenue, Brooklyn, New York 11219.
Our common shares are listed on The Nasdaq Global Select Market under the symbol "UROV."
This Executive Employment Agreement (the “Agreement”), is hereby made between Urovant Sciences, Inc. (the “Company”) and C. Walt Johnston (“you”) (collectively, the “Parties”). This Agreement shall become effective on June 1, 2020 (the “Effective Date”).

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

WHEREAS, you wish to remain employed by the Company and to provide personal services to the Company in return for certain compensation and benefits;

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

1. Employment by the Company.

1.1 Position. You will continue to serve as the Company’s SVP, Commercial. This is an exempt position, based in Illinois with the option to relocate to the Irvine, California area. During your employment with the Company you will devote your best efforts and substantially all of your business time and attention to the business of the Company, except for approved vacation periods and absences permitted by the Company’s general employment policies.

1.2 Duties and Location. You shall perform such duties as are required by the Company’s CEO (the “CEO”), to whom you will report. Your primary office location shall be home based in Illinois.. The Company reserves the right to reasonably require you to perform your duties at places other than your primary office location from time to time, and to require reasonable business travel.

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

2. Compensation.

2.1 Salary. For services to be rendered hereunder, you shall receive a base salary at the rate of Four hundred forty thousand ($440,000.00) per year (the “Base Salary”), subject to standard payroll deductions and withholdings and payable in accordance with the Company’s regular bi-monthly payroll schedule. Your Base Salary will subject to annual review by the Company’s Chief Executive Officer.

2.2 Bonus. You will be eligible to participate in the Company’s discretionary Performance Bonus Plan, with the potential to receive a target bonus of 40% of your Base Salary (the “Performance Bonus”). Your Performance Bonus eligibility is based on the Company’s fiscal year, which runs from April 1 through March 31 of the next calendar year. Whether you
receive a Performance Bonus for any given fiscal year, and the amount of any such Performance Bonus, will be determined by the Company in its sole discretion, and is based on Company performance and your achievement of objectives and milestones to be determined by the Company for the applicable fiscal year. The Performance Bonus will not be prorated for the fiscal year in which you begin employment or if the Company conducts your review or performance assessment for a period covering less than a full fiscal year. To earn a Performance Bonus, except as otherwise provided herein, you must be employed by the Company on the last day of the applicable fiscal year. Except as otherwise provided herein, you will not be eligible for, and will not earn, any Performance Bonus (including a prorated bonus) if your employment terminates for any reason before the end of the fiscal year. The Company will pay any earned Performance Bonus by no later than thirty (30) days after the end of the Company’s fiscal year, or by May 31.

3. **Equity Incentive.** Subject to the approval of the Board of Directors of Urovant Sciences Ltd. (USL), the company’s parent, you will receive a Stock Option Grant Notice for an option to purchase 69,197 common shares of USL and a Restricted Stock Unit Grant Notice for 108,647 Restricted Stock Units of USL pursuant to the 2017 Equity Incentive Plan, As Amended and Restated, (collectively, “Initial Equity Award”). This Initial Equity Award will be granted on June 2, 2020 and (i) will be subject to a 4-year vesting period, with 25% vesting at year one (1) and quarterly vesting thereafter for twelve (12) successive quarters, as well as any other terms and conditions contained in the grant agreements; and (ii) all stock options will expire and cease to be exercisable on the ten (10) year anniversary of the grant date. Per your Initial Equity Award Grant Notices, all shares received under this Initial Equity Award shall immediately become fully vested and exercisable immediately prior to (and contingent upon) a Change In Control as defined in the 2017 Equity Incentive Plan, Amended and Restated. In addition, any unvested outstanding equity awards, including awards that would otherwise vest only upon satisfaction of performance criteria, shall accelerate and become vested and exercisable immediately prior to (and contingent upon) a Change In Control as defined in the operative Equity Incentive Plan.

You will be eligible to receive additional discretionary annual equity incentive grants in amounts commensurate with your position (“Annual Equity Grants”). The Annual Equity Grants will be based upon meeting Company and individual performance metrics to be mutually agreed upon in writing annually. The Annual Equity Grants (i) will be subject to a 4-year vesting period, with 25% vesting at year one (1) and quarterly vesting thereafter for twelve (12) successive quarters, as well as any other terms and conditions contained in the grant agreements; and (ii) all stock options will expire and cease to be exercisable on the ten (10) year anniversary of the grant date. All shares received under the Annual Equity Grants shall immediately become fully vested and exercisable immediately prior to (and contingent upon) a Change In Control as defined in the operative Equity Incentive Plan, Amended and Restated. In addition, any unvested outstanding equity awards, including awards that would otherwise vest only upon satisfaction of performance criteria, shall accelerate and become vested and exercisable immediately prior to (and contingent upon) a Change In Control as defined in the operative Equity Incentive Plan.
4. **Sign On Bonus.**

You are eligible to receive a $150,000.00 sign on bonus, less taxes and deductions, paid in two installments as follows: the first installment of $75,000.00 will be paid in June 2021; the second installment of $75,000.00 will be paid in June 2022. You must be employed at the time of the sign on bonus installment payments to receive the sign on bonus installment payments and, should you voluntarily leave the Company within two years of your last installment payment, you agree to repay the most recent installment amount. Should your employment end for good reason or in the event of a change in control, any unpaid portion of your sign on bonus will be paid to you upon your termination.

5. **Relocation.** You are eligible to receive business travel reimbursement, per our travel and expense policy, to Irvine, California and other areas as deemed necessary for business related activities. You are also eligible for up to one year from your start date to receive relocation assistance in the amount of $75,000, less taxes and deductions, to assist you in the purchase of a property in Orange County, California. This payment will be made to you upon verification that you have purchased a residence in Orange County, California within one year from your start date. We will also reimburse you for any non-recurring expenses as a result of your home purchase and the Company will cover the costs on the shipment of your household goods to your new residence. Upon the purchase of a residence in Orange County, California the Company will no longer reimburse you for expenses for travel to Orange County, California from Illinois.

6. **Executive Vacation.** We believe that you are in the best position to determine when to work and when to take time away from work, while still responsibly performing your duties and responsibilities. Consequently, instead of providing you with a fixed number of vacation days each year, you may take time off with pay for rest and relaxation, or to attend to personal matters at your discretion, subject to fulfilling performance expectations and coordinating time off with our CEO.

7. **Standard Company Benefits.** You shall be entitled to participate in all other employee benefit programs for which you are eligible under the terms and conditions of the benefit plans that may be in effect from time to time and provided by the Company to its employees. These benefits include health, dental, and other insurance coverage, participation in the Company’s 401(k) plan, and holiday and sick leave. Insurance coverage will begin on the first day of the first full month after your employment begins. The official plan documents will control. The Company reserves the right to cancel or change the benefit plans or programs it offers to its employees at any time in its discretion.

8. **At-Will Employment.** Your employment relationship is at-will. The Company may modify your job title, compensation, duties, and other terms and conditions of employment as it deems necessary and appropriate in light of the Company’s needs and interests from time to time. Additionally, either you or the Company may terminate the employment relationship at any time, with or without cause or advance notice. Upon termination of your employment for any reason, you shall resign from all positions and terminate any relationships as an employee, advisor, officer, or director with the Company and any of its affiliates, each effective on the date of termination. Upon the termination of your employment for any reason, you shall be entitled to receive: (a) any earned but unpaid Base Salary; (b) any vested employee benefits in
accordance with the terms of the applicable employee benefit plan or program; (c) any unreimbursed business expenses incurred in accordance with Company policy; and (d) any earned but unpaid Performance Bonus for any performance years that were completed as of the date of termination. In addition, you may be eligible to receive additional payments and benefits, as set forth in more detail below.


9.1 Termination Without Cause or Resignation for Good Reason During the Change in Control Determination Period. In the event your employment with the Company is terminated by the Company without Cause, or you resign for Good Reason, in either event during the Change in Control Determination Period, then provided such termination constitutes a “separation from service” (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a “Separation from Service”), and provided that you remain in compliance with the terms of this Agreement, the Confidentiality Agreement, the Arbitration Agreement, and any other agreement between you and the Company, the Company shall provide you with the following Change in Control Severance Benefits:

   a. The Company shall pay you, as severance, the equivalent of 100% of your Base Salary in effect as of the date of your employment termination and disregarding for this purpose any decrease in annual base salary constituting Good Reason, subject to standard payroll deductions and withholdings (the “CIC Salary Severance”). The CIC Salary Severance will be paid as one-time, lump-sum payment no later than the first regularly-scheduled payroll date following the sixtieth (60th) day after your Separation from Service, provided the Separation Agreement (as discussed in Section 6.5) has become effective.

   b. The Company shall pay you, as additional severance, an amount equal to the sum of (i) 100% of your target annual Performance Bonus for the year of termination; and (ii) a pro rata target annual Performance Bonus for the year of termination, calculated by multiplying your target Performance Bonus amount as of the date of termination by a fraction, the numerator of which is the number of days worked in the performance year and the denominator of which is 365 (the “CIC Bonus Severance”). The CIC Bonus Severance will be paid as a one-time, lump-sum payment contemporaneously with the CIC Salary Severance, but in no event later than the first regularly-scheduled payroll date following the sixtieth (60th) day after your Separation from Service, provided the Separation Agreement (as discussed in Section 6.5) has become effective.

   c. If you timely elect continued group health plan continuation coverage under COBRA or a state or local equivalent, such as Cal-COBRA, the Company shall pay the full amount of your premiums on behalf of you for your continued coverage under the Company’s group health plans, including coverage for your eligible dependents, for 9 months or until such earlier date on which you become eligible for health coverage from another employer (the “COBRA CIC Payment Period”). The level of coverage will be the same (if possible) as the level of coverage selected by you and in effect at the time of your termination. Upon the conclusion of such period of insurance premium payments made by the Company, you will be responsible for the entire payment of premiums (or payment for the cost of coverage) required under COBRA for the duration of your eligible COBRA coverage period. Notwithstanding the
foresgoing, if you timely elect continued group health plan continuation coverage under COBRA and at any time thereafter 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 (including, without limitation, Section 2716 of the Public Health Service Act) or
violating Section 105(h) of the Code, then in lieu of paying the employer portion of the COBRA premiums on your behalf, the
Company will instead pay you on the last day of each remaining month of the COBRA CIC Payment Period a fully taxable cash
equal to 200% of the COBRA premium for that month, subject to applicable tax withholding (such amount, the “Special
CIC Severance Payments”). Such Special CIC Severance Payments shall end upon expiration of the COBRA CIC Payment
Period.

9.2 Termination Without Cause or Resignation for Good Reason Not During the Change in Control Determination Period.
In the event your employment with the Company is terminated by the Company without Cause, or you
resign for Good Reason, in either event not during the Change in Control Determination Period, then provided such termination
constitutes a Separation from Service, and provided that you remain in compliance with the terms of this Agreement, the
Confidentiality Agreement, the Arbitration Agreement, and any other agreement between you and the Company, the Company
shall provide you with the following Non-CIC Severance Benefits:

a. The Company shall pay you, as severance, the equivalent of 75% of your Base Salary in effect as of
the date of your employment termination and disregarding for this purpose any decrease in annual base salary constituting Good
Reason, subject to standard payroll deductions and withholdings (the “Non-CIC Salary Severance”). The Non-CIC Salary
Severance will be paid as one-time, lump-sum payment no later than the first regularly-scheduled payroll date following the
sixtieth (60th) day after your Separation from Service, provided the Separation Agreement (as discussed in Section 6.5) has
become effective.

b. The Company shall pay you, as additional severance, an amount equal to a pro rata target annual
Performance Bonus for the year of termination, calculated by multiplying your target bonus as of the date of termination by a
fraction, the numerator of which is the number of days worked in the performance year and the denominator of which is 365 (the
“Non-CIC Bonus Severance”). The Non-CIC Bonus Severance will be paid as a one-time, lump-sum payment
contemporaneously with the Non-CIC Salary Severance, but in no event later than the first regularly-scheduled payroll date
following the sixtieth (60th) day after your Separation from Service, provided the Separation Agreement (as discussed in Section
6.5) has become effective.

c. If you timely elect continued group health plan continuation coverage under COBRA, or a state or
local equivalent, such as Cal-COBRA, the Company shall pay a portion of your premiums on behalf of you for your continued
coverage under the Company’s group health plans, including coverage for your eligible dependents, for nine (9) months or until
such earlier date on which you become eligible for health coverage from another employer (the “COBRA Payment
Period”). The amount of this portion will be the same portion of the premium cost as was borne by the Company under the level
of coverage selected by you and in effect at the time of your termination. Upon the conclusion of such period of insurance
premium payments made by the Company, you will be responsible for the entire payment of premiums (or payment for the cost
of coverage) required under COBRA for the duration of your eligible
COBRA coverage period. Notwithstanding the foregoing, if you timely elect continued group health plan continuation coverage under COBRA and at any time thereafter 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 (including, without limitation, Section 2716 of the Public Health Service Act) or violating Section 105(h) of the Code, then in lieu of paying the employer portion of the COBRA premiums on your behalf, the Company will instead pay you on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to 200% of the employer’s portion of the COBRA premium for that month, subject to applicable tax withholding (such amount, the “Special Severance Payments”). Such Special Severance Payments shall end upon expiration of the COBRA Payment Period.

9.3 Termination as a Result of Death or Disability.

a. In the event that your employment is terminated as a result of your Disability, you will be eligible to receive the Non-CIC Bonus Severance, provided the Separation Agreement (as discussed in Section 6.5) has become effective.

b. In the event that your employment is terminated as a result of your death, you will not be eligible to receive any Severance Benefits pursuant to this Agreement.

9.4 Termination for Cause; Resignation Without Good Reason. If you resign without Good Reason or the Company terminates your employment for Cause, whether during the Change of Control Determination Period or not, then: (a) all payments of compensation by the Company to you hereunder will terminate immediately (except as to amounts already earned), and; (b) you will not be entitled to any Severance Benefits under this Section 6.

9.5 Conditions to Receipt of Severance Benefits. The receipt of any applicable Severance Benefits pursuant to this Section 6 will be subject to you signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the “Separation Agreement”). You shall also resign from all positions and terminate any relationships as an employee, advisor, officer or director with the Company and any of its affiliates, each effective on the date of termination. No Severance Benefits will be paid or provided until the Separation Agreement becomes effective.

9.6 Definitions.

a. Cause. For purposes of this Agreement, “Cause” for termination shall mean: (i) the continued failure by you to substantially perform your duties with the Company or any Subsidiary or Affiliate (other than any such failure resulting from incapacity due to physical or mental illness), after a written demand for substantial performance is delivered to you by the Company, or Subsidiary or Affiliate, that specifically identifies the alleged manner in which you have not substantially performed your duties and after you have been provided with a thirty (30) day cure period, or your deliberate violation of a Company policy; (ii) the engaging by you in illegal conduct or misconduct (including fraud, embezzlement, theft or dishonesty or material violation of any Company policy), or gross negligence, in any case that has caused or is reasonably expected to result in injury to the Company or any Subsidiary or Affiliate; (iii) your
commission of, or plea of no contest to, a felony or any misdemeanor crime involving fraud, moral turpitude or dishonesty; (iv) your material breach of any written agreement or restrictive covenants with the Company or (v) violation of any law, rule or regulation (collectively, “Law”) relating in any way to the business or activities of the Company or any Subsidiary or Affiliate, or other Law that is violated, during the course of your performance of services hereunder that results in your 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 or any Subsidiary or Affiliate intends to develop its activities.

b. **Change in Control.** For purposes of this Agreement, “Change in Control” means the occurrence after the Effective Date of this Agreement of a “Change in Control” as defined in the Urovant Sciences Ltd. 2017 Equity Incentive Plan, as Amended and Restated, as in effect on the Effective Date of this Agreement.

c. **Change in Control Determination Period.** For purposes of this Agreement, “Change in Control Determination Period” means the time period beginning on the date on which a Change in Control occurs and ending twelve (12) months following the Change in Control.

d. **Disability.** For purposes of this Agreement, “Disability” means total and permanent disability as defined in Section 22(e)(3) of the Internal Revenue Code of 1986, as amended.

e. **Good Reason.** For purposes of this Agreement, “Good Reason” for your resignation shall mean: (i) a material diminution in your Base Salary as compared to below that Base Salary as set as of the time of the reduction; 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) a material diminution in your authority, duties, or responsibilities; (iii) any requirement of the Company that you be based anywhere more than fifty (50) miles from your primary office location and in a new office location that is a greater distance from your principal residence; or (iv) the failure of any successor to expressly assume and agree to perform the severance provisions in this Agreement. Notwithstanding the foregoing, a termination for Good Reason shall not have occurred unless you give written notice to the Company of your intention to terminate employment within thirty (30) days after the occurrence of the event constituting Good Reason, specifying in reasonable detail the circumstances constituting Good Reason, and the Company has failed within thirty (30) days after receipt of such notice to cure the circumstances constituting Good Reason and you terminate employment on a mutually-agreeable date not more than thirty (30) days following the expiration of the Company’s cure period.

10. **Section 280G.** Any provision of the Plan to the contrary notwithstanding, if any payment or benefit a Covered Employee would receive from the Company and its Subsidiaries or an acquiror pursuant to the Plan or otherwise (a “Payment”) would (i) constitute a “parachute payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code
Excise Tax”), then such Payment will be equal to the Higher Amount (defined below). The “Higher Amount” will be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Covered Employee’s receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting “parachute payments” is necessary so that the Payment equals the Higher Amount, reduction will occur in the manner that results in the greatest economic benefit for a Covered Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata. Notwithstanding the foregoing, any reduction shall comply with Section 409A including, but not limited to, the ordering of any such reduction. In no event will the Company, any Subsidiary or any stockholder be liable to any Covered Employee for any amounts not paid as a result of the operation of this Section 7. The Company will use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Covered Employee and the Company within fifteen (15) calendar days after the date on which the Covered Employee’s right to a Payment is triggered (if requested at that time by the Covered Employee or the Company) or such other time as requested by the Covered Employee or the Company.

11. Section 409A. It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Code Section 409A provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent no so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), your right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if you are deemed by the Company at the time of your Separation from Service to be a “specified employee” for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon Separation from Service set forth herein and/or under any other agreement with the Company are deemed to be “deferred compensation,” then to the extent delayed commencement of any portion of such payments is required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to you prior to the earliest of (i) the expiration of the six-month period measured from the date of your Separation from Service with the Company, (ii) the date of your death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Paragraph shall be paid in a lump sum to you, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be
12. **Proprietary Information Obligations.** As a condition of employment, you shall execute and abide by the Company’s standard form of Agreement for Protection of Company Information (the “Confidentiality Agreement”), attached as Exhibit A. You acknowledge and agree that any prior assignments of intellectual property made by you to the Company in any separate or prior agreement remain in full force and effect.

13. **Arbitration Obligations.** As a condition of employment, you shall execute and abide by the Company’s standard form of Mutual Agreement to Arbitrate Claims (the “Arbitration Agreement”), attached as Exhibit B.

14. **Outside Activities During Employment.**

14.1 **Non-Company Business.** Except with the prior written consent of our CEO, you will not during the term of your employment with the Company undertake or engage in any other employment, occupation or business enterprise, other than ones in which you are a passive investor. You may engage in civic and not-for-profit activities so long as such activities do not materially interfere with the performance of your duties hereunder.

14.2 **No Adverse Interests.** You agree not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise.

15. **General Provisions.**

15.1 **Offer Conditions.** This Agreement and your continued employment with the Company are conditioned on you accepting and returning a signed copy of this Agreement. This Agreement is also conditioned on: (a) you not being subject to any confidentiality, non-competition, or any other similar type of restriction that may affect your ability to perform your work at the Company; and (b) you not having been debarred, or having 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 US or in any other country where the Company intends to develop its activities. By signing this Agreement, you represent and warrant that you are not subject to any such limitations or restrictions.

15.2 **Severability; Waiver.** Whenever possible, each provision of this Agreement will be interpreted in such a manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision of this Agreement, but this Agreement will be reformed, construed and enforced in such jurisdiction to the extent possible in keeping with the intent of the parties. Any waiver of any breach of any provisions of this Agreement must be in writing to be effective, and it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.
15.3 **Complete Agreement.** This Agreement, together with the Confidentiality Agreement and the Arbitration Agreement, constitutes the entire agreement between you and the Company with regard to this subject matter and is the complete, final, and exclusive embodiment of the Parties’ agreement with regard to this subject matter. This Agreement is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein; supersedes any other such promises, warranties or representations; and it cannot be modified or amended except in a writing signed by a duly authorized officer of the Company.

15.4 **Counterparts; Headings.** This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement. The headings of the paragraphs hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

15.5 **Successors and Assigns.** This Agreement is intended to bind and inure to the benefit of and be enforceable by you and the Company, and their respective successors, assigns, heirs, executors and administrators. The Company may freely assign this Agreement, without your prior written consent. You may not assign any of your duties hereunder and you may not assign any of your rights hereunder without the written consent of the Company.

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

15.7 **Term; Survival; Choice of Law.** This Agreement shall terminate upon your termination of employment with the Company. The obligations as forth under Sections 6, 7, 8, 9, and 11, as well as under the Confidentiality Agreement and the Arbitration Agreement, will survive the termination of your employment and this Agreement. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California.
IN WITNESS WHEREOF, the Parties have executed this Agreement on the day and year first written above.

UROVANT SCIENCES, INC.

By:  
Name: Nori Ebersole  
Title: Chief Human Resources Officer

EXECUTIVE

C. Walt Johnston

Date: ______________________

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**Exhibit A**

**Form of Agreement for Protection of Company Information**

In exchange for the opportunity for employment or continued employment with Urovant Sciences, Inc. and any related entities (collectively, the “Company”), because the Company has provided and will continue to actively provide me with confidential information as a result of such employment, and/or for other valuable consideration, I, the undersigned employee, agree to the following:

1. **Obligations to Prior Employers.** I agree that I will not bring and have not brought to the Company any trade secrets that belong to any prior employers of mine, and I will not use or disclose and have not used or disclosed any trade secrets of any prior employer of mine in performing work for the Company. I further agree that I will not violate and have not violated any valid contractual commitments I have made with any prior employer in connection with my work for the Company.

2. **Loyalty to the Company.** I understand that I must devote my undivided loyalty and best efforts to the business of the Company. As a result, during my employment, I will not, other than for the Company, engage in any other employment, activity, or business: (i) in which the Company is now or may hereafter become engaged; (ii) that directly competes with the current or future business of the Company; (iii) that uses any Company information, equipment, supplies, facilities or materials; or (iv) otherwise conflicts with or is detrimental to the Company’s business interests or causes, or may reasonably be expected to cause a disruption of its operations.

3. **Confidential Information of This Company.** I hereby acknowledge that during my employment with the Company, the Company has provided and will actively provide me access to certain confidential and/or proprietary information regarding the Company and its business (collectively, “Confidential Information”) that is not generally known outside of the Company and that would not otherwise be provided to me without my execution of this Agreement. Confidential Information includes, without limitation, the following materials and information (whether or not reduced to writing and whether or not patentable or protected by copyright): trade secrets; inventions; processes; formulae; programs; technical data; financial information; Company-developed software; engineering designs and documentation; customer proposals, specifications, requirements, as well as marketing and advertising plans and strategies; customer identities, lists, and confidential information about customers and their buying habits; confidential information about prospects, suppliers, vendors, and key employees; personal information relating to the Company’s employees; mailing and e-mail lists; and any other confidential or proprietary information relating to the Company’s business. I understand that the Confidential Information has economic value because it is not generally known to the public or to other persons who can obtain economic value from its disclosure or use and I further understand that the Company expends considerable efforts to maintain the secrecy of the Confidential Information. I understand and agree that I am authorized to access and use Confidential Information solely for Company business and that I am not authorized to access any
computer systems containing Confidential Information except in furtherance of the Company’s business.

4. **No Misappropriation.** During the term of my employment and thereafter, I hereby promise not to disclose or use, or induce or assist in the disclosure or use of, any Confidential Information except for the benefit of the Company. In addition, at no time after the end of my employment with the Company will I seek to obtain or misappropriate, or induce or assist in the obtaining or misappropriation, any of the Company’s trade secrets or other Confidential Information from any current or former Company employee, independent contractor, consultant, or any other source. Notwithstanding the confidentiality obligations set forth in this paragraph, I understand that, pursuant to the Defend Trade Secrets Act of 2016 (“DTSA”), I will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. I also understand that if I file a lawsuit for retaliation by the Company for reporting a suspected violation of law, I may disclose the trade secret to my attorney and use the trade secret information in the court proceeding, if I (A) file any document containing the trade secret under seal; and (B) do not disclose the trade secret, except pursuant to court order. I further understand that if a court of law or arbitrator determines that I misappropriated Company trade secrets willfully or maliciously, including by making permitted disclosures without following the requirements of the DTSA as detailed in this paragraph, then the Company may be entitled to an award of exemplary damages and attorneys' fees.

5. **Return of Property and Confidential Information.** I agree not to remove any Company property or Confidential Information from Company premises without express written permission, and I agree to return all Company property and Confidential Information, in any form, at the time my employment with the Company ends for any reason or upon the earlier request of the Company. To the extent that I possess any Confidential Information in digital or other electronic form, I will work with the Company to secure said Confidential Information in accordance with the Company’s direction. Upon the request of the Company, I will execute a document confirming my agreement to honor my responsibilities contained in this Agreement after my departure.

6. **Agreement Not to Solicit Employees.** I further agree that, during my employment with the Company, and for a period of one (1) year after the end of my employment relationship with the Company for any reason, I will not, directly or indirectly, either on my own behalf or on behalf of any other person or entity, attempt to employ, solicit for employment, or otherwise seek to employ or retain any employee or consultant of the Company, or in any way assist or facilitate any such employment, solicitation, or retention effort.

7. **Assignment of Intellectual Property.**

   (a) “Intellectual Property” means any idea, concept, design, suggestion, discovery, invention, copyright, patent, trademark, trade secret, or other intellectual property of any nature, including computer graphics, programs, and/or algorithms, processes, diagrams, know-how,
drawings, notes, memoranda, digital representations, illustrations, videos, photographs, and/or pictorial representations of any nature. “Inventions” means all discoveries, developments, designs, improvements, formulas, and processes.

(b) I agree to identify all Intellectual Property and Inventions, as defined above, of mine that existed prior to my employment with the Company within fourteen (14) days after beginning my employment by completing and returning Exhibit 1 hereto. I understand and agree that if I do not identify my Intellectual Property and Inventions within the 14-day period, all such Intellectual Property and Inventions will not be reserved and will be considered part of my background training and experience that I am providing to the Company as consideration for its employment of me. I have also received and understand the Limited Exclusion Notification attached as Exhibit 2 hereto.

(c) I acknowledge and agree that all works that I may create for or author during the period of my employment with the Company which relate or are useful to the business, or demonstrably anticipated business of the Company, whether or not created during my working time, are within the scope of my employment relationship with the Company and are works for hire, and that the Company owns all rights in such works of authorship. To the extent that such works of authorship are not works for hire, I hereby assign them to the Company as set out in subparagraph (e), below.

(d) I will fully and promptly disclose to the Company, and I hereby assign to the Company as set out in subparagraph (e), below, any and all Intellectual Property that is related or useful to the business, or demonstrably anticipated future business, of the Company which I may solely or jointly conceive, design, develop, create, or suggest or cause to be conceived, designed, developed, created, or suggested during my employment with the Company, whether or not conceived, designed, developed, created, or suggested during my working time. However, the foregoing sentence will not apply to any Invention that qualifies fully under the provisions of California Labor Code § 2870, where I developed the Invention entirely on my own time without using the Company’s equipment, supplies, facilities, or trade secret information, except for those Inventions that (i) relate at the time of their conception or reduction to practice to the Company’s business, or to actual or demonstrably anticipated research or development of the Company; or (ii) result from any work performed by me for the Company.

(e) Any works of authorship referred to in subparagraph (c), above, and any Intellectual Property referred to in subparagraph (d), above (except to the extent excluded from the scope of subparagraph (d) by virtue of the statute referenced therein), are referred to as “Company-Related Intellectual Property.” All right, title, and interest in and to the Company-Related Intellectual Property, including any renewal and extension rights, shall be the sole and absolute property of the Company. I agree that, without additional consideration or compensation of any kind, I will assign and I hereby do assign to the Company all my right, title, and interest in and to any Company-Related Intellectual Property now or hereafter existing and all renewal and extension rights, and I agree to execute any documents necessary to evidence the Company’s proprietary interest in any Company-Related Intellectual Property. I acknowledge and agree that new rights to the results and proceeds of my services may come into being in the future under law and/or in equity, and I hereby assign, grant, and convey to the Company any and all such rights, renewals, and extensions thereof in and to such results and proceeds. In the event the
Company is unable for any reason whatsoever to secure my signature to any lawful and necessary document required to apply for protection of, or enforce any action with respect to, Company-Related Intellectual Property, I hereby irrevocably designate and appoint the Company and its duly-authorized officers and agents as my agent and attorney-in-fact to act for and in my behalf to execute such documents and to do all other lawfully permitted acts to protect the Company’s interest in any Company-Related Intellectual Property with the same legal force and effect as if executed by me.

(f) I will not knowingly do anything to imperil the validity of any intellectual property rights of the Company, and will not do or omit to do any act which may invalidate any application for the same or in any way publish or cause to be published any material relating to Company-Related Intellectual Property.

8. Complete Agreement. This agreement constitutes the complete agreement between the Company and me relating to the subject matter of it and supersedes any and all prior written or oral agreements or understanding relating to the subject matter of this agreement. I understand that no representative of the Company has been authorized to enter into any agreement or commitment with me which is inconsistent in any way with the terms of this agreement. I also understand and agree that this agreement does not in any way change the at-will nature of my employment relationship with the Company. This Agreement may not be modified except in a writing signed by the party to be bound.

9. Governing Law. This agreement will be governed by the law of the state of California.

10. Severability. The invalidity or nonenforceability of any part of this agreement does not affect the validity or enforceability of any other part. If any part of this agreement is for any reason held to be excessively broad as to time, duration, activity or subject, it shall be construed by limiting and reducing it so as to be enforceable.

11. Successors. I understand and agree that this agreement is binding upon my heirs, executors, administrators and other personal and legal representatives of mine.

12. Voluntary Agreement. I understand that this agreement includes obligations in addition to those obligations which may be imposed or implied by law, and I certify that I have read, understand and voluntarily agree to and undertake the obligations set forth in this agreement. I agree that it is not necessary for the Company to sign this agreement for it to be binding on me.

Employee Signature: __________________________
Employee Printed Name: C. Walt Johnston
Dated: __________________________
EXHIBIT 1

Identification of Intellectual Property and Inventions

If no response is provided to any of the requests below, this will mean that your response to that item is “none.”

1. Please identify and describe any Intellectual Property (as defined in paragraph 8(a), above), which you have developed or in which you have some ownership interest:

2. Please describe any Inventions (as defined in paragraph 10(a), above), which you have developed or in which you have some ownership interest:

Employee Signature: ________________________________

Employee Printed Name: C. Walt Johnston

Dated: ________________________________

1.
Exhibit 2
Limited Exclusion Notification

This is to notify you in accordance with Section 2872 of the California Labor Code that the foregoing Agreement between you and Company does not require you to assign or offer to assign to Company any Invention that you develop entirely on your own time without using Company’s equipment, supplies, facilities or trade secret information, except for those Inventions that either:

(a) Relate at the time of conception or reduction to practice to Company’s business, or actual or demonstrably anticipated research or development; or

(b) Result from any work performed by you for Company.

To the extent a provision in the foregoing Agreement purports to require you to assign an Invention otherwise excluded from the preceding paragraph, the provision is against the public policy of this state and is unenforceable.

This limited exclusion does not apply to any patent or Invention covered by a contract between Company and the United States or any of its agencies requiring full title to such patent or Invention to be in the United States.
Exhibit B

Form of Mutual Agreement to Arbitrate Claims

Urovant Sciences, Inc. (the “Company”) and I, the undersigned employee, recognize and desire the benefits of a speedy, impartial, final and binding dispute resolution procedure. For these reasons, and in consideration of the mutual promises in this agreement to arbitrate (“Agreement”) and benefits of our employment relationship, the Company and I mutually consent to the resolution by arbitration of all claims or controversies (“claims”), past, present or future, whether or not arising out of my employment (or its termination), as stated below.

1. Arbitrable Claims. Arbitrable claims are those that the Company (or its subsidiaries and affiliates) may have against me or that I (and no other party) may have against any of the following: (1) the Company, (2) its officers, directors, employees or agents in their capacity as such or otherwise, (3) its parent, subsidiary and affiliated entities, (4) benefit plans or the plans’ sponsors, fiduciaries, administrators, affiliates and agents, and/or (5) all successors and assigns of any of them. The only claims that are arbitrable are those that could be brought under applicable state or federal law and which lawfully can be the subject of an agreement to arbitrate. Arbitrable claims include, but are not limited to: claims for wages, bonuses, or other compensation due; claims for breach of any contract or covenant (express or implied); tort claims; claims for discrimination (including, but not limited to, race, sex, sexual orientation, religion, national origin, age, marital status, military or veterans status, physical or mental disability or handicap, or medical condition), harassment or retaliation; claims for benefits (except claims under an employee benefit or pension plan that either specifies that its claims procedure shall culminate in an arbitration procedure different from this one, or is underwritten by a commercial insurer which decides claims); and claims for violation of any federal, state, or other governmental law, statute, regulation, or ordinance, except claims for: workers’ compensation or unemployment compensation benefits; claims covered by (and defined in the Franken Amendment, first enacted in Section 8116 of the Defense Appropriations Act of 2010, or any similar statute, regulation or executive order. Both the Company and I agree that neither of us shall initiate or prosecute any lawsuit in any way related to any claim covered by this Agreement, other than to seek temporary equitable relief in aid of arbitration where such relief is available by law. I understand that nothing in this Agreement prohibits me from filing a complaint, charge, or other communication with any administrative or other governmental agency.

2. Law Governing this Agreement. The Federal Arbitration Act shall govern the interpretation, enforcement and all proceedings pursuant to this Agreement. To the extent that the Federal Arbitration Act is inapplicable, or held not to require arbitration of a particular claim or claims, the arbitration law of the state in which I work or last worked for the Company shall apply.

3. Arbitration Provider and Rules. The arbitration will be conducted through Judicial Arbitration & Mediation Services (JAMS). The arbitration shall take place in the county (or comparable government unit) in which I am or was last employed by the Company, and no dispute affecting my rights or responsibilities shall be adjudicated in any other venue or forum. The arbitration will be conducted in accordance with the then-current JAMS Employment Arbitration Rules & Procedures (and no other JAMS rules), which currently are available at
I understand that the Company will provide me a written copy of those rules upon my request. The arbitrator shall be either a retired judge, or an attorney who is experienced in employment law and licensed to practice law in the state in which the arbitration is convened (the “Arbitrator”), selected as provided by the JAMS rules. If a JAMS arbitrator is not available to conduct an arbitration in the location where the arbitration is to occur, then another arbitration service provider will be selected by mutual agreement of the parties (and all references to JAMS will be deemed to be references to that arbitration service provider). If the parties cannot agree on an alternative arbitration service provider, the court upon petition or motion shall designate one. The Arbitrator shall apply the substantive law (and the law of remedies, if applicable) of the state in which the claim arose, or federal law, or both, as applicable to the claim(s) asserted. The Arbitrator is without jurisdiction to apply any different substantive law or law of remedies. The Arbitrator has the authority to hear and rule on dispositive motions (such as motions for summary adjudication or summary judgment). The Federal Rules of Evidence shall apply. The Arbitrator shall render an award and written opinion, which shall include the factual and legal basis for the award, normally within 30 days after a dispositive motion is heard, or an arbitration hearing (including any post-hearing briefing) is completed.

4. **Arbitration Costs and Fees.** The Company will be responsible for paying any filing fee and the fees and costs of the Arbitrator; provided, however, that if I am the party initiating the claim, in the first instance, I will contribute an amount equal to the filing fee to initiate a claim in the court of general jurisdiction in the state in which I am (or was last) employed by the Company, unless the JAMS rules or the Arbitrator allow me to proceed without doing so based on demonstrated financial hardship. Each party shall pay its own litigation costs and attorneys’ fees, if any. However, if any party prevails on a statutory claim which affords the prevailing party attorneys’ fees and litigation costs, or if there is a written agreement providing for attorneys’ fees and/or litigation costs, the Arbitrator shall rule upon a motion for attorneys’ fees and/or litigation costs under the same standards a court would apply under the law applicable to the claim(s) at issue.

5. **Procedure for Asserting Claims.** The party asserting the claim must give written notice of any claim to the other party no later than the expiration of the statute of limitations (deadline for filing) that the law prescribes for the claim. Otherwise, the claim shall be deemed waived. I understand that the party asserting the claim is encouraged to give written notice of any claim as soon as possible after the event or events in dispute so that arbitration of any differences may take place promptly. Written notice to the Company, or its officers, directors, employees or agents, shall be sent to the Company’s then-current headquarters address, c/o SVP, Head of Human Resources. I will be given written notice at the last address recorded in my personnel file. The written notice shall identify and describe the nature of all claims asserted, the facts upon which such claims are based and the relief or remedy sought. The notice shall be sent to the other party by certified or registered mail, return receipt requested.

6. **Discovery.** Each party shall have the right to take depositions of three fact witnesses and any expert witness designated by another party. Each party also shall have the right to make requests for production of documents consisting of up to 25 individual categories of requested documents in total to any party, and to subpoena documents from third parties. Requests for additional depositions or discovery may be made to the Arbitrator selected pursuant to this Agreement. The Arbitrator may grant such additional discovery if the Arbitrator finds that the party has demonstrated that it needs that discovery to adequately arbitrate the claim, taking into
account the parties’ mutual desire to have a speedy, less-formal, and cost-effective dispute-resolution mechanism.

7. **Individual Dispute Resolution.** To the maximum extent permitted by law, I hereby waive any right to bring on behalf of persons other than myself, or to otherwise participate with other persons in, any class, collective, or representative action (including but not limited to any representative action under the California Private Attorneys General Act (“PAGA”), or other federal, state or local statute or ordinance of similar effect). I understand, however, that to the maximum extent permitted by law I retain the right to bring claims in arbitration, including PAGA claims, for myself as an individual (and only for myself). If a court adjudicating a case involving the Company and me were to determine that there is an unwaivable right to bring a PAGA representative action, any such representative action shall be brought only in court, and not in arbitration.

8. **Finality.** The decision of the Arbitrator will be final, conclusive and binding on the parties to the arbitration, except as provided by law. Judgment may be entered on the Arbitrator’s decision in any court having jurisdiction.

9. **Complete Agreement.** This is the complete agreement between the Company and me on the subject hereof; provided, however, that if for any reason this Agreement is held unenforceable, then any prior agreement to arbitrate between the Company and me shall survive. No party is relying on any representations, oral or written, on the subject of the effect, enforceability or meaning of this Agreement, except as specifically set forth in this Agreement. This Agreement shall survive the termination of my employment and the expiration of any benefit plan.

10. **Company Bound.** I understand that, by the act of presenting this Agreement to me, the Company has agreed to bind itself to (and is entitled to invoke) this Agreement upon my execution of it, without need for a signature on its part.

11. **Severability.** If any provision of this Agreement is adjudged to be void or otherwise unenforceable, in whole or in part, such adjudication shall not affect the validity of the remainder of the Agreement. All other provisions shall remain in full force and effect based upon the mutual intent of the Company and me to create a binding agreement to arbitrate any disputes between us.

I UNDERSTAND THAT I AM GIVING UP MY RIGHT TO A JURY TRIAL. I FURTHER ACKNOWLEDGE THAT I HAVE BEEN GIVEN THE OPPORTUNITY TO DISCUSS THIS AGREEMENT WITH MY PRIVATE LEGAL COUNSEL AND HAVE AVAILED MYSELF OF THAT OPPORTUNITY TO THE EXTENT I WISHED TO DO SO.

Employee Signature
________________________

Date
________________________

C. Walt Johnston
Printed Name
<table>
<thead>
<tr>
<th>Subsidiary</th>
<th>Jurisdiction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urovant Sciences, Inc.</td>
<td>Delaware</td>
</tr>
<tr>
<td>Urovant Treasury Holdings, Inc.</td>
<td>Delaware</td>
</tr>
<tr>
<td>Urovant Sciences Treasury, Inc.</td>
<td>Delaware</td>
</tr>
<tr>
<td>Urovant Holdings Limited</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Urovant Sciences GmbH</td>
<td>Switzerland</td>
</tr>
</tbody>
</table>
We consent to the incorporation by reference in the following the Registration Statements:

(1) Registration Statement (Form S-8 No. 333-227593) pertaining to the Urovant Sciences Ltd. 2017 Equity Incentive Plan, as amended and restated,
(2) Registration Statement (Form S-8 No. 333-228386) pertaining to the Urovant Sciences Ltd. 2017 Equity Incentive Plan, as amended and restated,
(3) Registration Statement (Form S-3 No. 333-234620) of Urovant Sciences Ltd., and
(4) Registration Statement (Form S-8 No. 333-234621) pertaining to the Urovant Sciences Ltd. 2017 Equity Incentive Plan, as amended and restated and the Urovant Sciences Ltd. 2019 Employee Stock Purchase Plan;

of our report dated June 19, 2020, with respect to the consolidated financial statements of Urovant Sciences Ltd. included in this Annual Report (Form 10-K) of Urovant Sciences Ltd. for the year ended March 31, 2020.

/s/ Ernst & Young LLP

Irvine, California
June 19, 2020
I, James Robinson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Urovant Sciences Ltd.;

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

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

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: June 19, 2020

By: /s/ James Robinson
James Robinson
Principal Executive Officer
CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ajay Bansal, certify that:

1. I have reviewed this Annual Report on Form 10-K of Urovant Sciences Ltd.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: June 19, 2020

By: /s/ Ajay Bansal
   Ajay Bansal
   Principal Financial Officer
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Urovant Sciences Ltd. (the “Company”) for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, James Robinson, Principal Executive Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and 18 U.S.C. Section 1350, that to the best of his knowledge:

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

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

Date: June 19, 2020

By: /s/ James Robinson
James Robinson
Principal Executive Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Urovant Sciences Ltd. (the “Company”) for the period ended March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Ajay Bansal, Principal Financial Officer of the Company, hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and 18 U.S.C. Section 1350, that to the best of his knowledge:

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

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

Date: June 19, 2020

By: /s/ Ajay Bansal
    Ajay Bansal
    Principal Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.