Table of Contents

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

FORM 10-K

(Mark One)

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

For the fiscal year ended 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 001-37929

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

Bermuda	**98-1343578**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Suite 1, 3rd Floor **11-12 St. James's Square** **London** **SW1Y 4LB** **United Kingdom**	**Not Applicable**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **44 (207) 400-3351**

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

Title of each Class	Trading Symbol	Name of each exchange on which registered
Common Shares, $0.000017727 par value per share	MYOV	New York Stock Exchange

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 o 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 o No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No o

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (§ 15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of 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 $245.2 million based on the last reported sale price of the registrant's common shares as reported on the New York Stock Exchange on September 30, 2019 of $5.20 per common share. Common shares held by Roivant Sciences Ltd., our former majority shareholder, and each officer and director have been excluded in that such persons, on such dates, may have been deemed to be affiliates. This determination of affiliate status is not a conclusive determination for other purposes.

The number of the registrant's common shares, $0.000017727 par value per share, outstanding on May 14, 2020, was 89,869,374.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2020 Annual General Meeting of Shareholders (the "2020 Proxy Statement") to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by

reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

MYOVANT SCIENCES LTD.

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED MARCH 31, 2020

TABLE OF CONTENTS

PART I.

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, (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would" or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements.

The forward-looking statements appearing in several 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:

- the impact of pandemics, epidemics or outbreaks of infectious diseases, including the effect that the COVID-19 pandemic and related "shelter-in-place" orders and other measures will have on our business operations, financial conditions and results of operations;
- the success and anticipated timing of our clinical studies for relugolix combination therapy (relugolix 40 mg, plus estradiol 1.0 mg and norethindrone acetate 0.5 mg), relugolix 120 mg as a monotherapy, and MVT-602;
- the anticipated start dates, durations and completion dates of our ongoing and future nonclinical and clinical studies;
- the anticipated designs of our future clinical studies;
- the anticipated future regulatory submissions and the timing of, and our ability to, obtain and maintain regulatory approvals for relugolix combination tablet, relugolix monotherapy tablet, MVT-602 and any future product candidates;
- our ability to successfully plan for and commercialize relugolix combination tablet and relugolix monotherapy tablet, if approved;
- our ability to achieve commercial sales of any approved products, whether alone or in collaboration with others;
- our ability to obtain coverage for our products if commercialized;
- the rate and degree of market acceptance and clinical utility of any approved products;
- our ability to initiate and continue relationships with third-party clinical research organizations and manufacturers;
- our ability to quickly and efficiently identify and develop new product candidates;
- our ability to hire and retain our key scientific and management personnel;
- our ability to obtain, maintain and enforce intellectual property rights for our product candidates;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, access to capital, prospects, growth and strategies;
- our ability to continue to fund our operations with the cash, cash equivalents, and marketable securities currently on hand, including our expectations for how long these capital resources will enable us to fund our operations;
- our ability to draw under the Loan Agreement with Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma");
- our ability to raise additional capital;
- industry trends;
- developments and projections relating to our competitors or our industry; and
- the success of competing drugs that are or may become available.

Such 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 identified herein, particularly in the section titled "Risk Factors" set forth in Part I. Item 1A. of this Annual Report on Form 10-K, and in our other filings with the United States Securities and Exchange Commission ("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.

All brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective owners. Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Myovant," the "Company," "we," "us," and "our" refer to Myovant Sciences Ltd. and its wholly-owned subsidiaries.

Item 1. Business

Overview

We are a healthcare company focused on redefining care for women and for men. Our lead product candidate is relugolix, a once-daily, oral, gonadotropin-releasing hormone ("GnRH") receptor antagonist for which we have successfully completed multiple Phase 3 clinical studies across three distinct indications. We are preparing for potential commercial launches in the U.S. of relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) for women with heavy menstrual bleeding associated with uterine fibroids or pain associated with endometriosis and relugolix monotherapy tablet (120 mg) for men with advanced prostate cancer, in anticipation of U.S. Food and Drug Administration ("FDA") approval to market in these indications. We submitted our New Drug Application ("NDA") to the FDA for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer in April 2020, and currently expect to submit our NDA to the FDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids in May 2020. We announced positive results from the first of two replicate Phase 3 clinical studies evaluating relugolix combination therapy in women with pain associated with endometriosis, and expect to announce top-line results from the second study in the second quarter of calendar year 2020. In addition, we are developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG ("Takeda"), a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, granted us a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive right to develop and commercialize MVT-602 in all countries worldwide. On March 30, 2020, we entered into an exclusive license agreement with Gedeon Richter Plc. ("Richter") for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside of the U.S. Under this agreement, we have retained all of our rights to relugolix combination tablet in the U.S. and Canada, as well as rights to relugolix in other therapeutic areas outside of women's health. In March 2020, we submitted a Marketing Authorisation Application ("MAA") to the European Medicines Agency ("EMA") for relugolix combination tablet in uterine fibroids. The MAA submission has completed validation and is now under evaluation by the EMA.

Since our inception, we have devoted substantially all of our efforts to identifying and in-licensing our product candidates, organizing and staffing our company, raising capital, preparing for and advancing the clinical development of our product candidates and preparing for potential future regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet.

On December 27, 2019, Sumitovant BioPharma Ltd. ("Sumitovant"), a subsidiary of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma"), became our majority shareholder and a related party after acquiring approximately 50.2% of our common shares outstanding on December 27, 2019. These common shares were acquired from our former majority shareholder, Roivant Sciences Ltd. ("Roivant," "RSL," or "former majority shareholder") at the closing of a transaction between Roivant and Sumitomo Dainippon Pharma. As of March 31, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own approximately 52.1% of our outstanding common shares. As a result of the transfer of these common shares, Roivant no longer beneficially owns any of our common shares.

Our Strategy

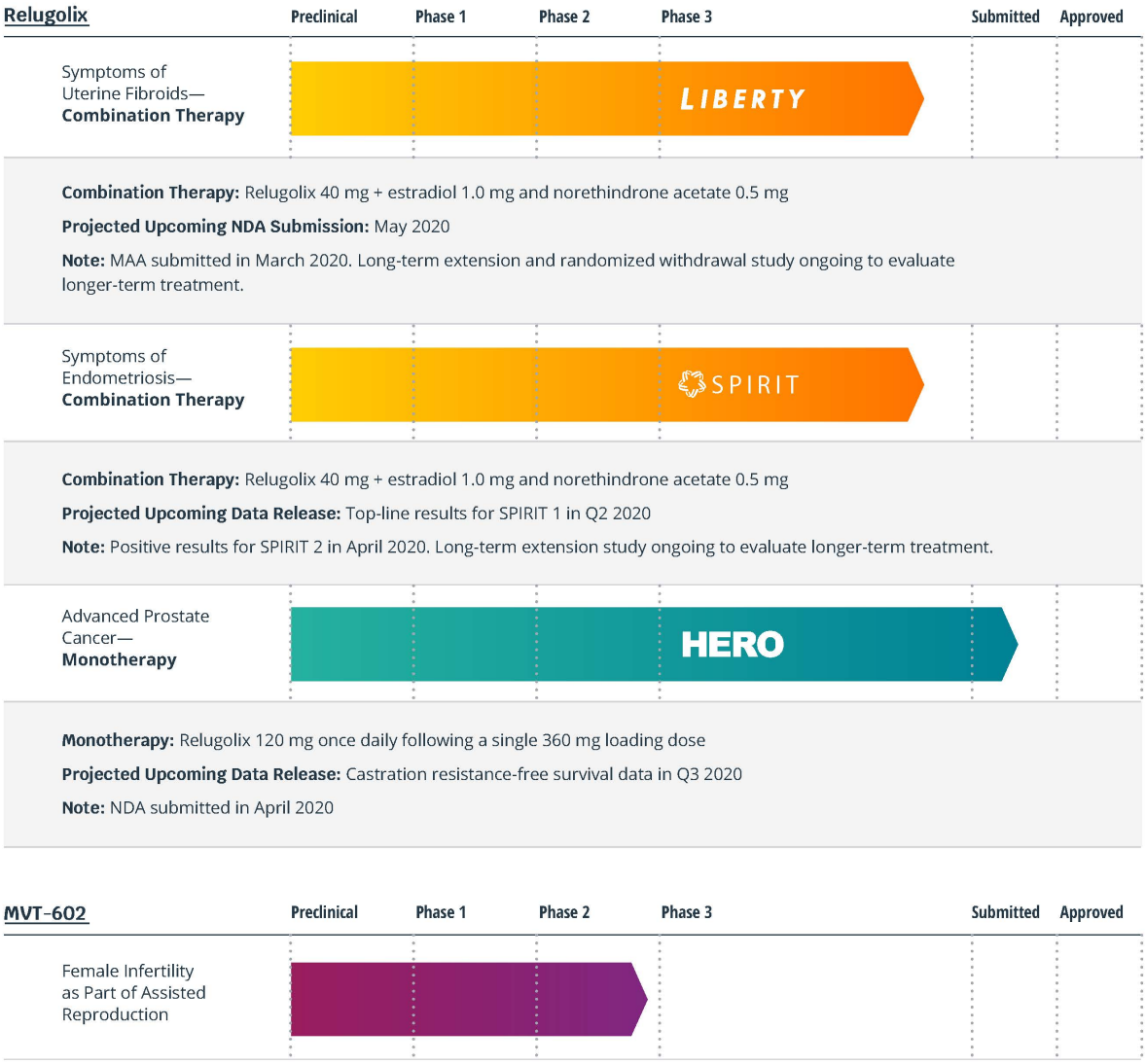
We aspire to be the leading healthcare company focused on redefining care for women and for men. The key elements of our strategy include the following:

- rapidly advance clinical development and submit regulatory filings and prepare for potential commercialization of relugolix monotherapy tablet for advanced prostate cancer;

- rapidly advance clinical development and submit regulatory filings and prepare for potential commercialization of relugolix combination tablet for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis;
- expand the clinical development of relugolix for additional potential indications;
- maximize the commercial potential of our product candidates;
- advance clinical development of MVT-602; and
- acquire or in-license additional clinical- or commercial-stage product candidates for the treatment of women's health diseases or prostate cancer in a capital-efficient manner.

Our Product Candidates

The following table summarizes the status of our relugolix and MVT-602 clinical programs and is followed by detailed descriptions of each program:



Relugolix

We are currently developing relugolix in three indications: heavy menstrual bleeding associated with uterine fibroids; pain associated with endometriosis; and advanced prostate cancer. Relugolix is an oral, once-daily, small molecule that acts as a GnRH

receptor antagonist that binds to and inhibits GnRH receptors in the anterior pituitary gland. Inhibition of GnRH receptors decreases the release of gonadotropins (luteinizing hormone ("LH") and follicle-stimulating hormone ("FSH")), thereby decreasing the downstream production of estrogen and progesterone by the ovaries in women and testosterone by the testes in men.

As a GnRH receptor antagonist, relugolix has a clinically-validated mechanism of action in each of our three targeted indications. The direct and rapid action of relugolix on the pituitary-gonadal axis is distinct from approved luteinizing hormone-releasing hormone ("LHRH") agonists which are administered as depot injections and result in an initial surge in levels of gonadotropins, and estrogen and progesterone or testosterone, before resulting in pituitary desensitization and a fall in hormone levels over weeks. Approved LHRH agonist injections such as leuprolide acetate are used in women to treat the symptoms of uterine fibroids and endometriosis, but the adoption and duration of use is limited due to bone mineral density loss and vasomotor symptoms.

We are developing relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) administered orally once-daily, with the goal of optimizing estradiol levels to achieve the long-term benefit of relugolix on symptoms of uterine fibroids and endometriosis, while maintaining bone health and mitigating side effects from a low-estrogen state, such as vasomotor symptoms. We have successfully completed a bioequivalence study, which demonstrated the bioequivalence of our relugolix combination tablet with relugolix combination therapy, the co-administered regimen used in the LIBERTY and SPIRIT clinical programs (one relugolix 40 mg tablet plus one tablet containing estradiol 1.0 mg and norethindrone acetate 0.5 mg). We expect to launch in the women's health indications with our single-tablet regimen.

Lowering estrogen and progesterone levels has been demonstrated, including in our two replicate Phase 3 studies, to effectively decrease heavy menstrual bleeding and pain in women with uterine fibroids. Similarly, relugolix combination therapy has been demonstrated in the first of our two replicate Phase 3 studies to reduce pelvic pain associated with endometriosis. Relugolix combination therapy achieved these results while maintaining a generally well-tolerated safety profile. We believe our combination approach has the potential to have a better safety and tolerability profile than the currently approved LHRH agonist therapies and has the potential to be used longer-term. We further believe our single tablet combination approach also has certain benefits over other oral GnRH antagonist therapies that are currently approved or in development. The goal of our relugolix combination tablet is to provide women with uterine fibroids and endometriosis a once-daily oral medical alternative to hysterectomy and other invasive procedures often recommended to treat these conditions that is suitable for long-term use.

Decreasing testosterone slows the growth and progression of advanced prostate cancer, such as when the disease recurs or the prostate-specific antigen ("PSA") is rising following prostatectomy or radiation therapy, when the disease progresses locally in the prostate bed, or when it becomes metastatic. We demonstrated in our Phase 3 HERO program that relugolix can achieve sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks in 96.7% of patients with a once-daily oral treatment. Relugolix was compared to the standard-of-care leuprolide injections in the HERO study and demonstrated superiority to leuprolide in the cumulative proportion of patients achieving sustained testosterone suppression (96.7% vs 88.0%). Data from this study are the basis for the NDA submission for relugolix in advanced prostate cancer. We are developing a distinct therapeutic candidate, relugolix monotherapy (120 mg), for men with advanced prostate cancer which, if approved, we expect to commercialize as a separately branded product from our relugolix combination tablet.

Uterine Fibroids

Uterine fibroids are noncancerous tumors that develop in or on the muscular walls of the uterus and are among the most common reproductive tract tumors in women. In addition to an individual's genetic predisposition, estrogens are well known to play an important role in the regulation of fibroid growth. Although uterine fibroids are benign tumors, they can cause debilitating symptoms such as abnormal uterine bleeding, heavy or painful periods, anemia, abdominal pain, backache, increased abdominal girth and bloating, urinary frequency or retention, constipation or painful defecation, pregnancy loss, painful intercourse and, in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations in normal activities of daily living, and social embarrassment. For most women, uterine fibroids and associated symptoms resolve at menopause when estrogen and progesterone levels fall.

We estimate that over 25% of women of reproductive age in the U.S., or approximately 19 million women, have uterine fibroids. Of those, approximately five million women are estimated to experience symptoms of uterine fibroids, approximately three million of whom are inadequately treated by current medical therapy and require further treatment.

The current approach to treating uterine fibroids includes both medical and surgical options. The recommended treatment for a given patient is dependent on factors such as the patient's desire to become pregnant in the future, the importance of uterine preservation, symptom severity, and tumor characteristics. Medical options include oral contraceptives, tranexamic acid, and LHRH agonists. The current standard of care for the treatment of patients with mild symptoms includes the use of oral or other hormonal contraceptives or nonsteroidal anti-inflammatory drugs ("NSAIDs"), which are generally prescribed at the time of initial diagnosis. These therapeutic options, however, often do not provide sufficient relief to the many patients with more moderate-to-severe symptoms. These women require additional treatment to relieve excessive bleeding and pain. Tranexamic acid, an antifibrinolytic agent, is approved for use to treat heavy menstrual bleeding. LHRH agonists are used for short-term therapy and

may involve low-dose estradiol and progestin hormonal combination therapy to mitigate the side effect of bone mineral density loss and reduce vasomotor symptoms generally associated with LHRH agonists. Other invasive procedures such as endometrial ablation and uterine artery embolization may also be tried. Surgical intervention, such as myomectomy or hysterectomy, are often used to treat the heavy bleeding and symptoms associated with uterine fibroids; however, these procedures may result in post-operative complications, complications with future pregnancy, or, as is the case in hysterectomies, preclude the potential for future pregnancies. Even if a future pregnancy is not desired, many women prefer to avoid surgical intervention. However, heavy menstrual bleeding associated with uterine fibroids is a leading cause of hysterectomy, resulting in approximately 250,000 hysterectomies per year in the U.S. alone.

Our Phase 3 Program for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids

We initiated a Phase 3 clinical program in January 2017, evaluating relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids. The program consisted of two multinational, replicate pivotal clinical studies, which we refer to as LIBERTY 1 and LIBERTY 2. Women in the LIBERTY 1 and LIBERTY 2 studies underwent a screening period requiring up to two menstrual cycles to document heavy menstrual bleeding and were randomized in a 1:1:1 ratio to one of three groups. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once-daily monotherapy for 12 weeks followed by relugolix combination therapy once-daily for an additional 12 weeks, or placebo once-daily for 24 weeks.

We enrolled 388 women in LIBERTY 1 and 382 women in LIBERTY 2. To be enrolled, women must have had a monthly menstrual blood loss volume of at least 80 mL in two consecutive cycles or 160 mL in one cycle, measured by the alkaline hematin method, a quantitative measure of menstrual blood loss from an assessment of collected menstrual products.

Eligible women who completed the LIBERTY 1 or LIBERTY 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women receive relugolix combination therapy for an additional 28-week period for a total treatment period of 52 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment. Upon completion of this 52-week total treatment period, eligible women could elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy, and to evaluate the need for maintenance therapy. We are also conducting a one-year observational study of bone mineral density in women with uterine fibroids or endometriosis to provide additional context for our phase 3 clinical programs.

The primary efficacy endpoint for LIBERTY 1 and LIBERTY 2 was the proportion of all women enrolled who achieved a menstrual blood loss volume of less than 80 mL and at least a 50% reduction in menstrual blood loss volume from baseline during the last 35 days of the 24-week treatment period as measured by the alkaline hematin method. The secondary endpoints included the proportion of women who achieved amenorrhea (defined as no or negligible blood loss) during the last 35 days of treatment, reduction in pelvic pain, reduction in fibroid volume, reduction in uterine volume, percent change from baseline to week 24 in menstrual blood loss, increase in hemoglobin, and an assessment of the impact of therapy on quality-of-life. Safety, including bone mineral density changes as measured by dual-energy x-ray absorptiometry (“DXA”), was also assessed.

On May 14, 2019 and July 23, 2019, we announced top-line results for the LIBERTY 1 and LIBERTY 2 studies, respectively. In addition, on July 23, 2019, we announced that a separate clinical study of relugolix combination tablet met all required and pre-specified FDA criteria for bioequivalence, providing data necessary to include the one tablet, once-daily dosing regimen of relugolix combination tablet in the NDA submission for approval of the treatment for uterine fibroids. In December 2019, we successfully completed one-year stability studies, which are required for FDA approval of relugolix combination tablet. On February 10, 2020, we announced positive safety and efficacy data from the Phase 3 LIBERTY long-term extension study with an 87.7% response rate and, on average, an 89.9% reduction in menstrual blood loss from baseline.

On March 9, 2020, we announced the submission of a MAA to the EMA for relugolix combination tablet for the treatment of women with moderate to severe symptoms associated with uterine fibroids. The application has completed validation and is now under evaluation by the EMA. We currently expect to submit an NDA to the FDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids in May 2020.

LIBERTY 1

On May 14, 2019, we announced that LIBERTY 1, the first of two Phase 3 studies evaluating once-daily relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids, met its primary efficacy endpoint and six key secondary endpoints. Relugolix combination therapy maintained bone mineral density at levels comparable to placebo over 24 weeks and was generally well tolerated.

In the primary endpoint analysis, 73.4% of women receiving once-daily oral relugolix combination therapy achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50 percent or greater reduction from baseline in menstrual blood loss volume during the last 35 days of the 24-week treatment period measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline, a clinically relevant secondary endpoint.

Bone mineral density was comparable between the relugolix combination therapy and placebo groups. The distribution of the change in bone mineral density, including outliers, was similar for the relugolix combination therapy and placebo groups at 24 weeks, as assessed by DXA.

The 24-week study achieved six key secondary endpoints with statistical significance compared to placebo, including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

The overall incidence of adverse events in the relugolix combination therapy and placebo groups was comparable (62% vs. 66%). In the relugolix combination therapy group, 5% of women discontinued treatment early due to adverse events compared with 4% in the placebo group. The only adverse event in the relugolix combination therapy arm occurring in at least 10% of women and more frequently than in the placebo arm was hot flash (11% versus 8%). There were no pregnancies in the relugolix combination therapy group and one in the placebo group. There were two serious adverse events related to the study drug: one fibroid expulsion and one for pelvic pain.

LIBERTY 2

On July 23, 2019, we announced that LIBERTY 2, the second of two Phase 3 studies evaluating once-daily relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids, met its primary efficacy endpoint and the same six key secondary endpoints as were achieved in LIBERTY 1. Also as observed in LIBERTY 1, relugolix combination therapy maintained bone mineral density at levels comparable to placebo over 24 weeks and was generally well tolerated.

In the primary endpoint analysis, 71.2% of women receiving once-daily oral relugolix combination therapy achieved the responder criteria compared with 14.7% of women receiving placebo ($p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of treatment measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced a highly significant 84.3% reduction in menstrual blood loss from baseline to week 24 ($p < 0.0001$). In addition, a significantly greater proportion of women suffering from moderate-to-severe pain from uterine fibroids at baseline experienced no pain or minimal pain during the last 35 days of treatment with relugolix combination therapy compared with women on placebo ($p < 0.0001$).

Changes in bone mineral density were comparable between the relugolix combination therapy and placebo groups at the end of treatment. The distribution of the change in bone mineral density, including outliers, was similar for the relugolix combination therapy and placebo groups at 24 weeks, as assessed by DXA.

The 24-week study achieved six key secondary endpoints with statistical significance compared to placebo including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and a reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

The overall incidence of adverse events in the relugolix combination therapy and placebo groups was comparable (60.3% vs. 58.9%). In the relugolix combination therapy group, 1.6% of women discontinued treatment early due to adverse events compared with 4.7% in the placebo group. There were no adverse events in the relugolix combination therapy group reported by at least 10% of women and more frequently than in the placebo group. The incidence of hot flashes in the relugolix combination therapy group was similar to placebo (5.6% versus 3.9%). There were no pregnancies in the relugolix combination therapy group and one in the placebo group.

LIBERTY Long-Term Extension Study

On February 10, 2020, we announced positive safety and efficacy data from the Phase 3 LIBERTY long-term extension study of once-daily, oral relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids.

In the primary endpoint analysis, 87.7% of women achieved the responder criteria defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of treatment measured using the alkaline hematin method. The primary endpoint result in the Phase 3 LIBERTY long-term extension study was consistent with LIBERTY 1 and LIBERTY 2, demonstrating a durability of response through one year. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline at one year.

Changes in bone mineral density through one year, as assessed by DXA every three months, demonstrated maintenance of bone density and were consistent with those in LIBERTY 1 and LIBERTY 2. The adverse events over one year were consistent with those observed in LIBERTY 1 and LIBERTY 2, with no new safety signals. Adverse events reported in more than 10% of women treated with relugolix combination therapy for one-year and more frequently than those reported in the placebo group after 6 months included only hot flashes. There were no pregnancies reported in the relugolix combination therapy group.

Endometriosis

Endometriosis is an estrogen-dependent, inflammatory disease in which tissue that normally lines the uterus is found outside the uterine cavity. Endometriosis lesions commonly appear in the lower abdomen or pelvis or on ovaries, the bladder, or the colon. During the menstrual cycle, the lesions grow, differentiate, and shed into the abdomen, thereby inducing a cascade of inflammatory events. The symptoms associated with endometriosis can include painful periods and chronic pelvic pain, painful ovulation, pain during or after sexual intercourse, heavy bleeding, fatigue, and infertility. Endometriosis can also impact general physical, mental, and social well-being.

Endometriosis affects an estimated 10% of women during their reproductive years and, in the U.S., can take approximately 7-10 years from the onset of symptoms to accurately diagnose, often leading to unnecessary or inappropriate treatment. We estimate that approximately 6 million women in the U.S. suffer from symptomatic endometriosis, 1.2 million of whom are inadequately treated by oral contraceptives and require additional treatment.

Similar to uterine fibroids, lowering estrogen levels has been shown to reduce pain associated with endometriosis, and there are a variety of medical and surgical treatments available. Initial treatment usually involves over-the-counter pain medications, including NSAIDs, because pain is the primary symptom. Hormonal contraceptives are also commonly used. In more severe cases, LHRH agonists such as leuprolide are used for short-term treatment and may involve hormonal add-back therapy with an estrogen and/or a progestin. The FDA has approved Lupaneta Pack (leuprolide administered with norethindrone acetate (5 mg)) to treat pain associated with endometriosis while lowering the side effect of bone mineral density loss and reducing vasomotor symptoms. For many patients, surgical intervention, typically laparoscopy with ablation of endometriotic lesions, is ultimately undertaken to relieve pain, and opioid medications are frequently needed to control pain both before and after surgery. After treatment with hormonal therapy or laparoscopic procedures, recurrence of endometriosis and related symptoms is common, resulting in repeated procedures for many women. In addition, approximately 100,000 endometriosis-related hysterectomies are performed each year in the U.S., although hysterectomy is not a cure for endometriosis and pain associated with endometriosis will not necessarily subside following hysterectomy.

Our Phase 3 Program for the Treatment of Pain Associated with Endometriosis

We initiated a Phase 3 clinical program in June 2017, evaluating relugolix combination therapy in women with pain associated with endometriosis. The program consists of two multinational, replicate pivotal clinical studies, which we refer to as SPIRIT 1 and SPIRIT 2. Each study randomized women 1:1:1 to one of three treatment arms. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once-daily monotherapy for 12 weeks followed by relugolix combination therapy once-daily for an additional 12 weeks, or placebo once-daily for 24 weeks.

We completed patient recruitment into SPIRIT 2 in August 2019 and SPIRIT 1 in October 2019 and the enrollment of 623 and 638 patients in the SPIRIT 2 and SPIRIT 1 studies, respectively. To be enrolled, women must have had a surgical diagnosis of endometriosis in the last 10 years and moderate-to-severe dysmenorrhea (menstrual pelvic pain) and nonmenstrual pelvic pain.

Eligible women who completed the SPIRIT 1 or SPIRIT 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women receive relugolix combination therapy for an additional 80-week period, resulting in a total treatment period of up to 104 weeks, designed to evaluate the safety and sustained efficacy of longer-term treatment.

The co-primary efficacy endpoints for the SPIRIT 1 and SPIRIT 2 studies are the proportion of all women enrolled with reductions in both dysmenorrhea and nonmenstrual pelvic pain, as assessed by an endometriosis-specific patient questionnaire based on the Numerical Rating Scale (“NRS”) completed daily on an electronic patient diary, with no increase in background pain medication. The NRS is an 11-point scale with 0 representing “no pain” and 10 representing “the worst pain you can imagine.” Secondary endpoints include additional questionnaires assessing functional changes associated with endometriosis-specific pain and quality of life, and the use of pain medications to treat endometriosis, including opioid medications. Safety, including bone mineral density changes as measured by DXA, is assessed.

On April 22, 2020, we announced top-line results from the SPIRIT 2 study. We expect to report top-line results from the SPIRIT 1 study in the second quarter of calendar year 2020.

SPIRIT 2

On April 22, 2020, we announced that SPIRIT 2, the first of two Phase 3 studies evaluating once-daily relugolix combination therapy in women with pain associated with endometriosis, met its co-primary efficacy endpoints and six key secondary endpoints.

In addition, relugolix combination therapy was generally well-tolerated including minimal bone mineral density loss over 24 weeks.

In the co-primary endpoint analysis of SPIRIT 2, 75.2% of women receiving once-daily oral relugolix combination therapy achieved a clinically meaningful reduction in dysmenorrhea versus 30.4% of women in the placebo group ($p < 0.0001$). For nonmenstrual pelvic pain, relugolix combination therapy achieved a clinically meaningful reduction in 66.0% of women versus 42.6% of women in the placebo group ($p < 0.0001$). On average, women receiving relugolix combination therapy had a 75.1% reduction on the 11-point (0 to 10) NRS for dysmenorrhea from 7.2 (severe pain) to 1.7 (mild pain).

Six key secondary endpoints measured at Week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the Endometriosis Health Profile-30 (EHP-30) pain domain, a greater proportion of women not using opioids (all p-values < 0.0001), changes in nonmenstrual pelvic pain ($p = 0.0012$), and dyspareunia (painful intercourse) ($p = 0.0489$). An endpoint evaluating change in analgesic use did not achieve statistical significance.

Relugolix combination therapy was generally well-tolerated with minimal bone mineral density loss over 24 weeks. The overall incidence of adverse events in the relugolix combination therapy and placebo groups was similar (80.6% vs. 75.0%). In the relugolix combination therapy group, 5.3% of women discontinued treatment early due to adverse events versus 3.9% in the placebo group. The most frequently reported adverse events, reported in at least 10% of women in the relugolix combination therapy group, were headache, nasopharyngitis, and hot flashes. There were three pregnancies in the relugolix combination therapy group and five in the placebo group.

Bioequivalence Study of Relugolix Combination Therapy and Relugolix Combination Tablet

On July 23, 2019, we announced that a separate clinical study of our relugolix combination tablet met all required and pre-specified criteria for bioequivalence to the two tablets (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) used in our Phase 3 uterine fibroid and endometriosis clinical studies, providing data necessary to include the once-daily dosing regimen of relugolix combination tablet in our NDA and MAA submissions for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis.

Ovulation Inhibition Study

On April 22, 2020, we announced results from an open-label, single-arm ovulation inhibition study consisting of a pre-treatment period to confirm ovulatory status, an 84-day treatment period (three cycles) to assess the effects of relugolix combination therapy on ovulation inhibition, and a post-treatment follow-up period to determine the time to the return of ovulation. Ovulation inhibition was based on the Hoogland-Skouby scale. In this study, relugolix combination therapy achieved 100% ovulation inhibition in 67 healthy women with no women ovulating during the 84-day treatment period, as evaluated by the Hoogland-Skouby assessment scale (score < 5). Furthermore, 100% of women resumed ovulation or menses upon discontinuation of treatment with an average time to ovulation of 23.5 days.

Advanced Prostate Cancer

Prostate cancer is the second most prevalent form of cancer in men and the second leading cause of death due to cancer in men in the U.S. Approximately 3 million men diagnosed with prostate cancer are alive in the U.S., and approximately 190,000 men are newly diagnosed each year, according to the National Cancer Institute. Men with prostate cancer are often asymptomatic at the earliest stages of disease and prostate cancer is generally understood to be slow to progress, leading to a median age at diagnosis of 66 years and a five-year survival rate of 98%.

If prostate cancer is diagnosed at a stage where it is confined to the prostate gland and immediate surroundings, it is generally treated by surgical removal of the prostate gland (prostatectomy) or with radiation. Often, these procedures are successful in curing men of their disease. Men whose disease progresses after prostatectomy or radiation are said to have advanced prostate cancer. Advanced prostate cancer is defined as any of the following: PSA biochemical relapse following primary surgical or radiation therapy of curative intent; newly diagnosed metastatic prostate cancer; or advanced localized disease for which immediate radiation or surgical therapy is not indicated.

First-line treatment for advanced prostate cancer typically involves treatment with androgen deprivation therapies (“ADT”), which are therapies that substantially reduce testosterone. This is because androgens, such as testosterone, promote the growth of cancerous prostate cells by binding to and activating the androgen receptor which, once activated, stimulates prostate cancer cell growth. ADT consisting of either medical castration or surgical castration (removal of the testes which produce testosterone) can be successful in delaying prostate cancer progression. As prostate cancer progresses, men remain on ADT while other therapies are added, typically until death.

The most commonly prescribed ADTs are LHRH agonists, such as long-acting leuprolide depot injections. LHRH agonists initially stimulate a testosterone surge, but with chronic stimulation of the LHRH receptors, the pituitary gland desensitizes and luteinizing hormone decreases with a resultant reduction in testosterone three to four weeks after the initiation of therapy. The initial stimulation of testosterone can cause an initial worsening of symptoms, or clinical flare. LHRH agonists are often given as depot formulations, requiring injections every month, three months or six months, and testosterone may remain suppressed for weeks and months after cessation of therapy.

Our Phase 3 Program for the Treatment of Advanced Prostate Cancer

We initiated a Phase 3 clinical study in March 2017, evaluating the safety and efficacy of relugolix monotherapy in men with advanced prostate cancer, which we refer to as the HERO study. The HERO study randomized 934 men with advanced prostate cancer who required ADT, in a 2:1 ratio to treatment with either oral relugolix 120 mg once-daily (after a single oral loading dose of 360 mg) or a depot injection of leuprolide (per national or regional product label) for a period of at least 48 weeks. Based on FDA discussions, we believe that we will be required to conduct only one Phase 3 study with a single relugolix arm to gain approval for relugolix in men with advanced prostate cancer in the U.S. Nonetheless, we designed the study to include a second arm with leuprolide to demonstrate that treatment with relugolix is noninferior to leuprolide in achieving sustained suppression of testosterone to castrate levels over 48 weeks, an outcome expected to be required for approval in other major markets such as Europe and Japan.

We enrolled 934 men in the HERO study for the primary endpoint analysis. To be enrolled, men must have had advanced prostate cancer that required ADT for at least 48 weeks and included prostate cancer defined as biochemical or clinical relapse, advanced localized disease or newly diagnosed metastatic disease. Screening PSA was > 2.0 ng/mL and serum testosterone levels within the normal range. We filed an amendment to the HERO study protocol to enroll 139 additional men with metastatic prostate cancer and to add the secondary objective of demonstrating that relugolix can delay the time to progression to the lethal state of the disease, castration-resistant prostate cancer, as compared to leuprolide, that completed enrollment in July 2019. We believe that relugolix, a direct GnRH receptor antagonist, has the potential to delay the time to castration-resistant disease as compared with leuprolide, a LHRH agonist, because relugolix more rapidly suppresses testosterone and PSA and more fully suppresses FSH than leuprolide. We currently expect to report additional data from the HERO study measuring castration resistance-free survival in the cohort of 434 men with metastatic prostate cancer, comprising 295 men from the original HERO study and the additional cohort of 139 men, in the third quarter of calendar year 2020. We may conduct additional clinical studies to further support the commercial potential of relugolix in prostate cancer in the U.S. and other major markets.

The primary efficacy endpoint for HERO accepted by the FDA was testosterone suppression (< 50 ng/dL) from week 5, day 1 through week 48, day 7. Relugolix monotherapy was required to demonstrate that the lower bound of the 2-sided 95% confidence interval for the percent of patients achieving testosterone suppression through 48 weeks was at least 90%. Testosterone suppression is an approvable endpoint in the U.S. and several hormonal therapies have been approved based on this endpoint. The secondary endpoints included rapid suppression of testosterone at Day 4 and Day 15, profound suppression of testosterone at Day 15, rapid suppression of PSA at Day 15, and suppression of FSH at Week 24. Testosterone recovery was also evaluated in a subset of men eligible to discontinue ADT at the completion for the 48-week study treatment.

On November 19, 2019, we announced that the Phase 3 HERO study evaluating the safety and efficacy of once-daily, oral relugolix monotherapy over 48 weeks in 934 men with advanced prostate cancer met its primary efficacy endpoint with 96.7% (95% CI: 94.9%, 97.9%) of men achieving sustained testosterone suppression to castrate levels. The study also met all tested key secondary endpoints, while demonstrating 54% fewer major adverse cardiovascular events as compared with leuprolide injections administered every 3 months. The five key secondary endpoints also demonstrated superiority to leuprolide acetate, including rapid suppression of testosterone at Day 4 and Day 15, profound suppression of testosterone at Day 15, rapid suppression of PSA at Day 15, and suppression of FSH at Week 24 (all p-values < 0.0001). In addition, relugolix demonstrated non-inferiority to leuprolide acetate on sustained testosterone suppression through 48 weeks (96.7% vs. 88.8%, respectively) with a between-group difference of 7.9% (95% CI: 4.1%, 11.8%), the primary endpoint required for regulatory submissions outside of the U.S. Superiority to leuprolide was also achieved as the lower bound of the 95% confidence interval for the between-group difference was greater than 0 (p-value < 0.0001). In addition, the pharmacodynamic results showed no testosterone flare after initiation of relugolix and mean testosterone levels returned to normal levels within 90 days after treatment discontinuation in a subset of 184 patients.

The overall incidence of adverse events in the relugolix and leuprolide acetate groups was comparable (92.9% vs. 93.5%, respectively). In the relugolix group, 3.5% of men discontinued the study early due to adverse events compared with 2.6% of men in the leuprolide acetate group. The most frequently reported adverse events, reported in at least 10% of men in the relugolix group, were hot flashes, fatigue, constipation, diarrhea, and arthralgia (defined as pain in a joint). Major adverse cardiovascular events were reported in 2.9% of men in the relugolix group versus 6.2% of men in the leuprolide acetate group in a prespecified safety analysis. These events included non-fatal myocardial infarction, non-fatal stroke, and all-cause mortality and were not adjudicated.

On April 21, 2020, we announced the submission of an NDA to the FDA for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer. New efficacy and cardiovascular safety data from our HERO study will be presented in an oral presentation at the American Society of Clinical Oncology Virtual Scientific Program on May 29, 2020.

MVT-602

As part of our license agreement with Takeda (the "Takeda License Agreement"), we acquired the worldwide rights to MVT-602, our second product candidate, which previously had been evaluated in over 150 men. MVT-602 is an oligopeptide kisspeptin-1 receptor agonist. Kisspeptin, the ligand, is a naturally occurring peptide that stimulates GnRH release and is required for puberty and maintenance of normal reproductive function, including production of sperm, follicular maturation and ovulation, and production of estrogen and progesterone in women and testosterone in men. MVT-602 is being developed as a potential treatment for female infertility in women as part of assisted reproduction, such as in vitro fertilization ("IVF"). Approximately 1.5 million assisted reproduction cycles are performed each year worldwide. Further, approximately 25% of women suffering from infertility have problems achieving ovulation, including the inability to produce fully matured eggs or the failure to ovulate, most commonly resulting from hormonal dysfunction in the GnRH-luteinizing hormone/follicle-stimulating hormone axis. We believe MVT-602 has the potential to be a safer alternative to human chorionic gonadotropin as a part of assisted reproduction for the treatment of female infertility.

We believe that MVT-602, an analog of the naturally-occurring kisspeptin peptide in humans, may mimic natural physiology by inducing a luteinizing hormone surge during IVF and other assisted reproductive technologies, enhancing the likelihood of successful egg maturation and ovulation at the right time without the serious side effect of ovarian hyperstimulation syndrome ("OHSS"). While assisted reproductive technologies are effective, typically resulting in pregnancy in 20% to 35% of patients, the standard procedure has remained largely unchanged since inception and has potentially serious side effects. The most serious side effect of assisted reproduction is OHSS. Severe OHSS has been reported to occur in up to 2% of the general assisted reproduction population, and in up to 20% of patients at high-risk for developing OHSS, including women with polycystic ovarian syndrome. OHSS is thought to occur as a result of the nonphysiologic elevations in luteinizing hormone that occur as a result of egg maturation triggered with human chorionic gonadotropin and to a lesser extent the GnRH receptor agonists. Symptoms can range from abdominal pain and bloating in milder cases to rapid weight gain, severe abdominal pain, nausea and vomiting, blood clots, decreased urination, kidney failure, and shortness of breath.

By acting upstream in the GnRH-axis to promote the release of physiologically normal levels of key hormones in the assisted reproduction cycle such as luteinizing hormone, kisspeptin agonists, such as MVT-602, may have the potential to trigger egg maturation without causing OHSS. A recently published investigator-sponsored study, where a native kisspeptin peptide (specifically, kisspeptin 54) was used in place of human chorionic gonadotropin as the egg-maturation trigger in the assisted reproduction cycle, showed that none of the 60 high-risk patients developed moderate-to-severe OHSS and resulted in a live birth rate of up to 65.1% at the maximally efficacious dose tested. These results validate the potential use of kisspeptin analogs as an alternative to the standard egg maturation trigger in assisted reproduction protocols. To our knowledge, MVT-602 is the only kisspeptin-1 receptor agonist in clinical development and thus has the potential to become a safe alternative egg-maturation trigger in this space.

In October 2018, we presented data from a Phase 1 study of MVT-602 at the American Society of Reproductive Medicine ("ASRM") Annual Congress. Results of the study showed that administration of MVT-602 in healthy premenopausal women in the follicular phase produced a dose-related increase in LH concentrations and expected effects on FSH and estradiol. A total of 24 women were randomized to one of three MVT-602 dose groups (0.3 µg, 1 µg or 3 µg) and then subsequently randomized within the assigned group to receive a single subcutaneous dose of MVT-602 or placebo in a 3:1 ratio. Results showed that administration of single subcutaneous doses of MVT-602 demonstrated dose-related increases in LH concentrations and expected post-dose increases in FSH and estradiol concentrations, with little effect observed on progesterone as expected. No serious adverse events were reported, and no subject discontinued from the study due to an adverse event. Adverse events were similar between the placebo and MVT-602 groups with no apparent dose-related effects.

Further assessment of the exposure-response profile of MVT-602 was conducted in a Phase 2a study during the pre-ovulatory phase in 75 fertile women following a minimal controlled ovarian stimulation protocol. After ovarian stimulation, women were randomized to one of four MVT-602 dose groups (0.1 µg, 0.3 µg, 1 µg or 3 µg), to triptorelin, 0.2 mg, or to placebo. Top-line results from this Phase 2a study were presented at the European Society of Human Reproduction and Embryology in Vienna, Austria in June 2019. The study demonstrated that MVT-602 was generally well-tolerated and produced the desired LH surge associated with high and dose-dependent rates of ovulation in healthy women following a minimal controlled ovarian stimulation protocol. This study provides information for dose selection for a future study of MVT-602 in infertile women seeking pregnancy.

Our Key Agreements

Takeda Agreements

Takeda License Agreement

On April 29, 2016, we entered into the Takeda License Agreement pursuant to which Takeda granted to us an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize relugolix and MVT-602, and products containing these compounds for all human diseases and conditions. The territory for our exclusive license for relugolix covers all countries worldwide, except that Takeda retains exclusive rights to Japan, China, Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam (including, in each case, the territories and possession of each of the foregoing), which we collectively refer to as the Takeda Territory. Takeda has granted us a nonexclusive license in the Takeda Territory to manufacture relugolix and to conduct development of relugolix for prostate cancer solely for the purpose of developing, manufacturing and commercializing relugolix in our territory. The territory for our exclusive license for MVT-602 covers all countries worldwide. Our license includes a right of reference to regulatory materials related to relugolix and MVT-602 controlled by Takeda. On May 31, 2018, Takeda announced that they entered into a licensing agreement granting ASKA Pharmaceutical Co., Ltd. exclusive commercialization rights for uterine fibroids and exclusive development and commercialization rights for endometriosis in Japan.

Under the Takeda License Agreement, we granted to Takeda an exclusive, royalty-bearing license in the Takeda Territory under certain patents and other intellectual property controlled by us to develop and commercialize relugolix and products containing relugolix for all human diseases and conditions, subject to our nonexclusive rights to conduct development and manufacturing as described above. We also granted to Takeda a nonexclusive license in our territory to manufacture relugolix and MVT-602; and to conduct development of relugolix for uterine fibroids and endometriosis solely for the purpose of developing, manufacturing and commercializing relugolix in the Takeda Territory. Takeda's license includes a right of reference to regulatory materials controlled by us. If Takeda determines not to seek regulatory approval for or to commercialize relugolix in any country in the Takeda Territory, then we have a right of first negotiation to acquire the rights to seek regulatory approval and commercialize relugolix in such country.

We are solely responsible, at our expense, for all activities related to the development of relugolix and MVT-602 in our territory and all activities related to the development of relugolix through the receipt of regulatory approval for prostate cancer in certain countries in the Takeda Territory. Pursuant to the terms of the Takeda License Agreement, we are required to use commercially reasonable efforts to develop and obtain regulatory approval of relugolix for the treatment, prevention, cure or control of symptoms associated with uterine fibroids or endometriosis and MVT-602 in our territory, as well as to develop and obtain regulatory approval of relugolix for prostate cancer in Japan and the U.S. We are solely responsible, at our expense, for all activities related to the commercialization of relugolix and MVT-602 in our territory and must use commercially reasonable efforts to do so in each country in our territory in which we obtain regulatory approval. Takeda is solely responsible, at its expense, for all activities related to the commercialization of relugolix in the Takeda Territory, and must use diligent efforts to commercialize relugolix for prostate cancer in the Takeda Territory following receipt of regulatory approval.

Under the Takeda License Agreement, we will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in our territory, subject to certain agreed reductions. Takeda will pay us a royalty at the same rate as ours on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest to occur of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country. Under the Takeda License Agreement, there was no upfront payment and there are no payments upon the achievement of clinical development or marketing approval milestones. We have also licensed additional patents and patent applications from Takeda directed to other oligopeptides that target the same pathway as MVT-602.

The Takeda License Agreement will expire, on a product-by-product and country-by-country basis, on the expiration of the royalty payment term described above for such product in such country. Either party may terminate the Takeda License Agreement for the other party's uncured material breach, challenge to the patents licensed under the Takeda License Agreement, or insolvency. Takeda may terminate the Takeda License Agreement with respect to a compound if we cease development or commercialization of such compound. We may terminate the agreement at will, in our sole discretion, in its entirety, or with respect to relugolix for prostate cancer or both endometriosis and uterine fibroids, or on a compound by compound basis for all fields, upon prior notice, with the notice period depending on the compound and field to be terminated and the regulatory status at the time that notice of termination is given. We may also terminate the agreement with respect to a compound for safety reasons or lack of commercial viability. If the agreement is terminated in its entirety or with respect to relugolix for prostate cancer, other than for safety reasons or by us for Takeda's uncured material breach, prior to receipt of the first regulatory approval of relugolix for prostate cancer in Japan, then we must either reimburse Takeda for its out of pocket costs and expenses directly incurred in connection with Takeda's completion of the relugolix development for prostate cancer, up to an agreed cap, or complete ourselves the conduct of any clinical

studies of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at our cost and expense. If we reimburse Takeda for such costs, then under certain circumstances we may be later reimbursed by Takeda through a royalty on sales of the terminated relugolix product.

Takeda Supply Agreements

In June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited ("Takeda Limited") entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited supplied us with, and we have obtained from Takeda Limited, all of our requirements for relugolix drug substance and drug product that were used under our development plans for all indications.

On May 30, 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda (the "Takeda Commercial Supply Agreement") pursuant to which Takeda has manufactured and supplied us with relugolix drug substance to support the commercial launch of relugolix, if marketing authorization is granted. Takeda has also assisted with the transfer of technology and manufacturing know-how to a second contract manufacturing organization of our subsidiary, Myovant Sciences GmbH. This second contract manufacturing organization for relugolix drug substance will be included in our regulatory submissions for all potential indications.

The initial term of the Takeda Commercial Supply Agreement began on May 30, 2018 and will continue for five years. At the end of the initial term, the Takeda Commercial Supply Agreement will automatically renew for successive one-year terms, unless either party gives notice of termination to the other at least 12 months prior to the end of the then-current term. The Takeda Commercial Supply Agreement may be terminated by either party upon 90 days' notice of an uncured material breach of its terms by the other party, or immediately upon notice to the other party of a party's bankruptcy. Each party will also have the right to terminate the Takeda Commercial Supply Agreement, in whole or in part, for any reason upon 180 days' prior written notice to the other party, provided that any then-open purchase orders will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase orders thereunder, will terminate immediately upon the termination of the Takeda License Agreement in accordance with its terms.

The Takeda Commercial Supply Agreement also includes customary provisions relating to, among others, delivery, inspection procedures, warranties, quality management, storage, handling and transport, intellectual property, confidentiality and indemnification.

Sumitomo Dainippon Pharma Agreements

Sumitomo Dainippon Pharma Loan Agreement

On December 27, 2019, we and our subsidiary, Myovant Sciences GmbH, entered into a Loan Agreement with Sumitomo Dainippon Pharma (the "Sumitomo Dainippon Pharma Loan Agreement"). Pursuant to the Sumitomo Dainippon Pharma Loan Agreement, Sumitomo Dainippon Pharma agreed to make revolving loans to us in the aggregate principal amount of up to $400.0 million. Funds may be drawn down by us once per calendar quarter, subject to certain terms and conditions, including consent of our board of directors. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of our outstanding common shares, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to us, in which case we would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. Interest is due and payable quarterly, and the outstanding principal amounts are due and payable in full on the five-year anniversary of the closing date of the Sumitomo Dainippon Pharma Loan Agreement. Loans under the Sumitomo Dainippon Pharma Loan Agreement are prepayable at any time without premium or penalty upon 10 business days' prior written notice.

Loans under the Sumitomo Dainippon Pharma Loan Agreement bear interest at a rate per annum equal to the 3-month London Interbank Offered Rate ("LIBOR") plus a margin of 3.0% payable on the last day of each calendar quarter. Our obligations under the Sumitomo Dainippon Pharma Loan Agreement are fully and unconditionally guaranteed by us and our subsidiaries. The loans and other obligations are senior unsecured obligations of us, Myovant Sciences GmbH, and subsidiary guarantees. The Sumitomo Dainippon Pharma Loan Agreement includes customary representations and warranties and affirmative and negative covenants.

The Sumitomo Dainippon Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties, breaches of covenants following any applicable cure period, cross acceleration to certain other debt, failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by us or any of our subsidiaries and certain breaches by us under the Investor Rights Agreement. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Dainippon Pharma may terminate its obligations to make loans to us and declare the principal amount of loans to become immediately due and payable, and Sumitomo Dainippon Pharma may take such other actions as set forth in the Sumitomo Dainippon Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Dainippon Pharma to make loans to us would automatically terminate and the principal amount of the loans would automatically become due and payable. In addition, if it becomes unlawful

for Sumitomo Dainippon Pharma to maintain the loans under the Sumitomo Dainippon Pharma Loan Agreement or within 30 days of a change of control with respect to us, we would be required to repay the outstanding principal amount of the loans.

Investor Rights Agreement

On December 27, 2019, we entered into an Investor Rights Agreement with Sumitomo Dainippon Pharma and Sumitovant (the "Investor Rights Agreement"). Pursuant to the Investor Rights Agreement, among other things, we agreed, at the request of Sumitovant, to register for sale, under the Securities Act of 1933, common shares beneficially owned by Sumitovant, subject to specified conditions and limitations. In addition, we agreed to periodically provide Sumitovant (i) certain financial statements, projections, capitalization summaries and other information and (ii) access to our books, records, facilities and employees during our normal business hours as Sumitovant may reasonably request, subject to specified limitations.

The Investor Rights Agreement also contains certain protections for our minority shareholders for so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially owns more than 50% of our common shares. These protections include: (i) a requirement that Sumitovant vote its shares for the election of independent directors in accordance with the recommendation of our board of directors (the "board") or in the same proportion as the shareholders not affiliated with Sumitovant vote their shares; (ii) a requirement that the audit committee of our board be composed solely of three independent directors; (iii) a requirement that any transaction proposed by Sumitomo Dainippon Pharma or certain of its affiliates that would increase Sumitomo Dainippon Pharma's beneficial ownership to over 60% of the outstanding voting power of us must be approved by our audit committee (if occurring prior to December 27, 2022) and be conditioned on the approval of shareholders not affiliated with Sumitovant approving the transaction by a majority of the common shares held by such shareholders; and (iv) a requirement that any related person transactions between Sumitomo Dainippon Pharma or certain of its affiliates and us must be approved by our audit committee.

Pursuant to the Investor Rights Agreement, we also agreed that at all times that Sumitomo Dainippon Pharma beneficially owns more than 50% of our common shares, Sumitomo Dainippon Pharma, by purchasing common shares in the open market or from us in certain specified circumstances, will have the right to maintain its percentage ownership in our common shares in the event of a financing event or acquisition event conducted by us, or specified other events, subject to specific conditions.

Roivant Sciences Ltd.

As a result of the closing of the Sumitomo Dainippon Pharma-Roivant Agreement, on December 27, 2019 all of our outstanding common shares held directly or indirectly by Roivant and not already held by Sumitovant were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo Dainippon Pharma. As a result of the transfer of these common shares, Roivant no longer beneficially owns any of our common shares. On December 27, 2019, in connection with the closing of the Sumitomo Dainippon Pharma-Roivant Agreement, the then existing Information Sharing and Cooperation Agreement between us and Roivant, the then existing Services Agreements between us and certain of our subsidiaries and Roivant and certain of its subsidiaries, and the then existing Option Agreement between us and Roivant were terminated.

Under the Services Agreements, we paid or reimbursed Roivant or its subsidiaries for expenses it, or third parties acting on their behalf, incurred for us or our subsidiaries. For any general and administrative ("G&A") and research and development ("R&D") activities performed by Roivant or its subsidiaries' employees for the benefit of us, we were charged based on the relative percentage of time utilized on our matters by the respective employee. All other third-party pass-through costs were billed to us at cost. In addition, Roivant previously allocated share-based compensation expense to us based upon the relative percentage of time spent by Roivant and its subsidiaries' employees on our matters.

Development and Commercialization Agreement with Richter

On March 30, 2020, we entered into an exclusive license agreement with Richter for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand. Under the terms of the agreement, we will continue to lead global development of relugolix combination tablet. Richter will be responsible for local clinical development, manufacturing, and all commercialization activities for its territories. We have also agreed to assist Richter in transferring manufacturing technology from our contract manufacturing organizations to Richter to enable Richter to manufacture relugolix combination tablet. If requested by Richter, we have agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to our agreements with our contract manufacturing organizations. We have also granted Richter an option to collaborate on relugolix combination tablet for future indications in women's health other than fertility. We have retained all of our rights to relugolix combination tablet in the U.S. and Canada, as well as rights to relugolix in other therapeutic areas outside of women's health.

Right of First Negotiation and Board Observer Agreement with Pfizer

In October 2016, we and an entity affiliated with Pfizer Inc. (the "Pfizer Affiliate") entered into a right of first negotiation and board observer agreement (the "Pfizer Agreement"), pursuant to which we granted to the Pfizer Affiliate a right of first negotiation with respect to certain license or sale of rights to develop and commercialize relugolix or MVT-602 or a change of control of

Myovant or a sale of substantially all of our assets. In addition, during the period that the Pfizer Affiliate held such right of first negotiation, one representative of the Pfizer Affiliate was entitled to attend any meetings of our board of directors in a non-voting observer capacity, subject to standard exceptions, such as conflict of interest. The right of first negotiation terminated on November 1, 2019 (the third anniversary of our initial public offering).

Sales and Marketing

We believe that we can maximize the value of our products by retaining substantial commercialization rights to our product candidates and, where appropriate, enter into collaborations for specific therapeutic indications or geographic territories. We intend to directly commercialize relugolix in the U.S. in women's health and prostate cancer and we are currently building our sales and marketing infrastructure. In other markets for which commercialization may be less capital efficient for us, we may selectively pursue strategic collaborations with third parties as we have done with Richter for certain territories outside the U.S. In order to commercialize our product candidates and maximize the commercial potential of our product candidates, if approved for commercial sale, we must further develop our sales and marketing infrastructure and/or collaborate with third-parties that have sales and marketing capabilities.

We are currently planning to establish separate, but efficient, sales teams for women's health and prostate cancer. In women's health, we intend to focus primarily on gynecology practices as this specialty accounts for the majority of treatments of both uterine fibroids and endometriosis. With a team of approximately 200 sales representatives, we estimate that we can effectively cover 70% of the market opportunity in these two disease areas. For our prostate cancer product launch, we intend to focus on both urologists and medical oncologists, as both specialties are heavy prescribers of ADT. As this market is even more concentrated, we anticipate utilizing a sales team of approximately 100 sales representatives.

Manufacturing

We do not own or operate, nor do we expect to own or operate, facilities for manufacturing, storage and distribution, or testing of our product candidates.

If there are delays in initiating new relationships with one or more other third-party manufacturers for relugolix and/or MVT-602, or if there are delays in completing technology transfer to any of these manufacturers, or if any of our third-party manufacturers experience adverse developments, including with respect to adverse findings during inspections and/or the COVID-19 pandemic, we could experience delays in our development and commercialization efforts.

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 relugolix and MVT-602 under current Good Manufacturing Practice ("cGMP") conditions, which set forth the regulatory standards for the production of pharmaceuticals to be used in humans.

Relugolix Development

In June 2016, we and Takeda Limited entered into an agreement for the manufacture and supply of relugolix. Under this agreement, Takeda Limited supplied us with, and we have obtained from Takeda Limited, all of our requirements for relugolix drug substance and drug product that were used under our development plans for all indications. We expect that the manufacturing support provided by Takeda to us under the Takeda License Agreement will be sufficient for us to complete our Phase 3 programs for relugolix. We also rely on a limited number of third-party contract manufacturers for packaging and distribution of finished drug products for our clinical studies, sourcing of comparator products, and development of new products.

Relugolix Commercialization

If relugolix is approved for marketing, we plan to rely on Takeda and other third-party manufacturers to supply us with sufficient commercial quantities of relugolix combination tablets and relugolix monotherapy tablets. On May 30, 2018, we entered into the Takeda Commercial Supply Agreement pursuant to which Takeda has manufactured and supplied us with some of the relugolix drug substance to support the commercial launch of relugolix, if marketing authorization is granted. Takeda has assisted us with the transfer of technology and manufacturing know-how to a second contract manufacturing organization of our subsidiary, Myovant Sciences GmbH. This second contract manufacturing organization for relugolix drug substance will be included in our regulatory submissions for all potential indications. In anticipation of receiving marketing approval by a regulatory agency for any of our product candidates, we have also entered into additional agreements with other third-party contract manufacturing organizations for the commercial production of those products. Under the Development and Commercialization Agreement with Richter, we have agreed to supply Richter with sufficient quantities of relugolix combination tablet, if requested by Richter, for commercialization in Richter's territories.

MVT-602

We have contracted with third-party contract manufacturers to complete the additional development and manufacturing activities for our current MVT-602 programs and to fill, finish, supply, store, and distribute drug product for these programs.

Competition

The pharmaceutical and biopharmaceutical industries are highly competitive and require an ongoing, extensive search for technological innovation. These industries are characterized by rapid and significant technological advancements, intense competition, and a strong emphasis on proprietary products. While we believe that our product candidates, knowledge, experience, and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our ability to compete will significantly depend upon our ability to effectively complete necessary clinical studies and regulatory approval processes, and effectively commercialize, market, and promote approved products. 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, acceptance by physicians, ease of patient compliance, dosing convenience, price, insurance and other reimbursement coverage, patent position, distribution, and marketing. Our competitors also may obtain FDA or other regulatory approvals for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our existing or potential future 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 U.S. and in foreign countries. Our current and certain potential future competitors also have significantly more experience in manufacturing and commercializing drugs that have been approved for marketing. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaboration agreements with larger more established companies. These competitors also compete with us in recruiting and retaining qualified scientific, sales force, and management personnel and establishing clinical study sites and patient enrollment and retention for clinical studies. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller 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 uterine fibroids, endometriosis or prostate cancer 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.

We consider relugolix's most direct competitor for the treatment of heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis to be ORILISSA™ (elagolix), an oral GnRH receptor antagonist, which has been approved as monotherapy (150 mg once a day or 200 mg twice a day) by the FDA and launched by AbbVie in August 2018 for the management of moderate-to-severe pain associated with endometriosis. Abbvie has one ongoing Phase 3b study of elagolix in combination with hormonal therapy in women with pain associated with endometriosis. In 2018, AbbVie announced that each of its two pivotal Phase 3 studies evaluating elagolix 300 mg twice a day with and without hormonal add-back therapy in women with heavy menstrual bleeding associated with uterine fibroids, met their primary endpoint and subsequently in August 2019 submitted an NDA to the FDA. In addition, ObsEva SA, a Swiss-based clinical-stage biopharmaceutical company, reported the commencement of two Phase 3 clinical studies of linzagolix (OBE2109), also an oral GnRH receptor antagonist, in women with heavy menstrual bleeding associated with uterine fibroids in the first half of 2017 and announced in December 2019 positive results from the first of these studies. In May 2019, ObsEva also initiated a Phase 3 program evaluating linzagolix in women with endometriosis-associated pain, however new patient screening and randomization in this study has been put on hold due to the COVID-19 pandemic. We believe the development of multiple GnRH receptor antagonists by other biopharmaceutical companies adds further validation to the therapeutic relevance of GnRH as a target for the treatment of women's health and endocrine diseases and will help fuel growth in this market which has lacked innovative new medical therapies.

Relugolix is the only oral GnRH receptor antagonist in development for men with prostate cancer. LHRH agonists, such as leuprolide acetate, are the standard of care treatment used to lower testosterone in men with advanced prostate cancer. These have been approved for three decades and are administered by injection on a monthly, quarterly or every 6-month basis and are expected to be the direct competitor for relugolix. Degarelix, a depot GnRH antagonist requiring monthly injections, is approved for use to lower testosterone in men with advanced prostate cancer, but clinical use is limited likely by the requirement for monthly high-volume injections with a rate of injection site reactions of approximately 35%. A phase 3 prospective cardiovascular study is currently underway evaluating the benefit of degarelix versus LHRH agonist therapy on the incidence of major adverse cardiovascular events in men with pre-existing cardiovascular disease. The study is no longer recruiting patients and is expected to report data in April 2021 according to clinicaltrials.gov. Other oral medications used for androgen deprivation therapy include androgen receptor inhibitors such as enzalutamide, apalutamide and darolutamide, androgen biosynthesis inhibitors such as

abiraterone acetate, and antiandrogens such as bicalutamide and flutamide, each commonly used in combination with a GnRH receptor antagonist or LHRH agonist.

In addition to other GnRH receptor antagonists and selective progesterone receptor modulators in active development, we are aware of other biotechnology and pharmaceutical companies as well as academic institutions, government agencies, and private and public research institutions that are developing, and may in the future develop and commercialize, products for gender-specific hormone disorders.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for relugolix, MVT-602 and any of our future product candidates. We seek to protect our proprietary position by, among other methods, filing and in-licensing U.S. and foreign patents and patent applications. We also rely on trademarks, trade secrets and know-how to develop and maintain our proprietary position.

Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent terms can be adjusted to recapture a portion of delay by the U.S. Patent and Trademark Office ("USPTO") in examining the patent application (patent term adjustment ("PTA")) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension ("PTE")), or both. In addition, we cannot provide any assurance that any patents will be issued from our pending or future applications or that any issued patents will adequately protect our products or product candidates.

Under the Takeda License 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 relating to relugolix and MVT-602.

For relugolix, we are the exclusive worldwide licensee, excluding the Takeda Territory. These patents and patent applications cover the relugolix molecule and certain analogs and the use of relugolix to treat sex-hormone dependent prostate cancer and hysteromyoma (uterine fibroids); methods of manufacturing; and certain formulations. The patent family directed to the relugolix molecule and its use will expire in 2024, subject to any extension of patent term that may be available in a particular country. We intend to apply for PTE for a patent covering relugolix. If granted, the term of this patent may be extended for up to five years, or 2029. The patents and patent applications, if issued, directed to methods of manufacturing relugolix will expire in 2033, subject to any adjustment or extension of patent term that may be available in a particular country. The patents and patent applications, if issued, directed to formulations of relugolix will expire in 2036, subject to any adjustment or extension of patent term that may be available in a particular country. We have filed patent applications directed to uses of relugolix combination therapy in treating, among other conditions, heavy menstrual bleeding associated with uterine fibroids and for pain associated with endometriosis. These applications are co-owned with Takeda under the Takeda License Agreement. If issued, they will expire in 2037 not including any adjustments or extensions. We have also filed patent applications directed to the use of relugolix as a monotherapy to treat advanced prostate cancer. The granted U.S. patent, and patent applications in this patent family, if issued, will expire in 2037, not including any adjustments or extensions. These patents and patent applications are also co-owned with Takeda.

For MVT-602, we are the exclusive worldwide licensee of multiple patents and patent applications in the U.S. and numerous foreign jurisdictions. These patents and patent applications cover the MVT-602 oligopeptide and its use in treating advanced prostate cancer, as well as certain sustained release formulations containing MVT-602. The patent family directed to the MVT-602 molecule and method of use expires in 2028 in the U.S. (because of PTA) and in 2026 ex-U.S., subject to any adjustment or extension of patent term that may be available in a particular country. The patents and patent applications directed to sustained-release formulations of MVT-602, if issued, would expire between 2030 and 2031, subject to any adjustment or extension of patent term that may be available in a particular country. We intend to apply for PTE for a patent covering MVT-602. If granted, the patent term covering MVT-602 may be extended. We are also the owner of patent applications directed to uses of MVT-602 in treating infertility. These applications, if issued, would expire in 2037 subject to any adjustment or extension of patent term that may be available in a particular country. We have licensed additional patents and patent applications from Takeda directed to other oligopeptides that target the same pathway as MVT-602.

In addition to patents, we also rely upon trademarks, trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We maintain both registered and common law trademarks. Common law trademark protection typically continues where and for as long as the mark is used. Registered trademarks continue in each country for as long as the trademark is registered. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our commercial partners and selected consultants. 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.

Obtaining patents does not guarantee our right to practice the patented technology or commercialize the patented product. Third parties may have or obtain rights to patents which could be used to prevent or attempt to prevent us from commercializing our product candidates. If third parties prepare and file patent applications in the U.S. 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 U.S., pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, 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, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

The process required before drugs may be marketed in the U.S. generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies, and formulation studies in accordance with the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an Investigational New Drug application ("IND") for human clinical testing, which must become effective before human clinical studies may begin;
- performance of adequate and well-controlled human clinical studies in accordance with Good Clinical Practice ("GCP") requirements to establish the safety and efficacy of the drug for each proposed indication;
- submission of an NDA to the FDA for commercial marketing, or of a supplemental New Drug Application ("sNDA") for approval of a new indication if the product is already approved for another indication;
- satisfactory completion of an FDA pre-approval inspection of manufacturing facilities at which the active pharmaceutical ingredient ("API") and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practice ("cGMP") requirements and selected clinical investigators or contract research organizations for their compliance with GCP;
- if the FDA convenes an advisory committee, satisfactory completion of the advisory committee review; and
- FDA review and approval of the NDA or sNDA.

The testing and approval process requires substantial time, effort, and financial resources, which 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 studies 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 study protocol. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical study. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical study can begin. A separate submission to the existing IND must be made for each successive clinical study conducted during product development. Further, an independent institutional review board ("IRB") for each medical center proposing to conduct the clinical study must review and approve the plan for any clinical study and provide its informed consent form before the study commences at that center. Regulatory authorities or an IRB or the study sponsor may suspend a clinical study at any time on various grounds including a finding that the subjects or patients are being exposed to an unacceptable health risk. Long-term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical studies to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap.

- Phase 1- Studies, which involve the initial introduction of the new drug product candidate into humans, are initially conducted in a limited number of subjects to assess pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

- Phase 2- Studies are conducted with groups of patients afflicted with a specified disease in order to provide enough data to evaluate the preliminary efficacy, metabolism, pharmacokinetics, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. Multiple Phase 2 clinical studies may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical studies.
- Phase 3- Phase 3 studies, also called pivotal or registration studies, are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical study sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical studies to demonstrate the efficacy of the drug. A single Phase 3 clinical study with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter study 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 study would be practically or ethically impossible.

The FDA may require, or companies may pursue, additional clinical studies after a product is approved. These so-called Phase 4 studies may be deemed a condition to be satisfied after a drug receives approval. Failure to satisfy such post-marketing commitments can result in FDA enforcement action, up to and including withdrawal of NDA approval.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all nonclinical, clinical, and other testing, and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The submission of most NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees.

The FDA has 60 days from its receipt of an NDA 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's goal is to review applications within ten months of the filing date or, if the application relates to an unmet medical need in a serious or life-threatening indication and is granted priority review, six months from the filing date. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether a drug candidate is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may refer applications 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 and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or some of the facilities at which the drug is manufactured or tested.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it issues either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. 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. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

As a condition of NDA approval, the FDA may require a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of the drug outweigh the potential risks. A REMS can include a medication guide, a communication plan for healthcare professionals, and elements to assure safe use, such as special training and certification requirements for individuals who prescribe or dispense the drug, requirements that patients enroll in a registry, and other measures that the FDA deems necessary to assure the safe use of the drug. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug'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.

Changes to some of the conditions established in an approved application, including changes in formulation, indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or sNDA before the change can be implemented. An sNDA 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 an sNDA as it does in reviewing NDAs.

Post-Approval Requirements

Any products for which we may receive FDA approval are subject to continuing regulation by the FDA. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing 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, drug manufacture, packaging, and labeling procedures must continue to conform to GMP requirements after approval, including for supply chain traceability. Drug 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 GMP requirements. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with GMP 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 studies;
- 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; or
- injunctions or the imposition of civil or criminal penalties.

Foreign Regulation

In addition to regulations in the U.S., we are subject to regulations of other countries governing clinical studies and the manufacturing, commercial sales and distribution of our products outside the U.S. 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 studies or marketing of the product in foreign countries or economic areas, such as the European Union ("EU"). Although many of the issues discussed above with respect to the U.S. apply similarly in the context of foreign countries and the EU, 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 shorter or 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 and Compliance Requirements

Although we currently do not have any products approved for marketing, our current and future business operations may be subject to additional healthcare regulation 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.

Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we have a Code of Business Conduct and Ethics and other corporate compliance policies, but 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. 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 significant 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 imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Anti-Kickback Laws

U.S. federal laws, including the federal Anti-Kickback Statute, prohibit fraud and abuse involving state and federal healthcare programs, such as Medicare and Medicaid. These laws are interpreted broadly and enforced aggressively by various federal agencies, including the Centers for Medicare & Medicaid Services ("CMS"), the Department of Justice, and the Office of the Inspector General for the United States Department of Health and Human Services ("HHS"), and various state agencies. These anti-kickback laws, among other things, make 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, directly or indirectly, that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item, or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, including cash, gifts or gift certificates, improper discounts, and free or reduced-price items and services. 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.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act ("ACA"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA 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.

Federal and State Prohibitions on False Claims

The federal false claims laws, including the civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Many states have enacted similar laws modeled after the federal civil False Claims Act that apply to items and services reimbursed under Medicaid and other state healthcare programs, and, in several states, such laws apply to claims submitted to all payors.

Federal Prohibitions on Healthcare Fraud and False Statements Related to Healthcare Matters

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created new federal civil and 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. Like the federal Anti-Kickback Statute, the ACA broadened the reach of certain criminal healthcare fraud statutes under HIPAA by amending the intent requirement 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.

Healthcare Privacy and Security Laws

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their implementing regulations, impose specific requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individual identifiable health information, relating to the privacy, security, and transmission of individually identifiable health information. 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. In addition, certain state and foreign laws, regulations, standards and regulatory guidance 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.

We have conducted, and may continue to conduct, clinical studies or continue to enroll subjects in our ongoing or future clinical studies in certain jurisdictions in which we may be subject to additional privacy restrictions. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating

to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data out of the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to the greater of 20 million Euros or 4% of annual global revenue, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Data protection authorities from the different EU member states have issued limited guidance, may interpret the GDPR and national laws differently and may impose additional requirements, which complicates the effort to comply with these laws. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom ("UK"). In particular, it is unclear how data transfers to and from the UK will be regulated.

Additionally, California recently enacted the California Consumer Privacy Act ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of California consumers and households. The CCPA, which went into effect on January 1, 2020, gives California residents expanded rights to access and requires deletion of their personal information, opting out of certain personal information sharing, and receiving detailed information about how their personal information is collected, used and shared. The California Attorney General will commence enforcement actions against violators beginning July 1, 2020. 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 studies data, as well as 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 wave 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.

Physician Payments Sunshine Act

There has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA through the enactment of the Physician Payments Sunshine Act, imposes, among other things, annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians, as defined by such law, and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members.

Many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. 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, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, as well as state and local laws that require the registration of pharmaceutical sales representatives. Additionally, to the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws.

Foreign Corrupt Practices Act

We are subject to the Foreign Corrupt Practices Act of 1977, as amended, ("FCPA"), which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or otherwise influence a person working in an official capacity to obtain a business advantage. The FCPA also requires public companies whose securities are listed in the U.S. to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls. 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.

Healthcare Reform

The U.S. and certain foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our future results of operations and our ability to sell our product candidates profitably, even if approved for sale. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and/or expanding access.

There has been increasing legislation and enforcement interest in the U.S. with respect to drug pricing practices. At the federal level, the U.S. Presidential administration's budget proposal for the fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. In addition, there have been several U.S. Congressional inquiries, hearings and proposed and enacted federal legislation designed to, among other things: reduce or limit the prices of drugs; reform the structure of Medicare Part D pharmaceutical benefits; bring more transparency to drug pricing rationale and methodologies; and facilitate the importation of certain lower-cost drugs from other countries, expedite the development and approval of generic drugs and biosimilars. Although a number of these and other measures may require additional authorization to become effective, Congress and the U.S. Presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing.

The U.S. pharmaceutical industry has been significantly impacted by major legislative initiatives and related political contests, including, for example, efforts to repeal, substantially modify or invalidate some or all of the provisions of the ACA. Notably, in December 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the penalty for enforcing the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Then in December 2019, the U.S. Court of Appeals for the 5th Circuit upheld this District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how this litigation and other efforts will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 ("BCA"), which began in 2013, and due to subsequent legislative amendments to the statute, including the BCA, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the Medicare sequester reductions from May 1, 2020 through December 31, 2020 and extended the sequester by one year, through 2030. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of our products, if and when approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government healthcare programs, private health insurers, and managed care organizations. Third-party payors generally decide which drugs they will cover and establish certain reimbursement levels for such drugs. In particular, in the U.S., private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, if and when approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our product candidates, and those of any future product candidate, will therefore depend substantially on the extent to which the costs of our product candidates, and those of any future product candidate, will be paid by third-party payors. Additionally, the market for our product candidates, and those of any future product candidate, will depend significantly on access to third-party payors' formularies without prior authorization, step therapy, or other limitations such as approved lists of treatments for which third-party payors provide coverage and reimbursement. Additionally, coverage and reimbursement for therapeutic 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.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and challenging the prices charged for medical products and services. 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. However, 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 and materially 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.

Other Applicable Laws

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the SEC and the regulations of the New York Stock Exchange, 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.

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.

Employees

As of March 31, 2020, we had 214 employees. Our employees are not represented by labor unions or covered by collective bargaining agreements, and we believe our relations with our employees are good.

Corporate Information

We are an exempted company limited by shares incorporated under the laws of Bermuda in February 2016 under the name Roivant Endocrinology Ltd. We changed our name to Myovant Sciences Ltd. in May 2016. Our principal executive offices are located at Suite 1, 3rd Floor, 11-12 St. James's Square, London, SW1Y 4LB, United Kingdom, and our telephone number is +44 (207) 400 3351. We maintain additional offices in Brisbane, California and Basel, Switzerland. Our common shares are currently listed on the New York Stock Exchange under the symbol "MYOV." Our website is www.myovant.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.

Available Information

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.

Investors and other interested parties should note that we also use our media and investor relations website (investors.myovant.com) and our social media channels to publish important information about Myovant that may be deemed material to investors. We encourage investors and other interested parties to review the information we may publish through our media and investor relations website and social media channels, in addition to our SEC filings. The information contained on our websites and social media channels is not included as part of, or incorporated by reference, into this Annual Report on Form 10-K.

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 "Forward-Looking Statements."

Risks Related to Our Financial Position and Capital Requirements

We believe our current cash, cash equivalents, marketable securities, and current borrowing capacity under the Loan Agreement with Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma") will not be sufficient for us to fund our anticipated level of operations until we become cash flow positive. If we fail to obtain additional capital, we will not be able to complete the development of, seek regulatory approval for, and commercialize our product candidates.

As of March 31, 2020, we had cash, cash equivalents, marketable securities, and committed funding available to us of $365.9 million consisting of $79.6 million of cash, cash equivalents, and marketable securities and $286.3 million of borrowing capacity available to us under our loan agreement with Sumitomo Dainippon Pharma (the "Sumitomo Dainippon Pharma Loan Agreement") for which we can draw upon on a quarterly basis subject to certain terms and conditions, including the consent of our board of directors. In April 2020, we borrowed an additional $80.0 million under this agreement. Based on our current operating plan, we believe that our existing cash, cash equivalents, marketable securities, and borrowing capacity currently available to us under the Sumitomo Dainippon Pharma Loan Agreement will be sufficient to fund our operating expenses and capital expenditure requirements at least through the end of our fiscal year ended March 31, 2021. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We anticipate that we will continue to incur net losses and negative operating cash flows for the foreseeable future.

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our product candidates. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned and ongoing clinical studies for our product candidates;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration (the "FDA") and comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or our products or any future product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities, including securing regulatory approval for commercial production;
- the cost of establishing sales, marketing and distribution capabilities for our products in regions where we choose to commercialize our products on our own; and
- the initiation, progress, timing and results of our commercialization of our product candidates, if approved for commercial sale.

Our current funds will not be sufficient to enable us to complete all necessary development and regulatory activities and commercially launch relugolix combination tablet or relugolix monotherapy tablet. These factors raise substantial doubt about our ability to continue as a going concern for the one-year period following the filing of this Annual Report on Form 10-K. We may be required to delay, limit, reduce, or terminate our drug development programs, commercialization efforts, and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. Management's plans in this regard are described in Note 2 of the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. In the event that these plans cannot be effectively realized, there can be no assurance that we will be able to continue as a going concern.

We are required to meet certain terms and conditions to draw down funds under the Sumitomo Dainippon Pharma Loan Agreement. If we are unable to meet such terms and conditions, we may not be able to access funding from the Sumitomo Dainippon Pharma Loan Agreement.

On December 27, 2019, we and our subsidiary, Myovant Sciences GmbH ("MSG") entered into the Sumitomo Dainippon Pharma Loan Agreement, pursuant to which Sumitomo Dainippon Pharma agreed to make revolving loans to us in an aggregate principal amount up to $400.0 million. As of March 31, 2020, approximately $286.3 million of borrowing capacity remained available to us under the Sumitomo Dainippon Pharma Loan Agreement. In April 2020 we borrowed an additional $80.0 million under this agreement. We may draw down additional funds under the Sumitomo Dainippon Pharma Loan Agreement once per calendar quarter, subject to certain terms and conditions, including the consent of our board of directors and no change of control having occurred with respect to us. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of the outstanding common shares of Myovant, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to us, in which case we would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. Furthermore, within 30 days of a change of control having occurred with respect to us, we will be obligated to repay the outstanding amount of loans and accrued interest under the Sumitomo Dainippon Pharma Loan Agreement. We may not be able to meet such terms and conditions in the future and may not be able to secure additional funds.

We may not be able to obtain funding through public or private offerings of our capital shares, debt financings, collaboration or licensing arrangements, or other sources.

As discussed above, our current cash, cash equivalents, marketable securities, and amounts currently available to us under the Sumitomo Dainippon Pharma Loan Agreement will not be sufficient for us to complete all necessary development and regulatory activities and commercially launch our product candidates. Accordingly, we will need to raise additional capital to fund our operations. We cannot be certain that additional capital will be available to us on acceptable terms, or at all. Even if additional capital is available to us, under the terms of the Sumitomo Dainippon Pharma Loan Agreement, we may not raise additional capital without obtaining the consent of Sumitomo Dainippon Pharma. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, when needed, we may have to significantly delay, scale back, or discontinue the development or commercialization of our product candidates or potentially discontinue operations. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development and commercialization 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 and anticipated product development programs and commercialization efforts.

Raising additional funds may cause dilution to existing shareholders and/or may restrict our operations or require us to relinquish proprietary rights.

As discussed above, we will need to raise additional capital to fund our operations. To the extent that we raise additional capital by issuing equity or convertible debt securities, our existing shareholders' ownership interest may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common shareholder. 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 raising additional capital, 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 grant licenses on terms that may not be favorable to us or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

We expect to incur significant operating losses and negative operating cash flows for the foreseeable future, and may never achieve or maintain profitability.

Investment in pharmaceutical 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. Since inception, we have incurred significant operating losses and negative operating cash flows. We expect to continue to incur significant operating losses and negative operating cash flows as we continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of our product candidates. If we obtain regulatory approval for our product candidates, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we may never achieve or maintain profitability.

Risks Related to Our Business Operations

We are heavily dependent on the success of relugolix combination tablet for our women's health indications of uterine fibroids and endometriosis, relugolix monotherapy tablet for men with advanced prostate cancer, and MVT-602, which are still under clinical development. If relugolix combination tablet, relugolix monotherapy tablet or MVT-602 does not receive regulatory approval or is not successfully commercialized, our business will be harmed.

We have invested and expect to continue to invest a substantial portion of our efforts and expenditures in the development and advancement of our product candidates, relugolix combination tablet, relugolix monotherapy tablet, and MVT-602. Our ability to generate product revenue and achieve profitability depends heavily on our ability to complete the development of our product candidates, obtain necessary regulatory approvals for, and have our product candidates manufactured and successfully marketed, which may never occur. 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 U.S. and other countries. We are not permitted to market our product candidates in the U.S. until we receive approval of NDAs or in any foreign country until we receive the requisite approvals from the appropriate regulatory authorities in such countries.

Obtaining approval of an NDA or similar foreign regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authority may delay, limit or deny approval of our product candidates.

Even if we receive regulatory approval for our product candidates, our ability to generate product revenues from our product candidates will depend upon the size of the markets in the territories for which we gain regulatory approval, the number of competitors in such markets, whether we own the commercial rights for those territories, and our ability to:

- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- establish effective sales, marketing, and distribution systems in jurisdictions around the world for our product candidates;
- initiate and continue relationships with third-party manufacturers and have adequate commercial quantities of our product candidates manufactured at acceptable cost and quality levels, including maintaining current good manufacturing practice ("cGMP") and Quality Systems Regulation standards required by various regulatory agencies;
- attract and retain experienced management, employees and consultants;
- achieve broad market acceptance of our products in the medical community and with third-party payors and consumers;
- launch commercial sales of our products, whether alone or in collaboration with others;
- establish the safety and efficacy of our product candidates in comparison to competing products, including through differentiated approved labeling; and
- maintain, expand, and protect our intellectual property rights.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment in us may be adversely affected.

The terms of the Sumitomo Dainippon Pharma Loan Agreement place restrictions on our operating and financial flexibility.

In December 2019, we, MSG, and Sumitomo Dainippon Pharma entered into the Sumitomo Dainippon Pharma Loan Agreement. Our obligations under the Sumitomo Dainippon Pharma Loan Agreement are senior unsecured obligations including customary representations and warranties as well as affirmative and negative covenants, that are guaranteed on a full and unconditional basis by all our subsidiaries.

The negative covenants include limitations on additional indebtedness, liens, certain corporate changes, certain restricted payments, investments transactions with affiliates, entry into certain restrictive agreements, change in the nature of business, and use of

proceeds. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our shareholders.

Additionally, the Sumitomo Dainippon Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties and certain covenants following any applicable cure period, cross acceleration to certain debt, other failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, certain breaches by us under our investor rights agreement with Sumitovant and Sumitomo Dainippon Pharma, dated December 27, 2019 (the "Investor Rights Agreement") and failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by us or any of our subsidiaries. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Dainippon Pharma may terminate its obligations to make loans to us and declare the principal amount of all outstanding loans and other obligations under the Sumitomo Dainippon Pharma Loan Agreement to become immediately due and payable, and Sumitomo Dainippon Pharma may take such other actions as set forth in the Sumitomo Dainippon Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Dainippon Pharma to make loans to us would automatically terminate and the principal amount of all outstanding loans and other obligations due under the Sumitomo Dainippon Pharma Loan Agreement would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Dainippon Pharma to maintain the loans under the Sumitomo Dainippon Pharma Loan Agreement, we would be required to repay the outstanding principal amount of the loans and if a change of control occurs with respect to us, we would be required to repay the outstanding principal amount of the loans within 30 days of such change of control. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our clinical development efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be substantially harmed as a result of any of these events.

We may not be successful in our efforts to identify and acquire or in-license additional product candidates.

Part of our strategy involves diversifying our product development risk by identifying and acquiring or in-licensing novel product candidates. We may fail to identify and acquire or in-license product candidates, including for reasons discussed in these risk factors and also:

- the process by which we identify and decide to acquire product candidates may not be successful;
- the competition to acquire or in-license promising product candidates is fierce and many of our competitors are large, multinational pharmaceutical, biotechnology and medical device companies with considerably more financial, development and commercialization resources and experience than we have;
- potential product candidates may, upon further study during the acquisition process, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance; and
- potential product candidates may not be effective in treating their targeted diseases.

In addition, we may choose to focus our efforts and resources on potential product candidates that ultimately prove to be unsuccessful. Further, time and resources spent searching for, identifying, acquiring, and developing potential product candidates may distract management's attention from our primary business. If we are unable to identify and acquire or in-license suitable product candidates, we will be unable to diversify our product risk. We believe that any such failure could have a significant negative impact on our prospects because the risk of failure of any particular development program in the pharmaceutical field is high.

We rely on agreements with Takeda to provide rights to the core intellectual property relating to our existing product candidates and to supply us with clinical study and some of our needed commercial material to support development and potential commercialization of relugolix. Any termination or loss of significant rights under those agreements or any adverse action harming our ability to utilize drug supply manufactured by Takeda would adversely affect our development or commercialization of relugolix.

In June 2016, we and one of Takeda's affiliates, Takeda Pharmaceutical Company Limited ("Takeda Limited") entered into an agreement for the manufacture and clinical supply of relugolix (the "Takeda Clinical Supply Agreement"). Under the Takeda Clinical Supply Agreement, as amended, Takeda Limited supplied us with, and we have obtained from Takeda Limited, all of our requirements for relugolix drug substance and drug product that were used under our development plans for all indications. On May 30, 2018, we entered into a Commercial Manufacturing and Supply Agreement with Takeda (the "Takeda Commercial Supply Agreement") pursuant to which Takeda has manufactured and supplied us with some of the relugolix drug substance quantities we need to support the commercial launch of relugolix, if marketing authorization is granted. If Takeda fails to fulfill its obligations to manufacture and supply clinical and/or commercial quantities of relugolix, or if any of the drug substance supplied by Takeda

cannot be utilized due to quality or cGMP concerns, adverse findings during regulatory inspections or other reasons, our development plans and commercialization of relugolix, if approved, could be significantly delayed or otherwise adversely affected.

Our future success depends on our ability to attract and retain key personnel.

We expect to hire additional employees and consultants. The market for talent in our industry is very competitive, especially in the San Francisco Bay Area where we have substantial operations. Many of the other pharmaceutical companies we compete against for qualified personnel and consultants have greater financial and other resources, more favorable risk profiles and a longer operating history in the biopharmaceutical 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. It is particularly difficult to hire new employees during the COVID-19 pandemic as conducting interviews remotely makes it more difficult to ensure we are recruiting and hiring high-quality employees, and the uncertainty created by the COVID-19 pandemic makes it less likely potential candidates will be willing to leave a stable job to explore a new opportunity.

In addition, our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the skills and leadership of our 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 or unable to attract and retain other personnel to accomplish our business objectives, our ability to successfully implement our business strategies could be seriously harmed.

We plan to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to expand our organization and hire additional employees. Our management is expected to have increasing responsibilities to identify, recruit, maintain, motivate, and integrate additional employees, consultants and contractors which may divert a disproportionate amount of its time and attention away from our day-to-day activities. The expected growth may also require significant capital expenditures and divert financial resources from other projects. 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 adversely affected, and we may not be able to implement our business strategy. As a result, our future financial performance and our ability to complete clinical development, obtain regulatory approval, and commercialize our product candidates or any potential future product candidate may be adversely affected.

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

We are exposed to the risk that our employees, contractors, advisers, including third-party manufacturers, principal investigators, consultants, commercial collaborators, service providers, and other vendors, or those of our affiliates, may engage in fraudulent, illegal activity, or other misconduct. 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 regulatory bodies, including: those laws that require the reporting of true, complete, and accurate information to such regulatory bodies; laws that require manufacturing by cGMP standards; federal, state and foreign healthcare fraud and abuse laws and data privacy laws; or laws and regulations 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 regulations intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations, and other abusive practices. See the Risk Factors titled "Our current and future relationships with investigators, healthcare professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties," and "International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S., which could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows." 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 studies, creating fraudulent data in our nonclinical or clinical studies or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We have a Code of Business Conduct and Ethics and other corporate compliance policies, but 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.

Business interruptions resulting from effects of pandemics or epidemics such as the novel strain of the coronavirus known as COVID-19, may materially and adversely affect our business and financial condition.

The majority of our employees are located in the U.S., primarily in the San Francisco Bay Area, with the rest of our employees located mainly in Switzerland. Our employees have been subject to "shelter-in-place" orders resulting from the COVID-19 pandemic that require our employees to work from home with limited exceptions. Our business may be negatively impacted from having all employees working remotely. For example, employees may be less efficient given competing priorities with home-schooling or caring for sick family members, and employee engagement and productivity may decrease from the stress of the COVID-19 pandemic resulting in delays in the progress of our business. In addition, we rely on third parties in the U.S. and in various parts of the world to assist in the conduct of our clinical studies and to supply us with sufficient drug supplies. Our ability to ensure continuous clinical drug supply to patients and our ability to ensure continuous patient follow up and data monitoring for our ongoing clinical studies may be adversely impacted. Likewise, while we currently expect that the drug supply we have on hand is sufficient to support our ongoing clinical studies and anticipated commercial launches, our supply chain for raw materials, drug substance and drug product is worldwide, and the continued spread of the coronavirus and the duration of its impact on the ability of our suppliers to operate could negatively impact our manufacturing supply chain for relugolix combination tablet and relugolix monotherapy tablet. If disruptions to our supply chain persist for an extended period of time, our clinical study timelines, our financial condition and our results of operations may be negatively impacted.

In order to successfully commercialize our product candidates, we need to continue to expand our capabilities, including the hiring of qualified employees, engage potential prescribers in scientific exchange, build commercial infrastructure, conduct market research, develop promotional campaigns and resources, and engage payers in scientific exchange to demonstrate the value of our products and negotiate favorable contracts. The COVID-19 pandemic is making this work more difficult and may result in delays. Conducting interviews remotely makes it more difficult to ensure we are recruiting and hiring high-quality employees, and the uncertainty created by the COVID-19 pandemic makes it less likely potential candidates will be willing to leave a stable job to explore a new opportunity. Our medical affairs team needs to ensure our scientific data are presented and published and our regional medical advisors need to engage potential prescribers in scientific exchange. Multiple medical conferences have been canceled and postponed resulting in fewer opportunities to present our scientific data and our medical affairs team members can only communicate virtually making it more difficult to educate and engage in scientific exchange. Travel restrictions may make it more difficult for us to maximize the potential of the Gedeon Richter ("Richter") partnership and provide adequate collaboration and oversight. The COVID-19 pandemic may negatively impact our ability to attract the human resources required to build out our commercial capabilities and may negatively impact our ability to rapidly and effectively educate potential prescribers and payers and, if significant delays result, commercialize our product candidates. The extent to which the coronavirus and global efforts to contain its spread will impact our operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the outbreak and the actions taken to contain or treat the coronavirus outbreak. In addition, the current COVID-19 pandemic may also have the effect of heightening many of the other risks described in this ''Risk Factors'' section.

International expansion of our business exposes us to business, legal, regulatory, political, operational, financial, economic, and other risks associated with conducting business outside of the U.S., which could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows.

Part of our business strategy involves international expansion, including establishing and maintaining operations outside of the U.S., and establishing and maintaining relationships with healthcare providers, payors, government officials, distributors, manufacturers and other third parties globally in case any of our product candidates is approved for marketing outside of the U.S.

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, immigration and labor laws, privacy and cybersecurity laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- possible 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, pricing and insurance 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 or no protection over intellectual property rights;
- business interruptions resulting from geopolitical actions, economic instability, or natural disasters, including, but not limited to, wars and terrorism, economic weakness, inflation, political instability in particular foreign economies and markets, boycotts, curtailment of trade, labor disputes, unexpected changes in tariffs, and other business restrictions, outbreak of disease (such as the COVID-19 pandemic), fires, earthquakes, hurricane, tornado, severe storm, power outage, system failure, typhoons or floods;
- failure to comply with foreign laws, regulations, standards and regulatory guidance governing the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Protection Regulation (the "GDPR") which introduced strict requirements for processing personal data of individuals within the European Union (the "EU");
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010, and similar antibribery and anticorruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

Any of these risks, if encountered, could interrupt our business operations and harm our future international expansion and, consequently, negatively impact our financial condition, results of operations, and cash flows. We have no prior experience in certain countries, and many biopharmaceutical companies have found the process of marketing their products in foreign countries to be very challenging.

The withdrawal of the United Kingdom (the "U.K.") from the EU, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the EU, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

On January 31, 2020, the U.K. withdrew from the EU. The U.K.'s withdrawal from the EU is commonly referred to as Brexit. Under the withdrawal agreement agreed between the U.K. and the EU, the U.K. will be subject to a transition period until December 31, 2020 (the "Transition Period") during which EU rules will continue to apply. During the Transition Period, negotiations between the U.K. and the EU are expected to continue in relation to the future customs and trading relationship between the U.K. and the EU following the expiration of the Transition Period. Due to the current COVID-19 global pandemic, negotiations between the U.K. and the EU scheduled for March, April and May have either been postponed or occurring in a reduced forum via video conference. There is, therefore, an increased likelihood that the Transition Period may need to be extended beyond December 31, 2020 (although it remains the position of the U.K. government that it will not be extended).

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and certain of our product candidates are derived from EU directives and regulations, Brexit following the Transition Period could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, as a result of the uncertainty surrounding Brexit, the European Medicines Agency (the "EMA") relocated to Amsterdam from London. Following the Transition Period, the U.K. will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including certain of our product candidates, will be required in the U.K., the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of certain of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles.

If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. or the EU for certain of our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the U.K. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

Our internal computer systems, and our third-party collaborators, consultants or contractors, may fail or suffer cybersecurity breaches and data leakage, which could result in a material disruption of our business and operations or liabilities that adversely affect our financial performance.

Our computer systems, as well as those of our contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other contractors, consultants, and law and accounting firms, may sustain damage or data leakage from computer viruses, unauthorized access or disclosure, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war, and telecommunication and electrical failures. We rely on our third-party providers to implement effective security and data recovery measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical study data from completed, ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data, access or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, suffer reputational damage, and the further development of any current or future product candidate could be delayed.

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, the California enacted the California Consumer Privacy Act ("CCPA") 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 study 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 studies 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 GDPR, which has 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 U.K. In particular, it is unclear whether, post Brexit, the U.K. will enact data protection legislation equivalent to the GDPR and how data transfers to and from the U.K. 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.

The failure to successfully implement and maintain an enterprise resource planning system could adversely affect our business and results of operations or the effectiveness of internal controls over financial reporting.

We have implemented and continue to optimize a company-wide enterprise resource planning ("ERP") system to upgrade certain existing business, operational, and finance processes and to ensure our operations are adequately scalable in support of our anticipated commercial launches. ERP implementations are complex and time-consuming projects that require transformations of business, operational, and finance processes. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations. The implementation of the new ERP system has required, and will continue to require, the investment of significant financial and human resources.

Any disruptions, delays, or deficiencies in the design or the ongoing maintenance and optimization of the new ERP system could adversely affect our ability to accurately maintain our books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Additionally, if the ERP system does not operate as intended, the effectiveness of our internal controls over financial reporting could be adversely affected and could cause us to fail to comply with the U.S. Securities and Exchange Commission (the "SEC") reporting obligations related to our management's assessment of our internal control over financial reporting. In addition, if we experience interruptions in service or operational difficulties and are unable to effectively manage our business following the implementation of the ERP system, our business and results of operations could be harmed.

The phase-out of the London Interbank Offered Rate ("LIBOR"), or the replacement of LIBOR with a different reference rate, may adversely affect interest rates.

On July 27, 2017, the Financial Conduct Authority (the authority that regulates LIBOR) announced that it would phase out LIBOR by the end of 2021. It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021, or if alternative rates or benchmarks will be adopted. The interest rate under the Sumitomo Dainippon Pharma Loan Agreement is calculated based on LIBOR and, when this occurs, we may need to agree with Sumitomo Dainippon Pharma to a new method of calculating the interest rate under the Sumitomo Dainippon Pharma Loan Agreement, which we may not be able to do. Changes in the method of calculating LIBOR, or the replacement of LIBOR with an alternative rate or benchmark, may adversely affect interest rates and result in higher borrowing costs. This could materially and adversely affect our results of operations, cash flows and liquidity. We cannot predict the effect of the potential changes to LIBOR or the establishment and use of alternative rates or benchmarks.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and could impact ongoing and planned clinical studies as well as limit commercialization of any products that we may develop.

The use of any of our product candidates in clinical studies 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 regulatory or governmental agencies, consumers, healthcare 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 studies;
- 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 products or any future product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased demand for our products or any future product candidate, if approved for commercial sale; and
- loss of revenue.

The product liability and clinical study insurance we currently carry, and any additional product liability and clinical study 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 any of 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 common 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 any product candidates we develop.

Use of social media platforms presents risks of inappropriate or harmful disclosures which could harm our business.

We believe that our potential patient population is active on social media. Social media practices in the pharmaceutical and biotechnology industries are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, a product candidate, which could result in reporting obligations. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our product candidates on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

Risks Related to Clinical Development, Regulatory Approval and Commercialization

Clinical studies are very expensive, time-consuming, difficult to design and implement, and involve uncertain outcomes. Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We cannot predict with any certainty the timing for commencement or completion of current or future clinical studies.

Any product candidate will require extensive clinical testing resulting in sufficiently positive outcomes before we are prepared to submit an NDA or other similar application for regulatory approval. Human clinical studies are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For example, the FDA or other regulatory authorities may not agree with our proposed plans for any clinical studies of relugolix combination therapy, relugolix monotherapy or MVT-602, which may delay the approval of an NDA or similar application. The clinical study process is also very time-consuming. The commencement and completion of clinical studies may be delayed by several factors, including:

- failure to obtain regulatory approval to commence a study;
- unforeseen safety issues;
- lack of effectiveness during clinical studies;
- identification of dosing issues;
- inability to reach agreement on acceptable terms with prospective CROs and/or clinical study sites, the terms of which can be subject to extensive negotiations and may vary significantly among different CROs and clinical study sites;
- slower than expected rates of patient recruitment and enrollment or failure to recruit suitable patients to participate in a study;
- failure to open a sufficient number of clinical study sites;
- unanticipated impact from changes in or modifications to clinical study design;
- inability or unwillingness of clinical investigators or study participants to follow our clinical and other applicable protocols, including missed assessments or impeded access to study sites due to government or institutional stay-at-home or shelter-in-place measures during the COVID-19 pandemic;
- premature discontinuation of study participants from clinical studies or missing data, including from patients unable to come to study visits during the COVID-19 pandemic;
- failure to manufacture or release sufficient quantities of relugolix, MVT-602, estradiol, progestin or placebo or failure to obtain sufficient quantities of concomitant medication, that in each case meet our quality standards, for use in clinical studies;
- inability to monitor patients adequately during or after treatment; or
- inappropriate unblinding of study patients or study results.

Clinical study failures can occur at any stage of clinical studies, and we could encounter problems that cause us to suspend, abandon or repeat clinical studies. We, the FDA or an institutional review board (“IRB”) or other regulatory authority may suspend our clinical studies at any time if it appears that we or our collaborators are failing to conduct a clinical study in accordance with regulatory requirements, including, the FDA’s current Good Clinical Practices (“cGCP”) or 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 Investigational New Drug application (“IND”) or other submissions or the manner in which the clinical studies are conducted. In

addition, product candidates in later stages of clinical development may fail to show the desired safety and efficacy outcomes despite having progressed successfully through prior stages of preclinical and clinical testing. Results from clinical studies may require further evaluation, delaying the next stage of clinical development or submission of an NDA. Therefore, we cannot predict with any certainty the timing for commencement or completion of current or future clinical studies. If we experience delays in the commencement or completion of our clinical studies, or if we terminate a clinical study prior to completion, the commercial prospects of any product candidates could be harmed, and our ability to generate product revenue from any product candidates may be delayed. In addition, any delays in our clinical studies could increase our costs, cause a decline in our common share price, slow down the regulatory 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 studies may also ultimately lead to the denial of regulatory approval of our product candidates.

Moreover, principal investigators for our clinical studies 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 study site and the utility of the clinical study itself may be jeopardized. Clinical study sites, CROs and manufacturing sites may be inspected for compliance with cGCP or cGMP. Any questions about data integrity or significant quality issues 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.

We are dependent on the research and development of relugolix and MVT-602 previously conducted by Takeda, and if Takeda did not conduct this research and development in compliance with applicable requirements this could result in increased costs and delays in our development of these product candidates.

Prior to our acquisition of worldwide rights (excluding Japan and certain other Asian countries) to relugolix and worldwide rights to MVT-602, we had no involvement with or control over the nonclinical or clinical development of relugolix or MVT-602. We are dependent on Takeda having conducted such research and development in accordance with the applicable protocols, legal, regulatory, and scientific standards, having accurately reported the results of all clinical studies and other research conducted prior to our acquisition of the rights to relugolix and MVT-602, having correctly collected and interpreted the data from these studies 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 any of such nonclinical or clinical work 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 these product candidates.

Recruitment, enrollment and retention of patients in clinical studies 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 studies on our current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to satisfactorily complete any of our clinical studies. Enrollment in our clinical studies may be slower than we anticipated, leading to delays in our development timelines. Patient enrollment and retention in clinical studies depends on many factors, including the size of the patient population, the nature of the study protocol, our ability to recruit clinical study 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 studies of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the study 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 studies will drop out of the studies before completion. In addition, unforeseen global instability, including political instability or instability from an outbreak of pandemic or contagious disease, such as the COVID-19 pandemic, in or around the countries in which we conduct our clinical studies, could delay the commencement or rate of completion of our clinical studies. Furthermore, any negative results we, Takeda or Richter may report in clinical studies of our product candidates may make it difficult or impossible to recruit, enroll, and retain patients in other clinical studies of that same product candidate. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment, enrollment, or retention in our clinical studies. Also, marketing authorization of competitors in the same class of product candidates may impair our ability to recruit, enroll, or retain patients into our clinical studies, delaying or potentially preventing us from completing clinical studies. 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.

The results of our clinical studies may not support our proposed claims for our product candidates. The results of previous clinical studies may not be predictive of future results, and interim or top-line data may be subject to change or qualification based on the complete analysis of data.

Even if our clinical studies are completed as planned, we cannot be certain that their results will support the efficacy or safety of our product candidates. For example, product candidates may not meet the criteria for success for their primary endpoint specified in the statistical analysis plan, highlighting the importance of appropriate selection of the primary endpoint, statistical powering of a clinical study, and diligent oversight of the treatment compliance of those patients enrolled into the study. Success in nonclinical testing and early clinical studies does not ensure that later clinical studies will be successful, and we cannot be sure that the results of later clinical studies will replicate the results of prior clinical studies and nonclinical testing. Likewise, promising results in interim analyses or other preliminary analyses do not ensure that the clinical study as a whole will be successful. In addition, the FDA may not agree that clinical study results are sufficient for approval for any product candidate, or even if approved, may not support a label that is capable of competing with existing treatments. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical studies, even after having achieved promising results in earlier nonclinical or clinical studies. These setbacks have been caused by, among other things, nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Positive results from any of our clinical studies may not be predictive of the results of any of our other ongoing and potential future clinical studies, and there can be no assurance that the results of studies conducted by third parties will be viewed favorably or are indicative of our own future study results. We may publicly disclose top-line or interim data from time to time, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review, audit and verification of the data related to the particular study. We 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 studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated.

A future failure of a clinical study to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical studies will delay the submission of our NDAs to the FDA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate product revenue.

Reported data or other clinical development announcements by Takeda may adversely affect our clinical development plan.

Takeda has developed relugolix for the treatment of women with uterine fibroid-associated pain and heavy menstrual bleeding in Japan. Takeda reported positive top-line results from its two Phase 3 clinical studies in Japan in women with uterine fibroids and has obtained market authorization in Japan from the Ministry of Health, Labor and Welfare for Relumina® Tablets 40 mg (generic name: relugolix) for the improvement of symptoms of uterine fibroids, including heavy menstrual bleeding, lower abdominal pain, lower back pain, and anemia. Favorable announcements by Takeda do not guarantee that the results of our clinical studies will also be favorable as the designs of our Phase 3 clinical studies differ from those of Takeda. Further, if clinical study or post-marketing adverse events regarding Relumina® are reported, or subsequent announcements by Takeda regarding relugolix are unfavorable, it could negatively impact our clinical development plans for or opinions of the FDA or other regulatory authorities with respect to relugolix. Additionally, the Phase 3 data from the Takeda studies of Relumina® will be available to us, and may be used to support our submissions to relevant regulatory authorities. We cannot provide assurance that the FDA or other health authorities will allow us to use the data from Takeda's clinical studies in support of any NDA or marketing authorization application that we may submit, and such data may be interpreted differently by the regulatory authorities and provide contradictory evidence in support of FDA's (or other regulatory authority) evaluation. If the FDA or other regulatory authorities do not allow us to use the data from Takeda's clinical studies, we may be required to perform additional clinical studies.

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. As a significant unmet medical need exists for the treatment of each of uterine fibroids, endometriosis, and advanced prostate cancer, as well as infertility in women, there are several large and small pharmaceutical companies focused on delivering therapies for the treatment of these indications. Further, it is likely that additional drugs are being developed or will become available in the future for the treatment of each of our target indications.

We are aware of several companies that are developing and commercializing drugs that would compete against relugolix combination tablet and relugolix monotherapy tablet for the treatment of heavy menstrual bleeding associated with uterine fibroids, pain associated with endometriosis, and/or advanced prostate cancer, and against MVT-602 for the treatment of female infertility as part of assisted reproduction.

Many of our current and potential future competitors have significantly more experience commercializing drugs and 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 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. Competition may reduce the number and types of patients available to us to participate in our clinical studies, because some patients who might have opted to enroll in our studies may instead opt to enroll in a study being conducted by one of our competitors or opt to take an approved product. The availability and pricing of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors.

The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, and inherently unpredictable. If we are not able to obtain required regulatory approvals, we will not be able to commercialize relugolix combination tablet, relugolix monotherapy tablet, or MVT-602, and our ability to generate product revenue will be materially impaired.

The time required to obtain approval of an NDA by the FDA or similar regulatory authorities outside of the U.S. is unpredictable but typically takes many years following the commencement of clinical studies 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 approvals may change during the course of a product candidate's clinical development and may vary among jurisdictions. Obtaining approval of an NDA from the FDA or a regulatory approval from a regulatory authority outside the U.S. is an expensive process. The submission of NDAs is subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual program user fees. We expect to incur additional costs in the fiscal year 2020 with the anticipated submission of NDAs to the FDA, including the fees associated with NDA and foreign equivalent submissions.

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 relugolix combination tablet, relugolix monotherapy tablet, and MVT-602 for the specified indication. The process of responding to the FDA information requests in the review process and preparing for and appearing at a public advisory committee will require significant human and financial resources. If the information from our completed clinical studies are insufficient to support regulatory approvals, we may have to complete ongoing or additional clinical studies. For example, GnRH receptor antagonists, like relugolix, when taken alone, may cause loss of bone mineral density due to the induced hypoestrogenic state that may limit duration of use. This risk, and a related risk of hot flash or vasomotor symptoms, may be mitigated by the co-administration of relugolix in combination with low-dose estradiol and a progestin. A key part of our relugolix clinical development strategy has been to formulate a single-tablet fixed-dose combination of relugolix with low-dose estradiol and a progestin (relugolix combination tablet) to maintain bone health and mitigate side effects of a low-estrogen state such as vasomotor symptoms, and to facilitate patient convenience and compliance. For our uterine fibroids NDA, we expect to submit data on a patient population followed for at least one year. If the FDA concludes that the data from these studies are insufficient to support regulatory approvals, we may be required to conduct further studies and we could face delays and increased expenses associated with our development programs and our commercial opportunity could be limited. If we are not able to obtain required regulatory approvals for relugolix combination tablet or if our competitors obtain regulatory approval of a fixed-dose combination with hormonal therapy before we do, we would be at a competitive disadvantage and this could limit our commercial opportunity.

We rely on third-party CROs and consultants to assist us in submitting 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 approvals or issues, including those related to gathering the appropriate data and the inspection process, may ultimately delay or affect our ability to obtain regulatory approvals, commercialize our product candidates, and generate product revenue. In addition, any adverse developments with respect to our contract manufacturing organizations, including adverse findings during inspections, or delays related to the COVID-19 pandemic may also ultimately delay or affect our ability to obtain regulatory approvals, commercialize our product candidates, and generate product revenue.

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 product candidates' full market potential.

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 in the U.S. does not ensure approval by regulatory authorities in any other country or jurisdiction. In addition, clinical studies 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 and additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical studies 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. We are reliant, in part, upon the regulatory expertise of Richter to gain approval for relugolix combination tablet in the licensed territories and are completely reliant on Richter to generate revenue in the licensed territories. If we or Richter 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.

Relugolix combination therapy, relugolix monotherapy and MVT-602 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 associated with relugolix combination therapy, relugolix monotherapy, or MVT-602 could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay, request modification of, or halt clinical studies and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in our clinical studies for relugolix combination therapy, relugolix monotherapy or MVT-602 or any future product candidates, our ability to obtain regulatory approval or a desirable label 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 study or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects.

In addition, the FDA has raised concern about a potential increase in the risk of diabetes and certain cardiovascular diseases in men with prostate cancer treated with GnRH receptor agonists. Further, if post-marketing adverse events related to Relumina® are reported, it could negatively impact our clinical development plans for relugolix.

If any of our 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 Risk Evaluation and Mitigation Strategy (a “REMS”) (or equivalent outside the U.S.) 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;
- we may be required to conduct post-marketing studies or clinical studies;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications or limit the duration of use;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we may be required to repeat a nonclinical or clinical study or terminate a program, even if other studies or studies 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 relugolix combination tablet, relugolix monotherapy tablet or MVT-602.

Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products may face future development risks 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 cGCP requirements for any clinical studies 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. Even if relugolix combination tablet, relugolix monotherapy tablet or MVT-602 receives marketing approval, if the indication approved by regulatory authorities is narrower than we expect or the accompanying label limits the approved use of our product, our sales of products could be limited and we may not generate significant revenue from sales of our products.

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. The FDA does not regulate the behavior of physicians in their choice of treatments and physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. However, the FDA does restrict manufacturer's communications on the subject of off-label use of their products. Regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use, and if regulatory authorities believe that we are in violation of these restrictions, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act in the U.S., 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 Attorney Generals and other foreign regulatory agencies alleging violations of U.S. 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 those discussed in the Risk Factor titled "Relugolix combination therapy, relugolix monotherapy and MVT-602 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."

Even if one of our 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 one of our 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, including the convenience and ease or duration of administration;
- the prevalence and severity of any side effects;
- the content of the approved product label and our ability to make compelling product claims;
- the effectiveness and adequacy of our marketing efforts, including direct-to-consumer advertising;
- the effectiveness of sales efforts;
- the patient out-of-pocket costs in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the willingness of the potential patient population to try new therapies and of physicians to prescribe these therapies;
- the breadth and cost of distribution support;
- the availability of third-party payor coverage;
- whether diagnosis and treatment rates increase for the diseases our products treat; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of relugolix combination tablet, relugolix monotherapy tablet and MVT-602, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of these product candidates to obtain market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, market access, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, if approved.

To market any product that may be approved, we must build our sales, market access, marketing, distribution, and other commercial capabilities or make arrangements with third parties to perform these services. There are significant expenses and risks involved with establishing our own sales, market access, marketing and distribution capabilities, including: (i) our inability to recruit, train, and retain adequate numbers of qualified and effective sales, market access and marketing personnel; (ii) our inability to attain access to adequate numbers of physicians to prescribe any drugs; (iii) the inability to negotiate with payors regarding reimbursement and formulary access for our products; and (iv) unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

Any failure or delay in the development of our internal sales, market access, marketing and distribution capabilities, or third-party marketing and distribution capabilities such as our relationship with Richter, could delay any product launch, which would adversely impact its commercialization. The COVID-19 pandemic may negatively impact our ability to attract the human resources required to build out our commercial capabilities and may negatively impact our ability to rapidly and effectively educate potential prescribers and, if significant delays result, to commercialize our product candidates.

We may not have the resources in the foreseeable future to allocate to the sales, market access, marketing and distribution of our product candidates in certain markets outside the U.S. We have pursued collaborative arrangements regarding these functions for certain markets outside the U.S.; however, it might be difficult for us to find third parties in other markets that are willing to enter into such transactions on acceptable economic terms, or at all.

To the extent that we depend on third parties for sales, market access, marketing and distribution, such as our relationship with Richter, the financial returns to us will depend on our future collaborators' capabilities. If any such future collaborator terminates its collaboration with us or fails to perform or satisfy its obligations to us, the sales, distribution and marketing of our product candidates would be delayed or may not occur and our business and prospects could be materially and adversely affected.

If we are unable to establish adequate sales, market access, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may not become profitable. We will be competing with 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.

Our current and future relationships with investigators, healthcare 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 channels, 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, the federal false claims laws, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the federal Physician Payments Sunshine Act and analogous state laws.

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, 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.

Changes in legislation may increase the difficulty and cost for us to obtain marketing approval for and commercialize relugolix combination tablet, relugolix monotherapy tablet or MVT-602 and affect the prices we may obtain.

In the U.S. 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 relugolix combination tablet, relugolix monotherapy tablet or MVT-602, restrict or regulate post-approval activities, and affect our ability to profitably sell any products for which we obtain marketing approval.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, President Trump previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs, that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020.This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, individual states in the U.S. have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. 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. It is also possible that additional governmental action is taken to address the COVID-19 pandemic.

Coverage may not be available for our product candidates, which could make it difficult for us to sell them profitably, if approved.

Market acceptance and sales of any approved product that we develop will depend in part on the extent to which coverage for these products will be available from third-party payors, including government health administration authorities and private health insurers. In the U.S., no uniform policy of coverage for products exists among third-party payors. Third-party payors decide which drugs they will pay for, what steps prescribers must take to obtain authorization for patients to fill their prescriptions, and how much patients must pay out of their own pocket. Payor decisions regarding the extent of coverage 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 for the product. Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an affordable out-of-pocket cost for patients will be established. 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 or prior authorizations. 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 may not use our products unless coverage is provided and out-of-pocket costs for them are affordable. Manufacturers have the ability to lower costs for patients with commercial insurance through various patients' saving offers such as co-pay cards or coupons. These types of consumer programs are not permissible for patients who participate in government health insurance programs such as Medicare or Medicaid.

Even if a payor places a product on its formulary, it may put in place procedures designed to control the utilization of our drugs, such as step-edits or prior-authorizations. Step edits require that a patient first try and fail to be adequately treated by one or more other prescription or over-the-counter medications. Prior authorizations require a physician to demonstrate with sufficient

paperwork that a patient meets one or more criteria, such as having a formal diagnosis of the condition for which the drug is indicated, before the coverage for such drug can be provided. As a result, these additional requirements may deter physicians from prescribing our drugs.

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 that such a payor will pay for the product. Even if we do obtain adequate levels of formulary access, 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 affordable patient out-of-pocket costs will be available for any product that we commercialize. Inadequate coverage, patient affordability, and drug utilization controls 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 U.S. and in some foreign jurisdictions that could affect our ability to sell any future drugs profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future drugs, if approved.

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 drug substance and drug product.

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. While relugolix and MVT-602 were being developed by Takeda, they were also being manufactured by Takeda and third-party CMOs. Under the Takeda Clinical Supply Agreement, Takeda supplied us with, and we obtained from Takeda, all of our requirements for relugolix drug substance and drug product that were used under our development plans for all indications. We expect that manufacturing support provided by Takeda will be sufficient for us to complete our ongoing Phase 3 programs for relugolix.

Takeda is no longer developing MVT-602. Additional process development and manufacturing would be required for us to complete further Phase 2 and Phase 3 clinical studies for MVT-602. Third-party vendors may be difficult to identify for MVT-602 process and formulation development and manufacturing due to special capabilities required and they may not be able to meet our quality standards.

If we need to replace a third-party manufacturer, or if any of our third-party manufacturers experience adverse developments, including with respect to adverse findings during inspections and/or the COVID-19 pandemic, we could experience a significant delay in the supply of a product candidate, or the raw material components thereof, which could result in a considerable delay in completing our clinical studies, 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.

We also will rely on Takeda and other third-party manufacturers to supply us with sufficient quantities of drug substance and drug product to be used, if approved, for the commercialization of any of our products. The facilities used by Takeda and our other contract manufacturers to manufacture our product candidates must be approved by the regulatory authorities pursuant to inspections that will be conducted after we submit our regulatory applications to such regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and other regulations and laws for the manufacture of relugolix drug substance and 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 and any applications that we submit to the FDA or other regulatory authorities that list those manufacturing facilities may be negatively affected. Our third-party contract manufacturing facilities must also be in an acceptable state of cGMP compliance and not be subject to a cGMP related regulatory or enforcement action that limits their ability to manufacture drug substance or drug product for commercial use. The FDA or other regulatory authority may withhold approval of any pending regulatory applications or supplements in which non-complaint facilities are listed. 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 and timing to develop, obtain regulatory approval for or market our product candidates, if approved.

Our product candidates contain highly potent compounds and therefore require specialized manufacturing facilities. Depending on actual commercial demand, additional third-party manufacturing facilities will have to be established to meet the demand through technology transfer, process validation and regulatory approval before product manufactured at the new facilities can be marketed. Any delay in the technology transfer and process validation could limit adequate supply to meet our commercial demand.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- delay or inability to manufacture relugolix combination tablet;
- failure of the drug substance transferred from Takeda or our other CMOs to meet our product specifications and quality requirements;
- 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 relugolix combination tablet, relugolix monotherapy tablet, or MVT-602, if approved, or any future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- adverse inspection findings by the FDA or other regulatory authorities at third-party manufacturing facilities and/or failure to remediate such findings;
- cGMP regulatory or enforcement action at our third-party manufacturing facilities that limit their ability to manufacture drug substance or drug product for commercial use;
- 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.

Any of these events could also lead to clinical study delays, cost overruns, delay or failure to obtain regulatory approval or impact our ability to successfully commercialize our products, as well as potential product liability litigation, product recalls or product withdrawals. Some of these events could be the basis for the FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production.

Regulatory requirements or manufacturing disruptions may make it difficult for us to be able to obtain materials or supplies necessary to conduct clinical studies or to manufacture and sell any of our product candidates, if approved.

To sustain our business, we need access to sufficient quantities of our product candidates to satisfy our clinical study needs and, if approved, to maintain sufficient commercial inventories of our products. If we are unable to purchase sufficient quantities of these materials or find suitable alternate materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture commercial products would be limited.

Suppliers of key components and materials must be named in the NDA or marketing authorization application filed with the FDA, the EMA, or other regulatory authority for any product candidate for which we are seeking marketing approval, and significant delays can occur if those suppliers are not approved or the qualification of a new supplier is required. Even after a manufacturer is qualified by the regulatory authority, the manufacturer must continue to expend time, money, and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the regulatory authorities both prior to and following initial approval. If, as a result of these inspections, a regulatory authority determines that the equipment, facilities, laboratories or processes do not comply with applicable regulations and conditions of product approval,

the regulatory authority may suspend the manufacturing operations, issue import restrictions or other cGMP or regulatory action that could affect our ability to obtain materials from such supplier. If the manufacturing operations of any single suppliers for any of our products are adversely affected or suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet demand, which could harm our business. In addition, if delivery of materials from our suppliers was interrupted for any reason, we may be unable to ship commercial products that may be approved for marketing or supply our products in development for clinical studies. In addition, some of our products and the materials that we utilize in our operations are made only at one facility, which we may not be able to replace in a timely manner and on commercially reasonable terms, or at all. Problems with any of the single suppliers we depend on, including in the event of a disaster, including an earthquake or a pandemic, equipment failure, or other difficulty, may negatively impact our development and commercialization efforts. If we were to encounter any of these difficulties, our ability to provide our products, if approved, and product candidates to patients would be jeopardized.

We are reliant on third parties to conduct, manage, and monitor our clinical studies, 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 ("GLP") requirements. We also do not currently have the ability to independently conduct any clinical studies. We rely substantially on CROs and clinical study sites to ensure the proper and timely conduct of our clinical studies, 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 current 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 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, respectively. The regulatory authorities enforce GCP regulations through periodic inspections of clinical study sponsors, principal investigators, and clinical study sites. Although we rely on CROs to conduct our GLP-compliant nonclinical studies and GCP-compliant clinical studies, we remain responsible for ensuring that each of our GLP nonclinical studies and GCP clinical studies 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 current GCP requirements, the clinical data generated in our clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities may reject our marketing applications or require us to perform additional clinical studies 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 studies, 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 the sponsor of those studies.

While we have agreements governing their activities, our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies, 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 studies 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.

In addition, we and our CROs are subject to various data privacy laws in the U.S., Europe, and elsewhere that are often uncertain, contradictory, and evolving. It is possible that these data privacy laws may be interpreted and applied inconsistent with our or our CROs practices. If so, this could result in government-imposed fines or orders requiring that we or our CROs change our practices, which could adversely affect our business. Also, see the Risk Factor titled "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."

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 materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition, and prospects.

Risks Related to Our Intellectual Property

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

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to relugolix, MVT-602, and any future product candidates. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our 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.

The patents and patent applications that we own or have in-licensed may fail to result in issued patents with claims that protect relugolix, MVT-602 or any future product candidate in the U.S. 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. Even if patents do successfully issue and even if such patents cover relugolix, MVT-602 or any future product candidate, 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 could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. 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 relugolix, MVT-602 or any future product candidate, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize future drugs. Any such outcome could have a materially 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 been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the U.S. 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 of these and other factors, 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 U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (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. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in

examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be 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 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 candidates.

We have licensed certain intellectual property rights covering our current product candidates from Takeda. If, for any reason, the Takeda License Agreement is terminated or we otherwise lose those rights, it could adversely affect our business. The Takeda License Agreement imposes, 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 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 relugolix, MVT-602 or any future product candidate, our competitors might be able to enter the market, which would have an adverse effect on our business.

Third party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent the development and commercialization of relugolix combination therapy, relugolix monotherapy, MVT-602, and any future product candidate.

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 U.S., involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation, and administrative law proceedings, *inter partes* review, and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties. Third parties may assert that we are infringing their patents or employing their proprietary technology without authorization.

Also, 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 which may later result in issued patents that our product candidates may infringe.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon rights. 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 were 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. We cannot provide any assurances that third-party patents do not exist which might be enforced against our drugs or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

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

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.

Changes in U.S. 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 U.S. has enacted and implemented wide-ranging patent reform legislation. The U.S. 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 U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce 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.

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 relugolix, MVT-602, and any future product candidate 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 U.S. 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.

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 relugolix combination therapy, relugolix monotherapy, MVT-602, and any future product candidates, and we expect to collaborate with third parties on the development of relugolix, MVT-602, and any future product candidates, we must, at times, share trade secrets with them. We also conduct joint R&D programs that may require us to share trade secrets under the terms of our R&D partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. 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. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Our Common Shares

We have agreements with Sumitovant Biopharma Ltd. ("Sumitovant"), our majority shareholder, and with Sumitovant's parent, Sumitomo Dainippon Pharma, that may be perceived to create conflicts of interest which, if other investors perceive that Sumitovant or Sumitomo Dainippon Pharma will not act in the best interests of all of our shareholders, may affect the price of our common shares and have other effects on our company.

There are a number of relationships that may give rise to certain conflicts of interest between Sumitovant and Sumitomo Dainippon Pharma, on the one hand, and the other investors of our common shares and us, on the other hand. We are party to a loan agreement with Sumitomo Dainippon Pharma that creates restrictions, including limiting or restricting our ability to take specific actions, such as raising additional capital, incurring additional debt, making capital expenditures, or declaring dividends. Further, we are party to an Investor Rights Agreement with Sumitovant and Sumitomo Dainippon Pharma that, although designed in part to provide protections for our minority shareholders, also provides rights to Sumitovant and Sumitomo Dainippon Pharma, such as the ability of Sumitomo Dainippon Pharma to appoint directors on our board, to maintain their share ownership percentage in our company, and provide Sumitomo Dainippon Pharma with certain information and give them access to certain of our records. We may enter into additional agreements with Sumitovant or Sumitomo Dainippon Pharma in the future. Sumitovant and Sumitomo Dainippon Pharma may have interests which differ from our interests or those of the minority holders of our common shares. Any material transaction between us and Sumitomo Dainippon Pharma and its affiliates is subject to our related party transaction policy and the Investor Rights Agreement, which requires prior approval of such transaction by our Audit Committee comprised of three independent 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 conduct business with us, all of which could have an adverse effect on our business, financial condition, results of operations, and cash flows, and on the market price of our common shares. Further, our agreements with Sumitovant and Sumitomo Dainippon Pharma may result in unanticipated risks or other unintended consequences on our business and on investor perception that could have a significant impact on the market price of our common shares.

The market price of our common shares has been and is likely to continue to be highly volatile, and you may lose some or all of your investment.

The market price of our common shares has been and is likely to continue to be highly volatile and may be subject to significant fluctuations in response to a variety of factors, including, but not limited to, the following:

- inability to obtain additional funding, or investor perception that we may be unable to obtain additional funding or funding on desirable terms;
- any delay in the commencement, enrollment, and ultimate completion of our clinical studies;
- actual or anticipated results of clinical studies of any of our product candidates or those of our competitors;
- any delay in submitting an NDA or similar application for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA or other regulatory authority's review of that NDA or similar application, as the case may be;
- failure to successfully develop and commercialize any of our current or future product candidates;
- regulatory or legal developments in the U.S. or other countries or jurisdictions applicable to any of our current or future product candidates;
- adverse regulatory decisions or findings;
- changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for any of our current or future product candidates, or the inability to do so at acceptable prices;
- inability to hire a qualified sales force in a timely fashion;
- inability to establish commercial capabilities and expertise including product marketing, sales, trade and distribution, pricing, market access, data analytics and insights, and other commercial operations functions;
- adverse developments or perceived adverse developments with respect to our third-party vendors on which we rely, including contract manufacturing organizations and contract research organizations;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to maintain effective internal control over financial reporting;

- failure to meet or exceed the estimates and projections of the investor 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;
- adverse developments or perceived adverse developments with respect to our alliance partners and affiliates including Takeda, Sumitovant, Sumitomo Dainippon Pharma and/or Richter;
- 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 management or other key personnel;
- short sales of our common shares;
- sales or purchases of a substantial number of our common shares in the public market, by any of our larger shareholders, or the perception in the market that the holders of a large number of our common shares intend to sell or purchase common shares;
- sales or purchases of our common shares by our executive officers;
- issuance of additional shares of our common shares, or the perception that such issuances may occur, including through our "at-the-market" equity offering program;
- negative coverage in the media or analyst reports, whether accurate or not;
- any changes in our relationship with Sumitovant and/or Sumitomo Dainippon Pharma, or actions taken or omission of actions with respect to the Sumitomo Dainippon Pharma Loan Agreement or the Investor Rights Agreement;
- issuance of subpoenas or investigative demands, or the public fact of an investigation by a government agency, whether meritorious or not;
- trading liquidity of our common shares;
- investors' general perception of our company, our business, and our majority shareholder;
- general political, economic, industry, and market conditions;
- effects of natural or man-made catastrophic events, including the COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

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

Stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory, and market conditions, may negatively affect the market price of our common shares, regardless of our actual operating performance.

Additionally, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant share price volatility in recent years. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations, and growth prospects.

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

We are currently a "controlled company" within the meaning of the NYSE corporate governance requirements. Under these rules, a "controlled company" may elect not to comply with certain corporate governance requirements. 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 afforded to shareholders of companies that are subject to all of the NYSE corporate governance requirements.

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

We have never declared or paid any cash dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. We are also subject to Bermuda legal constraints that may affect our ability to pay dividends on our common shares and make other payments. Additionally, our ability to pay dividends is currently restricted by the terms of the Sumitomo Dainippon Pharma Loan Agreement. As a result, capital appreciation, if any, of our common shares would be your sole source of gain on an investment in our common shares for the foreseeable future.

We are an exempted company limited by shares incorporated under the laws of Bermuda and it may be difficult for you to enforce judgments against us or our directors and executive officers.

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

Bermuda law differs from the laws in effect in the U.S. 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, (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 U.S., 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 U.S.

There are regulatory limitations on the ownership and transfer of our common shares.

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

approval of such issue or transfer. The general permission or the specific permission would cease to apply if we were to cease to be listed on the NYSE or another appointed stock exchange.

Legislation enacted in Bermuda as to economic substance may affect our operations.

Pursuant to the Economic Substance Act 2018 of Bermuda, as amended (the "Economic Substance Act") that came into force on January 1, 2019, a registered entity other than an entity which is resident for tax purposes in certain jurisdictions outside Bermuda (a "non-resident entity") that carries on as a business any one or more of the "relevant activities" referred to in the Economic Substance Act must comply with economic substance requirements. The Economic Substance Act may require in-scope Bermuda entities which are engaged in such "relevant activities" to be directed and managed in Bermuda, have an adequate level of qualified employees in Bermuda, incur an adequate level of annual expenditure in Bermuda, maintain physical offices and premises in Bermuda or perform core income-generating activities in Bermuda. The list of "relevant activities" includes carrying on any one or more of: banking, insurance, fund management, financing, leasing, headquarters, shipping, distribution and service centre, intellectual property and holding entities.

Based on the Economic Substance Act currently, for so long as we are a non-resident entity, we are not required to satisfy any such economic substance requirements other than providing the Bermuda Registrar of Companies annually information on the jurisdiction in which it claims to be resident for tax purposes together with sufficient evidence to support that tax residence. We currently do not anticipate material impact on our business or operations from the Economic Substance Act. However, since such legislation is new and remains subject to further clarification and interpretation, it is not currently possible to ascertain the precise impact of the Economic Substance Act on us. If we ceased to be a non-resident entity, we may be unable to comply with the Economic Substance Act or may have to restructure our business to comply with the Economic Substance Act, either of which may have a material adverse effect on our business.

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 U.K., and under current U.K. tax law, a company which is centrally managed and controlled in the U.K. is regarded as resident in the U.K. 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 U.K. 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 are incorporated under the laws of Bermuda. We currently have subsidiaries in the U.K., Switzerland, Ireland, and the U.S. 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 our subsidiaries and us. 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 tax authorities.

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting, and other laws, regulations, principles, and interpretations. In addition, our effective tax rate 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 tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. If tax 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 tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations, and cash flows.

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 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 other 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.

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 tax authorities in Europe (including the U.K. and Switzerland), the U.S., Bermuda, and other jurisdictions, as well as being affected by certain changes resulting from the Organization 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 was to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties, and reputational damage, which could adversely affect our business, results of our operations, and our financial condition.

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

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

A non-U.S. corporation is considered a CFC if more than 50 percent 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 U.S. shareholders (U.S. persons who own stock representing 10% or more of the vote 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 U.S. 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 U.S. 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 will be classified as CFCs in the current taxable year. For U.S. holders who hold 10% or more of the vote or value of our common shares, this may result in adverse U.S. federal income tax consequences, such as current U.S. taxation of Subpart F income and of any such shareholder's share of our accumulated non-U.S. earnings and profits (regardless of whether we make any distributions), taxation of amounts treated as global intangible low-taxed income under Section 951A of the Code with respect to such shareholder, and being subject to certain reporting requirements with the U.S. Internal Revenue Service. Any such U.S. holder who is an individual generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a U.S. corporation. If you are a U.S. holder who holds 10% or more of the vote or value of our common shares, you should consult your own tax advisors regarding the U.S. tax consequences of acquiring, owning, or disposing our common shares.

U.S. holders of our common shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would

be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Additionally, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our common shares may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our common shares. In addition, special information reporting may be required.

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. With respect to the taxable year that ended on March 31, 2020, we believe that we were not a PFIC; however, with respect to the current taxable year and foreseeable future taxable years, because the PFIC tests are based upon the value of our assets, including any goodwill and going concern value, and the nature and composition of our income and assets, which cannot be known at this time, we cannot predict whether we will or will not be classified as a PFIC. Because the determination of whether we are a PFIC for any taxable year is a fact-intensive determination made annually after the end of each taxable year, and because certain aspects of the PFIC rules are uncertain, we cannot provide any assurances regarding our PFIC status for the current or future taxable years.

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 are classified as a PFIC. In addition, recently proposed U.S. Treasury Regulations, which we are continuing to assess the impact of, may also adversely affect the treatment of these structures and arrangements with respect to our PFIC status.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located at Suite 1, 3rd Floor, 11-12 St. James's Square, London, United Kingdom SW1Y 4LB. Our registered office is located at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. We also have business operations in Brisbane, California and Basel, Switzerland. We do not own any properties.

We lease 40,232 square feet of office space located in Brisbane, California, pursuant to a lease agreement that expires in May of 2026, for which we have the option to extend the lease term for an additional seven years. We also sublease 20,116 square feet of office space pursuant to a sublease agreement that expires in February of 2024. 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 result, 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

Our common shares began trading on the New York Stock Exchange ("NYSE") under the symbol "MYOV" on October 27, 2016. Prior to that date, there was no 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 May 14, 2020, we had nine shareholders of record of our common stock. We believe that the number of beneficial owners of our common shares at that date was substantially greater. The number of holders of record is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

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. Furthermore, our ability to pay cash dividends is currently restricted by the terms of the Sumitomo Dainippon Pharma Loan Agreement.

Recent Sales of Unregistered Equity Securities

Not applicable.

Purchases of Equity Securities by the Issuer

None.

Item 6. Selected Financial Data

Under SEC rules and regulations, because we are considered to be a "smaller reporting company," we are not required to provide the information required by this item in this Annual Report on Form 10-K.

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. This section generally discusses the fiscal years ended March 31, 2020 and 2019 items and comparisons between these fiscal years. Discussions of the fiscal year ended March 31, 2018 items and comparisons between the fiscal years ended March 31, 2019 and 2018 that are not included in this Annual Report on Form 10-K can be found in Item 7 of Part II, "Management's Discussion and Analysis of Financial Condition and Results of Operations," of our Annual Report on Form 10-K for the fiscal year ended March 31, 2019 filed with the United States Securities and Exchange Commission on May 24, 2019.

Business Overview

We are a healthcare company focused on redefining care for women and for men. Our lead product candidate is relugolix, a once-daily, oral, gonadotropin-releasing hormone ("GnRH") receptor antagonist for which we have successfully completed multiple Phase 3 clinical studies across three distinct indications. We are preparing for potential commercial launches in the U.S. of relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) for women with heavy menstrual bleeding associated with uterine fibroids or pain associated with endometriosis and relugolix monotherapy tablet (120 mg) for men with advanced prostate cancer, in anticipation of U.S. Food and Drug Administration ("FDA") approval to market in these indications. We submitted our New Drug Application ("NDA") to the FDA for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer in April 2020, and currently expect to submit an NDA to the FDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids in May 2020. We announced positive results from the first of two replicate Phase 3 clinical studies evaluating relugolix combination therapy in women with pain

associated with endometriosis, and expect to announce top-line results from the second study in the second quarter of calendar year 2020. In addition, we are developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as a part of assisted reproduction. Takeda Pharmaceuticals International AG ("Takeda"), a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, granted us a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive right to develop and commercialize MVT-602 in all countries worldwide. On March 30, 2020, we entered into an exclusive license agreement with Gedeon Richter Plc. ("Richter") for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside of the U.S. Under this agreement, we have retained all of our rights to relugolix combination tablet in the U.S. and Canada, as well as rights to relugolix in other therapeutic areas outside of women's health. In March 2020, we submitted a Marketing Authorisation Application ("MAA") to the European Medicines Agency ("EMA") for relugolix combination tablet in uterine fibroids. The MAA submission has completed validation and is now under evaluation by the EMA. Additional information regarding our business and product candidates is included in Part I. Item 1., "Business," of this Annual Report on Form 10-K.

Since our inception, we have devoted substantially all of our efforts to identifying and in-licensing our product candidates, organizing and staffing our company, raising capital, preparing for and advancing the clinical development of our product candidates and preparing for potential future regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet.

On December 27, 2019, Sumitovant BioPharma Ltd. ("Sumitovant"), a subsidiary of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma"), became our majority shareholder and a related party after acquiring approximately 50.2% of our common shares outstanding on December 27, 2019. These common shares were acquired from our former majority shareholder, Roivant Sciences Ltd. ("Roivant," "RSL," or "former majority shareholder") at the closing of a transaction between Roivant and Sumitomo Dainippon Pharma. As of March 31, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own approximately 52.1% of our outstanding common shares. As a result of the transfer of these common shares, Roivant no longer beneficially owns any of our common shares.

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. Additional information regarding our relugolix and MVT-602 clinical programs is included in Part I. Item 1., "Business," of this Annual Report on Form 10-K.

Relugolix Clinical Programs

- ***Phase 3 Program for the Treatment of Advanced Prostate Cancer (HERO)***
  - On April 21, 2020, we announced the submission of an NDA to the FDA for once-daily, oral relugolix monotherapy tablet (120 mg) for the treatment of men with advanced prostate cancer. The NDA submission was supported by efficacy and safety data from the Phase 3 HERO study, a randomized pivotal study comparing relugolix monotherapy versus leuprolide acetate. In the HERO study, relugolix monotherapy met the primary efficacy endpoint with 96.7% of men achieving sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks, and all tested key secondary endpoints, while demonstrating 54% fewer major adverse cardiovascular events as compared with leuprolide injections administered every 3 months.
  - We enrolled 434 men with metastatic prostate cancer in the HERO study, comprising 295 men from the original HERO study and an additional cohort of 139 men that completed enrollment in July 2019. We filed an amendment to the HERO study protocol to enroll 139 additional men with metastatic prostate cancer and to add the secondary objective of demonstrating that relugolix can delay the time to progression to the lethal state of the disease, castration-resistant prostate cancer, as compared to leuprolide. We currently expect to report additional data from the HERO study measuring castration resistance-free survival in approximately 430 men with metastatic prostate cancer in the third quarter of calendar year 2020.
  - New efficacy and cardiovascular safety data from our HERO study will be presented in an oral presentation at the American Society of Clinical Oncology Virtual Scientific Program on May 29, 2020.
- ***Phase 3 Program for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids (LIBERTY)***
  - On May 14, 2019, we announced that LIBERTY 1, the first of two replicate Phase 3 studies evaluating once-daily relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids, met its primary efficacy endpoint and six key secondary endpoints. In the primary endpoint analysis, 73.4% of women receiving once-daily oral relugolix combination therapy achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). The 24-week study achieved six key secondary endpoints with statistical significance compared to placebo, including mean change in menstrual blood loss from baseline to week 24, reduction

in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.

- On July 23, 2019, we announced that LIBERTY 2, the second of two replicate Phase 3 studies evaluating once-daily relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids, met its primary efficacy endpoint and six key secondary endpoints. In the primary endpoint analysis, 71.2% of women receiving once-daily oral relugolix combination therapy achieved the responder criteria compared with 14.7% of women receiving placebo ($p < 0.0001$). The 24-week study achieved the same six key secondary endpoints with statistical significance compared to placebo as those in LIBERTY 1 including mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea (defined as no or negligible blood loss), improvement in anemia in those women with anemia at baseline, and reduction in uterine volume. The seventh key secondary endpoint, reduction in uterine fibroid volume, did not achieve statistical significance.
- In February 2020, we announced positive safety and efficacy data from the Phase 3 LIBERTY long-term extension study of relugolix combination therapy in women with heavy menstrual bleeding associated with uterine fibroids with an 87.7% response rate and, on average, an 89.9% reduction in menstrual blood loss from baseline, while demonstrating maintenance of bone mineral density through one year consistent with LIBERTY 1 and 2.
- On March 9, 2020, we announced the submission of a MAA to the EMA for relugolix combination tablet for the treatment of women with moderate to severe symptoms associated with uterine fibroids. The MAA submission has completed validation and is now under evaluation by the EMA.
- We currently expect to submit an NDA to the FDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids in May 2020.

- ***Phase 3 Program for the Treatment of Pain Associated with Endometriosis (SPIRIT)***
  - On April 22, 2020, we announced that SPIRIT 2, the first of two Phase 3 studies evaluating once-daily relugolix combination therapy in women with pain associated with endometriosis, met its co-primary efficacy endpoints and six key secondary endpoints. In the co-primary endpoint analysis of SPIRIT 2, 75.2% of women receiving once-daily oral relugolix combination therapy achieved a clinically meaningful reduction in dysmenorrhea versus 30.4% of women in the placebo group ($p < 0.0001$). For nonmenstrual pelvic pain, relugolix combination therapy achieved a clinically meaningful reduction in 66.0% of women versus 42.6% of women in the placebo group ($p < 0.0001$). On average, women receiving relugolix combination therapy had a 75.1% reduction on the 11-point (0 to 10) Numerical Rating Scale for dysmenorrhea from 7.2 (severe pain) to 1.7 (mild pain). Six key secondary endpoints measured at Week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the Endometriosis Health Profile-30 (EHP-30) pain domain, a greater proportion of women not using opioids (all p-values < 0.0001), changes in nonmenstrual pelvic pain ($p = 0.0012$), and dyspareunia (painful intercourse) ($p = 0.0489$). An endpoint evaluating change in analgesic use did not achieve statistical significance.
  - We completed enrollment of 638 patients in the SPIRIT 1 study and currently expect to report top-line results from the SPIRIT 1 study in the second quarter of calendar year 2020.

- ***Ovulation Inhibition Study***
  - On April 22, 2020, we announced results from an open-label, single-arm ovulation inhibition study consisting of a pre-treatment period to confirm ovulatory status, an 84-day treatment period (three cycles) to assess the effects of relugolix combination therapy on ovulation inhibition, and a post-treatment follow-up period to determine the time to the return of ovulation. Ovulation inhibition was based on the Hoogland-Skouby scale. In this study, relugolix combination therapy achieved 100% ovulation inhibition in 67 healthy women with no women ovulating during the 84-day treatment period, as evaluated by the Hoogland-Skouby assessment scale (score < 5). Furthermore, 100% of women resumed ovulation or menses upon discontinuation of treatment with an average time to ovulation of 23.5 days.

- ***Bioequivalence Study of Relugolix Combination Therapy and Relugolix Combination Tablet***

  - On July 23, 2019, we announced that a separate clinical study of our relugolix combination tablet met all required and pre-specified criteria for bioequivalence to the two tablets (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) used in our Phase 3 uterine fibroid and endometriosis clinical studies, providing data necessary to include the once-daily dosing regimen of relugolix combination tablet in our NDA and MAA submissions for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis.

Corporate

- On June 4, 2019, we completed an underwritten public equity offering of 17,424,243 of our common shares at a public offering price of $8.25 per common share. After deducting the underwriting discounts and commissions and offering costs paid by us, the net proceeds to us in connection with the underwritten public equity offering were approximately $134.5 million.
- On December 27, 2019, Sumitovant became our majority shareholder and a related party after acquiring 45,008,604 of our outstanding common shares, representing approximately 50.2% of our common shares outstanding on December 27, 2019. These common shares were acquired from our former majority shareholder, Roivant, at the closing of a transaction between Roivant and Sumitomo Dainippon Pharma. As of May 14, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,468,472 of our outstanding common shares, representing approximately 53.9% of our common shares outstanding on May 14, 2020.
- On December 27, 2019, we entered into an Investor Rights Agreement with Sumitomo Dainippon Pharma and Sumitovant that provides certain protections for our minority shareholders for so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially own more than 50% of our common shares. Pursuant to the Investor Rights Agreement, among other things, we agreed, at the request of Sumitovant, to register for sale, under the Securities Act of 1933, common shares beneficially owned by Sumitovant, subject to specified conditions and limitations. In addition, we agreed to periodically provide Sumitovant (i) certain financial statements, projections, capitalization summaries and other information and (ii) access to our books, records, facilities, and employees.
- On December 27, 2019, we, and our subsidiary, Myovant Sciences GmbH (“MSG”), entered into a loan agreement with Sumitomo Dainippon Pharma (the “Sumitomo Dainippon Pharma Loan Agreement”) under which Sumitomo Dainippon Pharma agreed to make revolving loans to us in an aggregate principal amount of up to $400.0 million, subject to the terms of the Sumitomo Dainippon Pharma Loan Agreement. Through March 31, 2020, we have borrowed $113.7 million under the Sumitomo Dainippon Pharma Loan Agreement, which was used to repay all outstanding obligations of us and our subsidiaries to Hercules Capital, Inc. (“Hercules”) and NovaQuest Capital Management (“NovaQuest”) and to satisfy certain other fees and expenses. As of March 31, 2020, approximately $286.3 million of borrowing capacity remained available to us under the Sumitomo Dainippon Pharma Loan Agreement. In April 2020, we borrowed an additional $80.0 million under the Sumitomo Dainippon Pharma Loan Agreement. The interest rate for any draws under the Sumitomo Dainippon Pharma Loan Agreement is the 3-month London Interbank Offered Rate (“LIBOR”) plus a margin of 3%.
- On March 30, 2020, we entered into an exclusive license agreement with Richter for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside of the U.S. We have retained all of our rights to relugolix combination tablet in the U.S. and Canada, as well as rights to relugolix in other therapeutic areas outside of women’s health. On March 31, 2020, we received an upfront payment of $40.0 million, which is included in current deferred revenue on our audited consolidated balance sheet, and are eligible to receive up to $40.0 million in regulatory milestones (of which $10.0 million was received in April 2020) and up to $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval. We have also agreed to assist Richter in transferring manufacturing technology from our contract manufacturing organizations to enable Richter to manufacture relugolix combination tablet. If requested by Richter, we have agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to our agreements with our contract manufacturing organizations.

Financial History

We have incurred, and expect to continue to incur, significant operating losses and negative operating cash flows as we continue to develop our product candidates and prepare for the potential future regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet. To date, we have not generated any product revenue, and we do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for one of our product candidates. We have funded our operations primarily from the issuance and sale of our common shares and from debt financing arrangements.

As of March 31, 2020 and 2019, we had an accumulated deficit of $791.0 million and $502.0 million, respectively. We had net losses of $289.0 million and $273.6 million for the years ended March 31, 2020 and 2019, respectively. As of March 31, 2020,

we had cash, cash equivalents, marketable securities, and committed funding available to us of $365.9 million consisting of $79.6 million of cash, cash equivalents, and marketable securities and $286.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement, as compared to $156.1 million of cash and cash equivalents and no committed funding available to us as of March 31, 2019. We are permitted to request quarterly draws under the Sumitomo Dainippon Pharma Loan Agreement, subject to certain terms and conditions, including consent of our board of directors. In April 2020, we borrowed an additional $80.0 million under the Sumitomo Dainippon Pharma Loan Agreement.

COVID-19 Pandemic

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic ("COVID-19 pandemic") based on the rapid increase in exposure globally.

To date, the impact of the COVID-19 pandemic on our ability to advance our clinical studies, regulatory activities, and preparation for the potential commercialization of our product candidates has been limited and all of our publicly announced milestones remain on track. However, if the COVID-19 pandemic persists, and depending on the further evolution of the pandemic and its effects on our activities, we may experience more significant impacts on our business operations. Refer to the risk factor titled "Business interruptions resulting from effects of pandemics or epidemics such as the novel strain of the coronavirus known as COVID-19, may materially and adversely affect our business and financial condition," as well as other risk factors included in the section titled "Risk Factors" set forth in Part I. Item 1A. of this Annual Report on Form 10-K.

Financial Operations Overview

Revenue

To date, we have not generated any product revenue, and we do not expect to generate any revenue, from the sale of any products unless and until we obtain regulatory approval of and commercialize relugolix combination tablet, relugolix monotherapy tablet, MVT-602, or a potential future product candidate.

Research and Development Expenses

Our research and development ("R&D") expenses to date have been primarily limited to the clinical development of our product candidates including the conduct of multiple Phase 3 and earlier clinical studies, the expansion of our team, and the initiation of activities in preparation for our anticipated commercial launches such as the establishment of our medical affairs function, as well as certain manufacturing activities. Our R&D expenses include program-specific costs, as well as costs that are not allocated to a specific program.

Program-specific costs primarily include third-party costs, which include expenses incurred under agreements with contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"), the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, manufacturing costs in connection with producing materials for use in conducting nonclinical and clinical studies, as well as costs related to manufacturing activities in connection with preparations for our anticipated commercial launches and regulatory submissions for relugolix combination tablet and relugolix monotherapy tablet, 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 for employees engaged in R&D activities including clinical operations, biostatistics, regulatory, and medical affairs, the cost of contractors and consultants who assist with R&D activities not specific to a program, and costs billed and allocated to us from our former majority shareholder pursuant to the Services Agreements that were terminated on December 27, 2019 (See Note 7(B) to the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K).

R&D activities have been, and will continue to be, central to our business model. Product candidates in later stages of clinical development, such as relugolix, 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 studies. It is difficult to determine with certainty the duration and completion costs of any clinical study that we may conduct. We expect our overall R&D expenses to continue to be a significant area of spend. We expect our overall R&D expenses to decrease over the next few quarters as we expect to complete our Phase 3 studies. However, we also expect the decreases in clinical study expenses will be partially offset by increases in other R&D expenses as we prepare regulatory submissions for our product candidates, establish a medical affairs function, and incur manufacturing expenses in connection with preparations for our anticipated commercial launches of relugolix combination tablet and relugolix monotherapy tablet.

The duration, costs and timing of clinical studies and development of relugolix combination therapy, relugolix monotherapy, MVT-602 and any other product candidates will depend on a variety of factors that include, but are not limited to: the number of

studies required for approval; the per patient study costs; the number of patients who participate in the studies; the number of sites included in the studies; the countries in which the studies are conducted; the length of time required to recruit and enroll eligible patients; the number of patients who fail to meet the study's inclusion and exclusion criteria; the number of study drug 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 study materials; and the efficacy and safety profile of the product candidate.

In addition, the probability of success for relugolix combination tablet, relugolix monotherapy tablet, MVT-602 and any other product candidates, if approved, will depend on numerous factors, including competition, manufacturing capability and commercial viability. As a result, we are unable to determine with certainty the duration and completion costs of our clinical programs or when and to what extent we will generate revenue from commercialization and sale of any of our product candidates. Our R&D 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 ("G&A") expenses consist primarily of personnel costs, such as salaries, benefits, share-based compensation and travel expenses for our executive, finance, human resources, legal, commercial operations and other administrative functions. G&A expenses also include expenses incurred under agreements with third parties relating to legal, accounting, auditing and tax services, rent and facilities costs, information technology costs, commercial operations, and general overhead. G&A costs in the periods presented also include costs billed and allocated to us from our former majority shareholder pursuant to Services Agreements that were terminated on December 27, 2019 (See Note 7(B) to the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K).

We anticipate that our G&A expenses will increase in future periods as we expand our operations. These increases will likely include costs related to the hiring of additional personnel, costs to implement and upgrade certain information technology systems, professional services fees and additional rent and other facilities related costs. In particular, we expect to incur increased costs associated with establishing sales, marketing, and commercialization functions in advance of potential regulatory approvals and commercialization of our product candidates. If relugolix combination tablet, relugolix monotherapy tablet, or MVT-602 obtains regulatory approval for marketing, we expect sales, marketing, and commercialization costs to be significant.

Interest Expense

Interest expense consists of interest expense related to our previously outstanding debt with Hercules and NovaQuest as well as the associated non-cash amortization of debt discounts and issuance costs.

Interest Expense (Related Party)

Interest expense (related party) consists of interest expense pursuant to the Sumitomo Dainippon Pharma Loan Agreement, which bears interest at a rate per annum equal to 3-month LIBOR plus a margin of 3% payable on the last day of each calendar quarter. The anticipated increases in our outstanding debt under the Sumitomo Dainippon Pharma Loan Agreement will result in an increase in interest expense (related party) in future periods.

Interest Income

Interest income consists primarily of interest earned on corporate bonds and money market funds and the accretion of discounts to maturity for commercial paper.

Loss on Extinguishment of Debt

Loss on extinguishment of debt represents the difference between the carrying amount of our previously outstanding debt with Hercules and NovaQuest and the amounts we paid to retire the outstanding debt obligations on December 31, 2019.

Results of Operations

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

	Years Ended March 31,	
	2020	2019
Operating expenses:		
Research and development	$ 192,560	$ 222,607
General and administrative	82,327	42,219
Total operating expenses	274,887	264,826
Interest expense	11,222	8,821
Loss on extinguishment of debt	4,851	—
Interest expense (related party)	1,441	—
Interest income	(2,552)	(881)
Other (income) expense, net	(1,621)	309
Loss before income taxes	(288,228)	(273,075)
Income tax expense	761	476
Net loss	$ (288,989)	$ (273,551)

Research and Development Expenses

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

	Years Ended March 31,		
	2020	2019	Change
Program-specific costs:			
Relugolix	$ 131,737	$ 182,602	$ (50,865)
MVT-602	1,698	4,919	(3,221)
Unallocated costs:			
Share-based compensation	14,524	7,161	7,363
Personnel expense	32,716	23,210	9,506
Services Agreements with former majority shareholder	—	748	(748)
Other expense	11,885	3,967	7,918
Total R&D expenses	$ 192,560	$ 222,607	$ (30,047)

R&D expenses decreased by $30.0 million, to $192.6 million, for the year ended March 31, 2020 compared to $222.6 million for the year ended March 31, 2019. R&D expenses in both periods primarily include expenses related to our Phase 3 clinical programs, manufacturing expenses, as well as personnel-related expenses for employees engaged in R&D activities. R&D expenses for the year ended March 31, 2019 reflected a ramp up in relugolix Phase 3 study costs primarily related to study enrollment, whereas R&D expenses for the year ended March 31, 2020 reflect declining relugolix Phase 3 study costs as certain studies are in the process of winding down. The decrease in relugolix Phase 3 study costs of approximately $50.9 million were partially offset by increases in other R&D expenses related predominantly to regulatory activities in connection with regulatory submissions for relugolix combination tablet and relugolix monotherapy tablet in multiple indications and jurisdictions and the build out of our medical affairs organization in connection with preparations for our anticipated commercial launches, as well as increases in personnel expenses, share-based compensation expense, and other R&D expenses.

R&D expenses for the year ended March 31, 2020 consisted primarily of program-specific costs comprised of CRO, drug supply and other study, regulatory, and manufacturing related costs of $133.4 million, personnel expenses of $32.7 million, share-based compensation expense of $14.5 million, and other R&D costs of $11.9 million, which primarily includes contractors, consultants, and information technology costs. Share-based compensation expense includes $1.8 million related to the accelerated vesting of certain equity awards as a result of a change in control in Myovant in connection with the closing of the transaction between Roivant and Sumitomo Dainippon Pharma.

R&D expenses for the year ended March 31, 2019 consisted primarily of CRO, clinical drug supply and other study and manufacturing related costs of $186.4 million, personnel-related expenses of $23.2 million, share-based compensation expense of $7.2 million, and costs billed to us under the then existing Services Agreements with Roivant of $2.3 million, including unallocated personnel expenses and third-party pass-through costs associated with our clinical and other research programs.

General and Administrative Expenses

G&A expenses increased by $40.1 million to $82.3 million for the year ended March 31, 2020 compared to $42.2 million for the year ended March 31, 2019, primarily due to increases in expenses related to commercial operations activities in advance of potential future regulatory approvals of relugolix combination tablet and relugolix monotherapy tablet, personnel-related expenses, and share-based compensation expenses, as well as professional service fees, other general overhead, administrative, and information technology expenses to support our headcount growth and expanding operations and the assumption of activities previously provided by Roivant, partially offset by a reduction of costs billed to us under the then existing Services Agreements with Roivant as a result of our assumption of these activities by our own personnel and other third party service providers. G&A expenses for the year ended March 31, 2020 include certain one-off increases as a result of the change in control in Myovant in connection with the closing of the transaction between Roivant and Sumitomo Dainippon Pharma, namely $10.2 million in share-based compensation expense related to the accelerated vesting of certain equity awards as well as a $3.6 million capital tax accrual.

For the year ended March 31, 2020, G&A expenses consisted primarily of share-based compensation expense of $25.7 million, personnel-related expenses of $19.1 million, commercial operations expenses of $12.7 million, general overhead, administrative and information technology expenses of $11.9 million, professional service fees of $6.0 million, capital tax accrual of $3.6 million, and rent and other facilities related costs of $2.8 million. Share-based compensation expense includes $10.2 million related to the accelerated vesting of certain equity awards as a result of a change in control in Myovant in connection with the closing of the transaction between Roivant and Sumitomo Dainippon Pharma.

For the year ended March 31, 2019, G&A expenses consisted of personnel-related and general overhead expenses of $21.9 million, share-based compensation expenses of $11.5 million, costs of $2.5 million billed to us under the then existing Services Agreements with Roivant, including personnel expenses, overhead allocations and third-party pass-through costs, legal and professional service fees of $4.2 million and rent and other facilities related costs of $2.1 million.

Interest Expense

Interest expense increased by $2.4 million, to $11.2 million for the year ended March 31, 2020 compared to $8.8 million for the year ended March 31, 2019. The increase was primarily the result of higher outstanding debt balances under our financing arrangements with NovaQuest and Hercules during the year ended March 31, 2020 (until the outstanding debt was repaid) as compared to the prior year. On December 31, 2019, we repaid all of our outstanding obligations to NovaQuest and Hercules.

Interest Expense (Related Party)

Interest expense (related party) was $1.4 million for the year ended March 31, 2020, and represents interest expense under the Sumitomo Dainippon Pharma Loan Agreement, which we entered into on December 27, 2019. There were no such amounts in the prior year. We expect our interest expense (related party) to increase in future periods as a result of expected draws under the Sumitomo Dainippon Pharma Loan Agreement.

Interest Income

Interest income increased by $1.7 million to $2.6 million for the year ended March 31, 2020 compared to $0.9 million for the year ended March 31, 2019. During the fourth quarter of the prior year, we began investing a portion of our cash in a combination of money market funds, commercial paper and short-term corporate bonds. As a result, the prior year financial results include interest income earned during one fiscal quarter, whereas financial results for the year ended March 31, 2020 include interest income earned during four fiscal quarters.

Loss on Extinguishment of Debt

For the year ended March 31, 2020, we incurred a $4.9 million loss on extinguishment of debt associated with the write-off of unamortized debt issuance costs and debt discounts, prepayment penalties and early redemption fees in connection with the repayment of outstanding obligations to NovaQuest and Hercules. There were no such amounts in the prior year.

Other (Income) Expense, net

Other (income) expense, net consists of the impact of changes in foreign currency exchange rates on our foreign exchange denominated liabilities. The impact of foreign exchange rates on our results of operations fluctuates period over period based on our foreign currency exposures resulting from changes in applicable exchange rates associated with our foreign denominated

liabilities. For the year ended March 31, 2020, we recorded a foreign exchange gain of $1.6 million. For the year ended March 31, 2019, we recorded a foreign exchange loss of $0.3 million.

Income Tax Expense

Our income tax expense for the years ended March 31, 2020 and 2019, were $0.8 million and $0.5 million, respectively. Our effective tax rate for the years ended March 31, 2020 and 2019 was (0.26)% and (0.17)%, respectively, and is driven by our jurisdictional earnings by location and a valuation allowance that eliminates our global net deferred tax assets.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily from the issuance and sale of our common shares and from debt financing arrangements. As of March 31, 2020, we had cash, cash equivalents, marketable securities, and committed funding available to us of $365.9 million, consisting of $79.6 million of cash, cash equivalents, and marketable securities and $286.3 million of borrowing capacity available to us under the Sumitomo Dainippon Pharma Loan Agreement, as compared to $156.1 million of cash and cash equivalents and no committed funding available to us as of March 31, 2019. Additional funds may be drawn down by us under the Sumitomo Dainippon Pharma Loan Agreement once per calendar quarter, subject to certain terms and conditions, including consent of our board of directors. In April 2020, we borrowed an additional $80.0 million under the Sumitomo Dainippon Pharma Loan Agreement. For additional information about the Sumitomo Dainippon Pharma Loan Agreement, see Note 7(A) to the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Pursuant to our exclusive license agreement with Richter, we received an upfront payment of $40.0 million on March 31, 2020, and are eligible to receive up to $40.0 million in regulatory milestones and up to $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval. In April 2020, we received a $10.0 million regulatory milestone payment pursuant to this agreement.

As of March 31, 2020, we had approximately $10.4 million of capacity available to us under our “at-the-market” equity offering program that we established in April 2018.

Capital Requirements

For the years ended March 31, 2020 and 2019, we had net losses of $289.0 million and $273.6 million, respectively. As of March 31, 2020, we had an accumulated deficit of $791.0 million.

We have incurred, and expect to continue to incur, significant operating losses and negative operating cash flows as we continue to develop our product candidates and prepare for the potential future regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet. We have not generated any product revenue to date and do not expect to generate product revenue unless and until we successfully complete development and obtain regulatory approval for one of our product candidates. Our operating losses and negative operating cash flows may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical studies, anticipated regulatory filings, pre-commercialization efforts and our expenditures on other R&D and G&A activities.

We anticipate that our capital requirements will be significant as we:

- submit NDAs and other regulatory filings for our product candidates;
- expand our chemistry, manufacturing, and control and other manufacturing related activities;
- seek to identify, acquire, develop, and commercialize additional product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand, and protect our intellectual property portfolio;
- hire scientific, clinical, regulatory, quality, and administrative personnel;
- add operational, accounting, finance, quality, commercial, and management information systems and personnel;
- seek regulatory approvals for any product candidates that successfully complete clinical studies;
- establish a medical affairs group with a medical scientific liaison team;
- establish a sales, marketing, and distribution infrastructure and increase the scale of our external manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- service our debt obligations and associated interest payments; and

- operate as a public company.

Our primary use of cash has been to fund the development of relugolix combination therapy, relugolix monotherapy, and MVT-602. We expect our operating expenses to continue to increase over the near term as we expand our operations to continue to develop our product candidates and prepare for potential future regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet. In addition, we expect that our outstanding debt levels will increase in future periods, which will result in an increase in our quarterly interest payment obligations.

Based on our current operating plan, we expect that our cash, cash equivalents, marketable securities and amounts available to us under the Sumitomo Dainippon Pharma Loan Agreement will be sufficient to fund our operating expenses and capital expenditure requirements at least through the end of our fiscal year ended March 31, 2021. This estimate is based on our current assumptions, including assumptions relating to our ability to manage our spend, that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our current cash, cash equivalents, marketable securities, and amounts currently available to us under the Sumitomo Dainippon Pharma Loan Agreement will not be sufficient to enable us to complete all necessary development and regulatory activities and commercially launch relugolix combination tablet or relugolix monotherapy tablet. We anticipate that we will continue to incur net losses and negative operating cash flows for the foreseeable future.

To continue as a going concern, we will need, among other things, additional capital resources. We continually assess multiple options to obtain additional funding to support our operations, including through financing activities in public or private capital markets. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. Although we expect to draw under the Sumitomo Dainippon Pharma Loan Agreement on a quarterly basis, such draws are contingent upon the consent of our board of directors. If Sumitomo Dainippon Pharma fails to own at least a majority of our common shares, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to us, in which case we would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. ASC 240-40, *Going Concern*, does not allow us to consider future financing activities that are uncertain in our assessment of our future cash burn for the purpose of our liquidity assessment. Due to these uncertainties, there is substantial doubt about our ability to continue as a going concern. If we are unable to raise capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back, or discontinue operations.

Until such time, if ever, as we can generate substantial revenue from sales of relugolix combination tablet, relugolix monotherapy tablet, MVT-602, or any future product candidate, we expect to fund our operations through a combination of cash, cash equivalents, and marketable securities currently on hand, equity offerings, debt financings, structured transactions such as royalty financings, collaboration, license or development agreements, or other collaborations, as well as quarterly draws under the Sumitomo Dainippon Pharma Loan Agreement, subject to the consent of our board of directors. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our common shareholders' ownership interest may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common shareholders' rights. The Sumitomo Dainippon Pharma Loan Agreement 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, raising capital through equity offerings, 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 additional funds when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table sets forth a summary of our cash flows (in thousands):

	Years Ended March 31,	
	2020	**2019**
Net cash used in operating activities	$ (221,172)	$ (224,088)
Net cash used in investing activities	$ (3,935)	$ (1,236)
Net cash provided by financing activities	$ 145,926	$ 273,899

Operating Activities

For the year ended March 31, 2020 we used $221.2 million in operating activities primarily due to our ongoing clinical studies, activities related to our preparation for potential regulatory approvals and commercialization of relugolix combination tablet and

relugolix monotherapy tablet, and the expansion of our company. This was primarily attributable to a net loss for the period of $289.0 million and a decrease of $24.6 million in accrued expenses resulting primarily from a decrease in accrued R&D expenses and decreases of $1.1 million in interest payable and $2.3 million in deferred interest payable related to our previously outstanding debt which was repaid in full on December 31, 2019. These amounts were partially offset by an increase of $40.0 million in current deferred revenue related to the upfront payment we received from Richter on March 31, 2020, an increase in accounts payable of $4.3 million, due to timing of invoice payments, and an increase in other liabilities of $3.6 million, due to a capital tax accrual as a result of the change in control in Myovant, along with non-cash items including $40.3 million of share-based compensation expense as a result of an increase in headcount (which also includes $12.0 million related to the accelerated vesting of certain equity awards as a result of the change in control in Myovant in connection with the closing of the transaction between Roivant and Sumitomo Dainippon Pharma), $3.3 million of total depreciation and amortization expense, and a $4.9 million loss on extinguishment of debt associated with the write-off of unamortized debt issuance costs and debt discounts, prepayment penalties and early redemption fees in connection with the repayment of outstanding obligations to NovaQuest and Hercules on December 31, 2019.

For the year ended March 31, 2019, we used $224.1 million in operating activities primarily due to our ongoing development and clinical studies for relugolix and MVT-602. This was primarily attributable to a net loss for the period of $273.6 million, an increase of $5.1 million in prepaid expenses and other current assets along with a decrease of $1.8 million in amounts due to our former majority shareholder and its subsidiaries. These amounts were partially offset by an increase of $23.3 million in accrued expenses resulting primarily from an increase in accrued R&D expenses due to the progress of our clinical studies and an increase in accrued compensation-related expenses as a result of an increase in personnel, $6.4 million in accounts payable due to the progress of our clinical studies and growth of our company, $2.0 million in deferred interest payable related to our then existing outstanding debt with NovaQuest which was to be paid on a deferred basis pursuant to the terms of the NovaQuest Securities Purchase Agreement, $18.7 million of non-cash share-based compensation expense as a result of an increase in headcount, and $2.5 million of total depreciation and amortization expense.

Investing Activities

For the year ended March 31, 2020, we used $3.9 million in investing activities, which consisted of $32.1 million for purchases of marketable securities and $1.1 million for the purchase of property and equipment, partially offset by proceeds of $29.2 million from the maturities of marketable securities. For the year ended March 31, 2019, we used $1.2 million for the purchase of property and equipment.

Financing Activities

For the year ended March 31, 2020, financing activities provided $145.9 million. This was primarily due to the net proceeds of $134.5 million we received from the issuance and sale of 17,424,243 common shares in our underwritten public equity offering, proceeds of $113.7 million borrowed under the Sumitomo Dainippon Pharma Loan Agreement, and net proceeds of $2.5 million that we received from the sale of 106,494 common shares through our “at-the-market” equity offering program. In addition, we received proceeds of $0.9 million from the exercise of stock options under our 2016 Equity Incentive Plan. These amounts were partially offset by the repayment of our financing obligations and redemption fees to NovaQuest and Hercules, including payments to NovaQuest of $60.0 million for repayment of principal, an early redemption fee of $2.4 million, and an annual debt administration fee of $0.3 million, and payments to Hercules of $40.0 million for repayment of principal, a prepayment penalty of $0.4 million, and an end of term charge of $2.6 million.

For the year ended March 31, 2019, financing activities provided $273.9 million of cash. This was primarily due to the net proceeds of $74.4 million we received from the issuance and sale of 3,533,399 common shares in our underwritten public equity offering, $84.1 million we received from the sale of 3,970,129 common shares through our “at-the-market” equity offering program that we established in April 2018, gross proceeds of $22.5 million we received from the issuance and sale of 1,110,015 common shares to our former majority shareholder in a private placement, net proceeds from debt financings with NovaQuest of $54.0 million, and net proceeds of $38.0 million from the issuance and sale of 2,286,284 common shares to NovaQuest. In addition, we received cash proceeds of $1.3 million from the exercise of stock options under our 2016 Equity Incentive Plan and paid an annual debt administration fee of $0.3 million to NovaQuest under the NovaQuest Securities Purchase Agreement.

Contractual Obligations

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):

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Related party debt obligations, including interest charge [1]	$ 141,898	$ 5,640	$ 11,279	$ 124,979	$ —
Operating lease obligations [2]	17,454	2,939	6,155	5,462	2,898
Total	$ 159,352	$ 8,579	$ 17,434	$ 130,441	$ 2,898

[1] Related party debt obligations, including interest charge consists of principal and future interest payments due to Sumitomo Dainippon Pharma pursuant to the terms of the Sumitomo Dainippon Pharma Loan Agreement based upon the amounts outstanding at March 31, 2020 and the interest rate in effect at March 31, 2020. In April 2020, we borrowed an additional $80.0 million under the Sumitomo Dainippon Pharma Loan Agreement, which is not included in the table above. See Note 7(A) to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

[2] Operating lease obligations consist of future rent payments under lease and sublease agreements for office space located in Brisbane, California. See Note 12 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

License Agreement with Takeda

In connection with the Takeda License Agreement, we will be required to pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in our territory. We cannot, at this time, determine when or if royalty payments will be required or what the total amount of such payments may be. Therefore, such payments are not included in the table above. See Note 4 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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 U.S. generally accepted accounting principles ("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, and disclosures of contingent assets and liabilities as of the dates of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. 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 believe that the estimates derived from the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. In addition, refer to Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding our accounting policies. We have discussed our accounting policies with the audit committee of our board of directors, and we believe that our estimates and judgments relating to revenue recognition, share-based compensation, R&D expenses and accruals, leases, and income taxes have the greatest potential impact on our consolidated financial statements. We consider these to be our critical accounting policies and estimates.

Revenue Recognition

In accordance with Accounting Standards Codification ASC ("ASC") 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as we satisfy a performance obligation.

When applying the revenue recognition criteria of ASC 606 to license and collaboration agreements, we apply significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

- *Licenses of intellectual property:* If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, we apply judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the related revenue recognition accordingly.
- *Milestone payments:* At the inception of each arrangement that includes research, development or regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price on a cumulative catch-up basis in earnings in the period of the adjustment.
- *Royalties and commercial milestone payments:* For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

Share-Based Compensation

Share-based awards are valued at fair value on the date of grant and we recognize that fair value on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. We recognize forfeitures in the period in which such forfeiture occurs and record share-based compensation expense as though all awards are expected to vest.

We estimate the grant date fair value of stock options, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model, which requires the use of subjective assumptions. These assumptions include:

- *Expected Term.* The expected term represents the period that our share-based awards are expected to be outstanding and is determined using the simplified method in accordance with the Securities and Exchange Commission (“SEC”), Staff Accounting Bulletin (“SAB”), No. 107 and No. 110 (based on the mid-point between the vesting date and the end of the contractual term).
- *Expected Volatility.* The expected volatility considers our historical volatility and weighted average measures of volatility of a peer group of companies for a period equal to the expected term of the stock options. Our peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle, or area of specialty.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the interest rates paid on securities issued by the U.S. Treasury with a term approximating the expected term of the stock options.
- *Expected Dividend.* We have never paid, and do not anticipate paying, cash dividends on our common shares. Therefore, the expected dividend yield was assumed to be zero.

We base share-based compensation expense associated with time-vesting restricted stock awards and restricted stock units 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 estimate share-based compensation expense associated with restricted stock awards subject to market conditions on the grant date using a Monte Carlo valuation model. We recognize the resulting fair value as share-based compensation expense ratably over the derived service period regardless of whether the market conditions are satisfied.

We base share-based compensation expense associated with performance stock unit awards 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 performance stock unit awards if the performance criteria are deemed probable of being met.

No tax benefits for share-based compensation has been recognized in the consolidated statements of shareholders' (deficit) equity or consolidated statements of cash flows. We have not recognized, and do not expect to recognize in the near future, any tax benefits related to share-based compensation as a result of our full valuation allowance on net deferred tax assets and net operating loss carryforwards.

Research and Development Expenses and Accruals

R&D expenses primarily include personnel-related costs for employees engaged in R&D activities and costs of third-parties who conduct clinical study and clinical manufacturing activities on our behalf, and are expensed as incurred unless there is an alternative future use in other R&D projects. 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 R&D.

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 R&D expenses when incurred.

Our accruals for clinical studies and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical study sites, CROs, and CMOs. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price, upon achievement of a milestone event, or on a time and materials basis. Payments under these agreements depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical study or similar conditions. The objective of our accrual policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical studies and other R&D activities are recognized based on our estimate of the degree of completion of the event or events specified in the agreements.

Our accrual estimates are dependent upon the timeliness and accuracy of data provided by third parties regarding the status and cost of studies, and may not match the actual services performed by these organizations. During the course of a clinical study, we adjust our rate of clinical study expense recognition if actual results differ from our estimates. We make estimates of our clinical study expense as of each balance sheet date based on facts and circumstances known at that time. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and result in us reporting amounts that are too high or too low for any particular period. This could result in adjustment to our R&D expense in future periods.

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 ASU 2016-2, *Leases (Topic 842)* ("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.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that our deferred tax assets will be realizable.

When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. When and if we were to recognize interest and penalties related to unrecognized tax benefits, they would be reported in income tax expense.

Recent Accounting Pronouncements

For information regarding recently issued accounting pronouncements and the expected impact on our consolidated financial statements, see Note 2 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 are considered to be a “smaller reporting company,” we are not required to provide the information required by this item in this Annual Report on Form 10-K.

Item 8. Financial Statements and Supplementary Data

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS OF MYOVANT SCIENCES LTD.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Myovant Sciences Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Myovant Sciences Ltd. (the Company) as of March 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, shareholders' (deficit) equity and cash flows for each of the three 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 three years in the period ended March 31, 2020, in conformity with U.S. generally accepted accounting principles.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases during the year ended March 31, 2020 due to the adoption of Accounting Standards Update ("ASU") No. 2016-2, Leases ("Topic 842"), effective April 1, 2019, using the modified retrospective approach.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred recurring losses, expects continuing future losses, cannot guarantee its ability to finance operations, and stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2016.

Redwood City, California
May 18, 2020

MYOVANT SCIENCES LTD.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2020	March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 76,644	$ 156,074
Marketable securities	2,997	—
Prepaid expenses and other current assets	8,269	10,194
Income tax receivable	—	524
Total current assets	87,910	166,792
Property and equipment, net	2,497	2,071
Operating lease right-of-use asset	11,146	—
Other assets	4,373	4,114
Total assets	$ 105,926	$ 172,977
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 15,334	$ 11,019
Interest payable	—	1,077
Interest payable (related party)	15	—
Accrued expenses	29,060	53,735
Deferred revenue	40,000	—
Operating lease liability	1,516	—
Current maturities of long-term debt	—	6,142
Total current liabilities	85,925	71,973
Deferred rent	—	1,157
Deferred interest payable	—	2,273
Long-term operating lease liability	10,996	—
Long-term debt, less current maturities	—	93,240
Long-term debt, less current maturities (related party)	113,700	—
Other	3,582	—
Total liabilities	214,203	168,643
Commitments and contingencies (Note 14)		
Shareholders' (deficit) equity:		
Common shares, par value $0.000017727 per share, 564,111,242 shares authorized, 89,833,998 and 72,057,490 issued and outstanding at March 31, 2020 and 2019, respectively	2	1
Additional paid-in capital	684,381	505,851
Accumulated other comprehensive (loss) income	(1,646)	507
Accumulated deficit	(791,014)	(502,025)
Total shareholders' (deficit) equity	(108,277)	4,334
Total liabilities and shareholders' (deficit) equity	$ 105,926	$ 172,977

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

MYOVANT SCIENCES LTD.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Years Ended March 31,		
	2020	**2019**	**2018**
Operating expenses:			
Research and development [1]	$ 192,560	$ 222,607	$ 116,832
General and administrative [2]	82,327	42,219	24,231
Total operating expenses	274,887	264,826	141,063
Interest expense	11,222	8,821	2,046
Loss on extinguishment of debt	4,851	—	—
Interest expense (related party)	1,441	—	—
Interest income	(2,552)	(881)	—
Other (income) expense, net	(1,621)	309	(67)
Loss before income taxes	(288,228)	(273,075)	(143,042)
Income tax expense	761	476	213
Net loss	$ (288,989)	$ (273,551)	$ (143,255)
Net loss per common share — basic and diluted	$ (3.37)	$ (4.09)	$ (2.41)
Weighted average common shares outstanding — basic and diluted	85,839,303	66,910,060	59,520,747

[1] Includes $76, $2,575 and $4,537 of costs allocated from the Company's former majority shareholder during the years ended March 31, 2020, 2019 and 2018, respectively. Also includes share-based compensation expense (see Note 10).

[2] Includes $617, $2,873 and $4,182 of costs allocated from the Company's former majority shareholder during the years ended March 31, 2020, 2019 and 2018, respectively. Also includes share-based compensation expense (see Note 10).

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

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

	Years Ended March 31,		
	2020	**2019**	**2018**
Net loss	$ (288,989)	$ (273,551)	$ (143,255)
Other comprehensive (loss) income:			
Foreign currency translation adjustment	(2,153)	483	(116)
Total other comprehensive (loss) income	(2,153)	483	(116)
Comprehensive loss	$ (291,142)	$ (273,068)	$ (143,371)

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

MYOVANT SCIENCES LTD.
Consolidated Statements of Shareholders' (Deficit) Equity
(in thousands, except share and per share data)

	Common Shares		Common Shares Subscribed	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' (Deficit) Equity
	Shares	Amount					
Balance at March 31, 2017	60,275,757	$ 1	$ (1)	$ 251,733	$ 140	$ (85,097)	$ 166,776
Adjustment to adopt ASU 2016-09	—	—	—	122	—	(122)	—
Shares issued to settle the Takeda warranty liability	4,432	—	—	58	—	—	58
Share-based compensation expense	564,111	—	—	10,587	—	—	10,587
Capital contribution from former majority shareholder — share-based compensation	—	—	—	996	—	—	996
Foreign currency translation adjustment	—	—	—	—	(116)	—	(116)
Stock option exercises	15,195	—	—	36	—	—	36
Shares issued to NovaQuest, net of issuance costs of $624	138,361	—	—	1,857	—	—	1,857
Warrants issued with debt financing	—	—	—	789	—	—	789
Settlement of former majority shareholder common shares subscribed	—	—	1	—	—	—	1
Net loss	—	—	—	—	—	(143,255)	(143,255)
Balance at March 31, 2018	60,997,856	1	—	266,178	24	(228,474)	37,729
Issuance of shares in connection with "at-the-market" equity offering, net of commissions and offering costs of $2,919	3,970,129	—	—	84,052	—	—	84,052
Issuance of shares in connection with Private Placement with former majority shareholder	1,110,015	—	—	22,500	—	—	22,500
Share-based compensation expense	—	—	—	18,067	—	—	18,067
Capital contribution from former majority shareholder — share-based compensation	—	—	—	629	—	—	629
Capital contribution from former majority shareholder	—	—	—	752	—	—	752
Foreign currency translation adjustment	—	—	—	—	483	—	483
Issuance of shares in connection with public equity offering, net of commissions and offering costs of $5,110	3,533,399	—	—	74,391	—	—	74,391
Shares issued to NovaQuest, net of issuance costs	2,286,284	—	—	37,982	—	—	37,982
Issuance of shares upon exercise of stock options and vesting of RSUs	159,807	—	—	1,300	—	—	1,300
Net loss	—	—	—	—	—	(273,551)	(273,551)
Balance at March 31, 2019	72,057,490	1	—	505,851	507	(502,025)	4,334
Issuance of shares in connection with "at-the-market" equity offering, net of commissions of $79	106,494	—	—	2,546	—	—	2,546
Issuance of shares in connection with public equity offering, net of commissions and offering costs of $9,292	17,424,243	1	—	134,457	—	—	134,458
Share-based compensation expense	—	—	—	40,102	—	—	40,102
Capital contribution from former majority shareholder — share-based compensation	—	—	—	149	—	—	149
Capital contribution from former majority shareholder	—	—	—	334	—	—	334
Foreign currency translation adjustment	—	—	—	—	(2,153)	—	(2,153)
Issuance of shares upon exercise of stock options and vesting of PSUs and RSUs	245,771	—	—	942	—	—	942
Net Loss	—	—	—	—	—	(288,989)	(288,989)
Balance at March 31, 2020	89,833,998	$ 2	$ —	$ 684,381	$ (1,646)	$ (791,014)	$ (108,277)

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

MYOVANT SCIENCES LTD.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended March 31,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Net loss	$ (288,989)	$ (273,551)	$ (143,255)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation	40,251	18,696	11,583
Depreciation and amortization [1]	1,765	438	243
Amortization of debt discount and issuance costs	1,486	2,084	662
Loss on extinguishment of debt	4,851	—	—
Other items	(1,980)	1,235	(116)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,925	(5,055)	(1,918)
Deferred tax assets	—	—	208
Income tax receivable	524	476	(895)
Other assets	(10)	76	(3,065)
Accounts payable	4,315	6,441	1,249
Interest payable	(1,077)	795	282
Interest payable (related party)	15	—	—
Accrued expenses	(24,554)	23,349	18,287
Operating lease liabilities	(882)	—	—
Deferred revenue	40,000	—	—
Due to former majority shareholder	(121)	(1,839)	(1,070)
Deferred rent	—	749	295
Deferred interest payable	(2,273)	2,018	255
Other	3,582	—	—
Net cash used in operating activities	(221,172)	(224,088)	(117,255)
Cash flows from investing activities:			
Purchases of marketable securities	(32,076)	—	—
Maturities of marketable securities	29,240	—	—
Purchases of property and equipment	(1,099)	(1,236)	(604)
Net cash used in investing activities	(3,935)	(1,236)	(604)
Cash flows from financing activities:			
Proceeds from issuance of common shares in “at-the-market” equity offering, net of issuance costs paid	2,546	84,052	—
Proceeds from issuance of common shares in public equity offerings, net of issuance costs paid	134,458	74,391	—
Proceeds from issuance of common shares in private placement with former majority shareholder	—	22,500	—
Proceeds from related party debt financing	113,700	—	—
Proceeds from third party debt financing, net of financing costs paid	—	53,974	43,751
Proceeds from issuance of common shares to NovaQuest, net of issuance costs paid	—	37,982	1,857
Proceeds from stock option exercises	942	1,300	36
Settlement of former majority shareholder common shares subscribed	—	—	1
Payments on third party debt financings and redemption fees	(105,420)	—	—
Payment of annual debt administration fee to NovaQuest	(300)	(300)	—
Net cash provided by financing activities	145,926	273,899	45,645
Net change in cash, cash equivalents and restricted cash	(79,181)	48,575	(72,214)
Cash, cash equivalents and restricted cash, beginning of period	157,199	108,624	180,838
Cash, cash equivalents and restricted cash, end of period	$ 78,018	$ 157,199	$ 108,624
Non-cash financing activities:			
Warrants issued to Hercules	$ —	$ —	$ 789
Supplemental disclosure of cash paid:			
Income taxes	$ 38	$ —	$ 900
Interest	$ 13,030	$ 3,923	$ 845
Interest (related party)	$ 1,426	$ —	$ —

[1] Includes amortization of operating lease right-of-use asset.

MYOVANT SCIENCES LTD.
Notes to Consolidated Financial Statements

Note 1—Description of Business

Myovant Sciences Ltd. (or together with its wholly-owned subsidiaries, the "Company") is a healthcare company focused on redefining care for women and for men. The Company's lead product candidate is relugolix, a once-daily, oral, gonadotropin-releasing hormone ("GnRH") receptor antagonist for which the Company has successfully completed multiple Phase 3 clinical studies across three distinct indications. The Company is preparing for potential commercial launches in the U.S. of relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg and norethindrone acetate 0.5 mg) for women with heavy menstrual bleeding associated with uterine fibroids or pain associated with endometriosis and relugolix monotherapy tablet (120 mg) for men with advanced prostate cancer, in anticipation of U.S. Food and Drug Administration ("FDA") approval to market in these indications. The Company submitted its New Drug Application ("NDA") to the FDA for relugolix monotherapy tablet for the treatment of men with advanced prostate cancer in April 2020, and currently expects to submit an NDA for relugolix combination tablet for the treatment of women with heavy menstrual bleeding associated with uterine fibroids in May 2020. The Company announced positive results from the first of two replicate Phase 3 clinical studies evaluating relugolix combination therapy in women with pain associated with endometriosis, and expects to announce top-line results from the second study in the second quarter of calendar year 2020. In addition, the Company is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG ("Takeda"), a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, granted the Company a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive right to develop and commercialize MVT-602 in all countries worldwide. On March 30, 2020, the Company entered into an exclusive license agreement with Gedeon Richter Plc. ("Richter") for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in certain territories outside of the U.S. Under this agreement, the Company has retained all of its rights to relugolix combination tablet in the U.S. and Canada, as well as rights to relugolix in other therapeutic areas outside of women's health. In March 2020, the Company submitted a Marketing Authorisation Application ("MAA") to the European Medicines Agency ("EMA") for relugolix combination tablet in uterine fibroids. The MAA submission has completed validation and is now under evaluation by the EMA.

The Company is an exempted company limited by shares incorporated under the laws of Bermuda in February 2016 under the name Roivant Endocrinology Ltd. The Company changed its name to Myovant Sciences Ltd. in May 2016. Since its inception, the Company has devoted substantially all of its efforts to identifying and in-licensing its product candidates, organizing and staffing the Company, raising capital, preparing for and advancing the clinical development of its product candidates, and preparing for potential future regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet.

The Company has incurred, and expects to continue to incur, significant operating losses and negative operating cash flows as it continues to develop its product candidates and prepares for potential future regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet. To date, the Company has not generated any product revenue, and it does not expect to generate product revenue unless and until it successfully completes development and obtains regulatory approval for at least one of its product candidates. The Company has funded its operations primarily from the issuance and sale of its common shares and from debt financing arrangements.

On December 27, 2019, Sumitovant Biopharma Ltd. ("Sumitovant"), a subsidiary of Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo Dainippon Pharma") became the Company's majority shareholder and a related party after acquiring 45,008,604 of the Company's outstanding common shares, representing approximately 50.2% of the Company's common shares outstanding on December 27, 2019. The common shares were acquired from the Company's former majority shareholder, Roivant Sciences Ltd. ("Roivant," "RSL," or "former majority shareholder") at the closing of a transaction between Roivant and Sumitomo Dainippon Pharma. See Note 7(A). As of March 31, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 46,788,604 of the Company's outstanding common shares, representing approximately 52.1% of the Company's common shares outstanding on March 31, 2020. As a result of the transfer of these common shares, Roivant no longer beneficially owns any of the Company's common shares.

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation

The Company's fiscal year ends on March 31, and its first three fiscal quarters end on June 30, September 30 and December 31. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

The accompanying consolidated financial statements have been prepared in accordance with United States ("U.S.") generally accepted accounting principles ("U.S. GAAP"). Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codification ("ASC"), and Accounting Standards Update

("ASU") issued by the Financial Accounting Standards Board ("FASB"). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued. During the year ended March 31, 2020, the Company incurred net losses of $289.0 million and used $221.2 million of cash and cash equivalents in operations. The Company expects to continue to incur significant and increasing operating losses and negative operating cash flows as it continues to develop its product candidates and prepares for potential future regulatory approvals and commercialization of relugolix combination tablet and relugolix monotherapy tablet. In addition, the Company expects that its outstanding debt levels will increase in future periods, which will result in an increase in its quarterly interest payment obligations. The Company has not generated any product revenue to date and does not expect to generate product revenue unless and until it successfully completes development and obtains regulatory approval for at least one of its product candidates. Based on its current operating plan, the Company expects that its existing cash, cash equivalents, marketable securities, and its ability to borrow under the terms of the Sumitomo Dainippon Pharma Loan Agreement (See Note 7(A)) will be sufficient to fund its operating expenses and capital expenditure requirements at least through the end the Company's fiscal year ending March 31, 2021. This estimate is based on the Company's current assumptions, including assumptions relating to its ability to manage its spend, that might prove to be wrong, and it could use its available capital resources sooner than it currently expects. Current cash, cash equivalents, marketable securities and amounts currently available under the Sumitomo Dainippon Pharma Loan Agreement will not be sufficient to enable the Company to complete all necessary development and regulatory activities and commercially launch relugolix combination tablet or relugolix monotherapy tablet. The Company anticipates that it will continue to incur net losses and negative operating cash flows for the foreseeable future.

To continue as a going concern, the Company will need, among other things, additional capital resources. The Company continually assesses multiple options to obtain additional funding to support its operations, including through financing activities in public or private capital markets. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all. Although the Company expects to draw under the Sumitomo Dainippon Pharma Loan Agreement on a quarterly basis, such draws are contingent upon the consent of the Company's board of directors. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of the Company's outstanding common shares, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to the Company, in which case the Company would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. ASC 240-40, *Going Concern*, does not allow the Company to consider future financing activities that are uncertain in its assessment of the Company's future cash burn for the purpose of its liquidity assessment.

Due to these uncertainties, there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements and footnotes have been prepared on the basis that the Company will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

(B) Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to assets and liabilities, and disclosures of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Areas where management uses subjective judgments include, but are not limited to, the evaluation of the Company's ability to continue as a going concern, revenue recognition, share-based compensation expenses, research and development ("R&D") expenses and accruals, leases, 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 at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period, that are not readily apparent from other sources. Estimates and assumptions are periodically reviewed in light of changes in circumstances, facts, or experience. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

(C) Revenue Recognition

In accordance with ASC 606, *Revenue from Contracts with Customers*, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify

the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

When applying the revenue recognition criteria of ASC 606 to license and collaboration agreements, the Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

- *Licenses of intellectual property:* If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are not distinct from other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.
- *Milestone payments:* At the inception of each arrangement that includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price on a cumulative catch-up basis in earnings in the period of the adjustment.
- *Royalties and commercial milestone payments:* For arrangements that include sales-based royalties, including commercial milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Achievement of these royalties and commercial milestones may solely depend upon performance of the licensee.

(D) Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, risks of failure or unsatisfactory results of nonclinical and clinical studies, the need to obtain additional capital to fund the future development of its product candidates and the commercialization of any product candidates that may obtain marketing approval, the need to obtain marketing approval for its product candidates, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development by competitors of technological innovations, ability to transition from pilot-scale manufacturing to large-scale production of products, and dependence on third-party service providers such as contract research organizations ("CROs") and contract manufacturing organizations ("CMOs").

(E) Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk include cash, cash equivalents, and marketable securities, consisting of money market funds, commercial paper, and corporate bonds. As of March 31, 2020, cash, cash equivalents, and marketable security balances are diversified between three financial institutions. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and the issuers of its money market funds, commercial paper, and corporate bonds. The Company maintains its cash deposits and cash equivalents in highly-rated, federally-insured financial institutions in excess of federally insured limits. The Company has established guidelines relative to diversification and maturities of investments to maintain safety and liquidity. 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.

(F) Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents include cash deposits in banks and all highly liquid investments that are readily convertible to cash. The Company considers all highly liquid investments with a maturity of three months or less at the time of purchase to be cash equivalents. Interest income consists of interest earned on money market funds and the accretion of discounts to maturity for commercial paper.

Restricted cash consists of non-interest bearing legally restricted deposits held as compensating balances against the Company's corporate credit card program and irrevocable standby letters of credit provided as security for the Company's office lease and sublease.

Cash as reported on the consolidated statements of cash flows includes the aggregate amounts of cash, cash equivalents, and restricted cash, and consists of the following (in thousands):

	March 31,		
	2020	2019	2018
Cash and cash equivalents	$ 76,644	$ 156,074	$ 108,624
Restricted cash [1]	1,374	1,125	—
Total cash, cash equivalents and restricted cash	$ 78,018	$ 157,199	$ 108,624

[1] Included in other assets on the consolidated balance sheets.

(G) Marketable Securities

Investments in marketable securities are held in a custodial account at a financial institution and managed by the Company's investment advisor based on the Company's investment guidelines. The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities. As of March 31, 2020, the Company's marketable securities consisted of commercial paper with maturities of greater than three months but less than twelve months at the time of purchase. These short-term commercial paper are classified as current assets on the Company's consolidated balance sheets under the caption marketable securities.

The Company classifies its marketable securities as available-for-sale at the time of purchase and reevaluates such designation at each balance sheet date. Unrealized gains and losses on available-for-sale marketable securities are excluded from earnings and are recorded in accumulated other comprehensive (loss) income until realized. Any unrealized losses are evaluated for other-than-temporary impairment at each balance sheet date. Realized gains and losses are determined based on the specific identification method and are recorded in other (income) expense, net in the consolidated statements of operations. See Note 3.

(H) Fair Value Measurements

The Company utilizes fair value measurement guidance prescribed by accounting standards to value its financial instruments. The guidance establishes a fair value hierarchy for financial instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

Fair value is defined as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the reporting date. As a basis for considering market participant assumptions in fair value measurements, the guidance establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1—Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2—Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3—Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's financial instruments include cash, cash equivalents, marketable securities, accounts payable and debt obligations. Cash, cash equivalents, and accounts payable are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. Marketable securities are recorded at their estimated fair value and are included in Level 2 of the fair value hierarchy.

(I) Property and Equipment, net

Property and equipment, net consisting of computers, equipment, furniture and fixtures, leasehold improvements, and software, is recorded at cost, less accumulated depreciation. 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 are removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation is recorded for property and equipment using the straight-line method over the estimated useful lives of the assets, which range from three to seven years once the asset is installed and placed into service. Leasehold improvements are amortized using the straight-line method over their estimated useful life or the remaining lease term, whichever is shorter.

The Company reviews the recoverability of its 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, based on undiscounted cash flows. If such assets are considered to be impaired, an impairment loss is recognized and is measured as the amount by which the carrying amount of the assets exceed their estimated fair value, which is measured based on the projected discounted future net cash flows arising from the assets.

(J) Leases

The Company determines if an arrangement includes a lease at the inception of the agreement. For each of the Company's lease arrangements, the Company records a right-of-use asset representing the Company's right to use an underlying asset for the lease term and a lease liability representing the Company's obligation to make lease payments. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the net present value of the lease payments over the lease term. In determining the weighted-average discount rate used to calculate the net present value of lease payments, the Company uses its incremental borrowing rate based on information available at the lease commencement date. The Company's leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that the Company will exercise any such options. Lease expense for the Company's operating leases is recognized on a straight-line basis over the lease term. The Company has elected not to apply the recognition requirements for short-term leases.

(K) Debt Issuance Costs and Debt Discount

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 on the consolidated balance sheet 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.

(L) Contingencies

The Company may be, from time to time, a party to various disputes and claims arising from normal business activities. The Company continually assesses litigation to determine if an unfavorable outcome would lead to a probable loss or reasonably possible loss which could be estimated. In accordance with the guidance of the FASB on accounting for contingencies, the Company accrues for all contingencies at the earliest date at which the Company deems it probable that a liability has been incurred and the amount of such liability can be 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 amount in the range. In the cases where the Company believes that a material reasonably possible loss exists, the Company discloses the facts and circumstances of the contingency, including an estimable range, if possible.

(M) Research and Development Expenses

R&D costs are expensed as incurred. Clinical study costs are accrued over the service periods specified in the contracts and adjusted as necessary based on an ongoing review of the level of effort and costs actually incurred. R&D expenses primarily consist of employee-related expenses, such as salaries, share-based compensation, benefits and travel expenses for employees engaged in R&D activities, payments made under third-party license agreements, certain costs allocated to the Company for activities performed by the Company's former majority shareholder and its subsidiaries under services agreements with the Company, as well as share-based compensation expense allocated from the Company's former majority shareholder, and expenses from third parties who conduct R&D activities on behalf of the Company. The Company expenses in-process R&D projects acquired as asset acquisitions which have not reached technological feasibility and which have no alternative future use.

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 R&D expenses when incurred.

(N) Share-Based Compensation

Share-based awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service period, which is generally the vesting period of the respective award. The Company recognizes forfeitures in the period in which such forfeiture occurs and records share-based compensation expense as though all awards are expected to vest.

The Company estimates the grant date fair value of stock options, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model, which requires the use of subjective assumptions. These assumptions include:

- *Expected Term.* The expected term represents the period that the Company's share-based awards are expected to be outstanding and is determined using the simplified method in accordance with the Securities and Exchange Commission ("SEC"), Staff Accounting Bulletin ("SAB") No. 107 and No. 110 (based on the mid-point between the vesting date and the end of the contractual term).
- *Expected Volatility.* The expected volatility considers the Company's historical volatility and weighted average measures of volatility of a peer group of companies for a period equal to the expected term 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.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the interest rates paid on securities issued by the U.S. Treasury with a term approximating the expected term 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.

Share-based compensation expense associated with time-vesting restricted stock awards and 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.

Share-based compensation expense associated with restricted stock awards subject to market conditions is estimated on the grant date using a Monte Carlo valuation model. The resulting fair value is recognized as share-based compensation expense ratably over the derived service period regardless of whether the market conditions are satisfied.

Share-based compensation expense associated with performance stock unit awards 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 performance stock unit awards if the performance criteria are deemed probable of being met.

No tax benefits for share-based compensation have been recognized in the consolidated statements of shareholders' (deficit) equity or consolidated statements of cash flows. The Company has not recognized, and does not expect to recognize in the near future, any tax benefits related to share-based compensation as a result of its full valuation allowance on net deferred tax assets and net operating loss carryforwards.

(O) Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is recorded when, after consideration of all positive and negative evidence, it is not more likely than not that the Company's deferred tax assets will be realizable.

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. Interest and/or penalties related to income tax matters are recognized as a component of income tax expense as incurred.

(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, reduced, where applicable, for outstanding yet unvested shares of restricted common stock. The computation of diluted net loss per common share is based on the weighted-average number of common shares outstanding during the period plus, when their effect is dilutive, incremental shares consisting of shares subject to stock options, restricted stock units, restricted stock awards, performance stock units, and warrants. 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 equal. 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 losses. 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.

As of March 31, 2020, 2019 and 2018, potentially dilutive securities were as follows:

	March 31,		
	2020	2019	2018
Stock options	7,723,302	5,396,465	3,549,405
Restricted stock awards (unvested)	634,623	916,679	1,198,735
Restricted stock units (unvested)	645,689	39,387	15,000
Performance stock units (unvested)	299,870	—	—
Warrants	73,710	73,710	73,710
Total	9,377,194	6,426,241	4,836,850

(Q) Foreign Currency

The results of the Company's 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 balance sheet date and shareholders' (deficit) equity is translated using historical rates. Adjustments resulting from the translation of the 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' (deficit) equity. Foreign currency exchange transaction gains and losses are included in other (income) expense, net in the Company's consolidated statements of operations.

(R) Pushdown Accounting

In November 2014, the FASB issued ASU 2014-17, *Business Combinations* (Topic 805): *Pushdown Accounting*. The ASU 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 7(A).

(S) Recently Adopted Accounting Standards

(1) Leases

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842), which is a comprehensive new lease standard that amended various aspects of existing accounting guidance for leases. The core principle of Topic 842 requires lessees to recognize on the consolidated balance sheets a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating leases with lease terms greater than twelve months. The lease liability is measured at the present value of the unpaid lease payments and the right-of-use asset is derived from the calculation of the lease liability. Topic 842 also requires lessees to disclose key information about leasing arrangements. Topic 842 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018, with early adoption permitted.

A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application ("Transition Date"). An entity may choose to use either (i) its effective date or (ii) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company adopted the new standard on April 1, 2019 and used the effective date as its date of initial application.

The new standard provides a number of optional practical expedients in transition. The Company elected the "package of practical expedients," which permitted it to not reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs. As a result, the Company has continued to account for existing leases - i.e. leases for which the commencement date is before April 1, 2019 - in accordance with Topic 840 throughout the entire lease term, including periods after the effective date, with the exception that the Company applied the new balance sheet recognition guidance for operating leases and applied Topic 842 for remeasurements and modifications after the Transition Date.

The most significant impact of the adoption of Topic 842 on the Company's consolidated financial statements was the recognition of a $9.4 million operating lease right-of-use asset, a $0.8 million current operating lease liability, and a $9.8 million long-term operating lease liability on the Company's consolidated balance sheet. In addition, the Company reclassified a $1.2 million deferred

rent liability to the related operating lease right-of-use asset. There was no material impact to the Company's consolidated statement of operations, and no cumulative-effect adjustment to accumulated deficit. See Note 12.

(2) Others

In February 2018, the FASB issued ASU 2018-02, *Income Statement-Reporting Comprehensive Income*, (Topic 220): *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* ("ASU 2018-02"). ASU 2018-02 allows companies to reclassify stranded tax effects resulting from the newly enacted federal corporate income tax rate under the Tax Cuts and Jobs Act, from accumulated other comprehensive (loss) income to retained earnings. ASU 2018-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018 and early adoption is permitted. The Company adopted the new standard on April 1, 2019. The adoption of ASU 2018-02 did not have an impact on the Company's consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation* (Topic 718)*: Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. ASU 2018-07 is effective for interim and annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company adopted the new standard on April 1, 2019. The adoption of ASU 2018-07 did not have a material impact on the Company's consolidated financial statements and related disclosures**.**

In July 2018, the FASB issued ASU 2018-09, *Codification Improvements* ("ASU 2018-09") to make changes to a variety of topics to clarify, correct errors in, or make minor improvements to the ASC. Certain items in the amendments in ASU 2018-09 are effective for the Company in annual periods beginning after December 15, 2018. The adoption of ASU 2018-09 on April 1, 2019 did not have a material impact on the Company's consolidated financial statements and related disclosures**.**

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 the Company to, have a material impact on the Company's consolidated financial statements and related disclosures.

(T) Recently Issued Accounting Standards Not Yet Adopted

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform* (Topic 848): *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides optional expedients and exceptions for applying generally accepted accounting principles to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. These amendments apply only to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. The amendments are effective for all entities as of March 12, 2020 through December 31, 2022. The expedients and exceptions provided by the amendments do not apply to contract modifications made and hedging relationships entered into or evaluated after December 31, 2022, except for hedging relationships existing as of December 31, 2022, that an entity has elected certain optional expedients for and that are retained through the end of the hedging relationship. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements* (Topic 808): *Clarifying the Interaction Between Topic 808 and Topic 606*, which is intended to clarify the circumstances under which certain transactions in collaborative arrangements should be accounted for under the revenue recognition standard. Certain transactions between collaboration arrangement participants should be accounted for as revenue under ASC Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2019. The Company is currently evaluating the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses* (Topic 326): *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 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 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. In February 2020, the FASB issued ASU 2020-02, *Financial Instruments-Credit Losses* (Topic 326) *and Leases* (Topic 842)*- Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases* (Topic 842), which amends the effective date of the original pronouncement for smaller reporting companies. ASC 2016-13 and its amendments will be effective for annual and interim periods beginning after December 15, 2022 for smaller reporting companies. The Company is currently assessing the impact the adoption of this new standard will have on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement* (Topic 820): *Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). ASU 2018-13 amends the disclosure requirements in Topic 820 to promote the exercise of discretion by entities when considering fair value measurement disclosures and clarifies that materiality is an appropriate consideration when evaluating fair value measurement disclosure requirements. Certain required disclosures were added, modified, or removed, including removing the required disclosure of the amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy. ASU 2018-13 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 currently expect that the adoption of this new standard will have a material impact on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software* (Subtopic 350-40): *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract* ("ASU 2018-15"), which amends ASC 350-40, *Internal-Use Software*, to include in its scope implementation costs of a cloud computing arrangement that is a service contract. Consequently, the accounting for costs incurred to implement a cloud computing arrangement that is a service arrangement is aligned with the guidance on capitalizing costs associated with developing or obtaining internal-use software. ASU 2018-15 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 is currently assessing the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes* (Topic 740) ("ASU 2019-12") that eliminates certain exceptions to the general principles in ASC 740 related to intra-period tax allocation, deferred tax liability and general methodology for calculating income taxes. ASU 2019-12 also simplifies U.S. GAAP by making other changes for matters such as, franchise taxes that are partially based on income, transactions with a government that result in a step up in the tax basis of goodwill, separate financial statements of legal entities that are not subject to tax, and enacted changes in tax laws in interim periods. ASU 2019-12 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2020. Early adoption is permitted, including adoption in any interim period. The Company is currently assessing the impact the adoption of this standard will have on its consolidated financial statements and related disclosures.

Note 3— Investments and Fair Value Measurements

As of March 31, 2020, the Company's $3.0 million marketable securities balance consisted of available-for-sale commercial paper. There were no material unrealized gains or losses on marketable securities as of March 31, 2020. There were no marketable securities as of March 31, 2019.

Fair Value Measurements

As of March 31, 2020, assets measured at fair value on a recurring basis consisted of money market funds and commercial paper, which are included in cash and cash equivalents on the consolidated balance sheets, and commercial paper, which is included in marketable securities on the consolidated balance sheets. The following table summarizes these assets and their assigned levels within the fair value hierarchy (in thousands):

	March 31, 2020			
	Level 1	Level 2	Level 3	Total Fair Value
Assets:				
Money market funds	$ 11,348	$ —	$ —	$ 11,348
Commercial paper	—	7,042	—	7,042
Total assets	$ 11,348	$ 7,042	$ —	$ 18,390

As of March 31, 2019, assets measured at fair value on a recurring basis consisted of money market funds and commercial paper, which are included in cash and cash equivalents on the consolidated balance sheet. The following table summarizes these assets and their assigned levels within the fair value hierarchy (in thousands):

	March 31, 2019			
	Level 1	Level 2	Level 3	Total Fair Value
Assets:				
Money market funds	$ 83	$ —	$ —	$ 83
Commercial paper	—	126,050	—	126,050
Total assets	$ 83	$ 126,050	$ —	$ 126,133

Money market funds are included in Level 1 of the fair value hierarchy and are valued at the closing price reported by an actively traded exchange. Commercial paper is included in Level 2 of the fair value hierarchy and is valued using third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.

There were no liabilities measured at fair value on a recurring basis as of March 31, 2020 or 2019. There were no transfers of assets or liabilities between the fair value hierarchy levels that occurred during the years ended March 31, 2020, 2019 or 2018.

Note 4—Takeda Agreements

(1) Takeda License Agreement

On April 29, 2016, the Company entered into a license agreement pursuant to which Takeda granted to the Company an exclusive, royalty-bearing license under certain patents and other intellectual property controlled by Takeda to develop and commercialize relugolix and MVT-602, and products containing these compounds for all human diseases and conditions. Under the Takeda License Agreement, the Company will pay Takeda a fixed, high single-digit royalty on net sales of relugolix and MVT-602 products in the Company's territory, subject to certain agreed reductions. Takeda will pay the Company a royalty at the same rate on net sales of relugolix products for prostate cancer in the Takeda Territory, subject to certain agreed reductions. Royalties are required to be paid, on a product-by-product and country-by-country basis, until the latest to occur of the expiration of the last to expire valid claim of a licensed patent covering such product in such country, the expiration of regulatory exclusivity for such product in such country, or 10 years after the first commercial sale of such product in such country. Under the Takeda License Agreement, there was no upfront payment and there are no payments upon the achievement of clinical development or marketing approval milestones. As the amount and timing of any potential future payments under the Takeda License Agreement are not probable and estimable, no such potential commitments have been included on the consolidated balance sheets.

If the Takeda License Agreement is terminated in its entirety or with respect to relugolix for prostate cancer, other than for safety reasons or by the Company for Takeda's uncured material breach, prior to receipt of the first regulatory approval of relugolix for prostate cancer in Japan, then the Company must either reimburse Takeda for its out of pocket costs and expenses directly incurred in connection with Takeda's completion of the relugolix development for prostate cancer, up to an agreed upon cap, or complete by itself the conduct of any clinical studies of relugolix for prostate cancer that are ongoing as of the effective date of such termination, at its cost and expense.

(2) Takeda Commercial Supply Agreement

In May 2018, the Company entered into a Commercial Manufacturing and Supply Agreement with Takeda (the "Takeda Commercial Supply Agreement"), pursuant to which Takeda agreed to supply the Company and the Company agreed to obtain from Takeda certain quantities of relugolix drug substance according to agreed-upon quality specifications and in order to commercialize relugolix in accordance with the Takeda License Agreement. Under the Takeda Commercial Supply Agreement, the Company and Takeda entered into an initial firm order in which Takeda supplied the Company with relugolix drug substance at a fixed price per kilogram through December 31, 2019. For relugolix drug substance manufactured or delivered on or after such date, the Company will pay Takeda a price per kilogram of relugolix drug substance to be agreed upon between the parties at the beginning of each fiscal year.

The initial term of the Takeda Commercial Supply Agreement began on May 30, 2018 and will continue for five years. At the end of the initial term, the Takeda Commercial Supply Agreement will automatically renew for successive one-year terms, unless either party gives notice of termination to the other at least 12 months prior to the end of the then-current term. The Takeda Commercial Supply Agreement may be terminated by either party upon 90 days' notice of an uncured material breach of its terms by the other party, or immediately upon notice to the other party of a party's bankruptcy. Each party will also have the right to terminate the Takeda Commercial Supply Agreement, in whole or in part, for any reason upon 180 days' prior written notice to the other party, provided that any then-open purchase orders will remain in effect and be binding on both parties. The Takeda Commercial Supply Agreement, including any then-open purchase orders thereunder, will terminate immediately upon the termination of the Takeda License Agreement in accordance with its terms.

The Takeda Commercial Supply Agreement also includes customary provisions relating to, among others, delivery, inspection procedures, warranties, quality management, storage, handling and transport, intellectual property, confidentiality and indemnification.

Note 5—Accrued Expenses

As of March 31, 2020 and 2019, accrued expenses consisted of the following (in thousands):

	March 31,	
	2020	2019
Accrued R&D expenses	$ 15,500	$ 46,947
Accrued compensation-related expenses	9,309	5,024
Accrued professional service fees	1,126	370
Accrued other expenses	3,125	1,394
Total accrued expenses	$ 29,060	$ 53,735

Note 6—Financing Arrangements

(A) NovaQuest

In October 2017, the Company, its subsidiaries, as guarantors, and NovaQuest Capital Management ("NovaQuest") entered into (i) a Securities Purchase Agreement (the "NovaQuest Securities Purchase Agreement") and (ii) an Equity Purchase Agreement (the "NovaQuest Equity Purchase Agreement"). Pursuant to the NovaQuest Securities Purchase Agreement, the Company issued $60.0 million aggregate principal amount of notes, of which $6.0 million was issued in October 2017 and $54.0 million was issued in December 2018. Concurrent with each purchase of notes, NovaQuest was obligated to purchase up to $20.0 million of the Company's common shares on a pro rata basis, subject to certain terms and conditions. With the issuance of $6.0 million aggregate principal amount of notes in October 2017, NovaQuest purchased 138,361 common shares for $2.0 million, and with the issuance of $54.0 million aggregate principal amount of notes in December 2018, NovaQuest purchased 1,082,977 common shares for $18.0 million. The equity purchase price for each such purchase was equal to 105% of the average of the volume-weighted average price for the five consecutive trading days immediately prior to the relevant purchase date. Pursuant to the NovaQuest Equity Purchase Agreement, NovaQuest committed to purchase an additional $20.0 million of the Company's common shares from time to time at the Company's discretion. In December 2018, the Company exercised this option and issued and sold 1,203,307 common shares for $20.0 million. The purchase price for the common shares issued was equal to 105% of the average of the volume-weighted average price for the five consecutive trading days immediately prior to the relevant purchase date.

The notes bore interest at a rate of 15% per annum, of which 5% was payable quarterly, and 10% was payable on a deferred basis on the earlier of the Amortization Date (as defined below) and the repayment in full of the notes. The scheduled maturity of the notes was October 16, 2023. The Company was required to amortize the principal amount of the notes in equal quarterly installments commencing on November 1, 2021 (the "Amortization Date") provided certain terms and conditions were met. Early redemption of the notes was subject to a redemption charge. The Company's obligations under the NovaQuest Securities Purchase Agreement were secured by a second-lien security interest in substantially all of the Company's and its subsidiaries' respective assets (other than intellectual property). The NovaQuest Securities Purchase Agreement included customary affirmative and restrictive covenants and representations and warranties, including a minimum cash covenant that applied commencing on the Amortization Date, and also included customary events of default and a default interest rate of an additional 5% applied to the outstanding note balance.

The Company repaid all of its obligations to NovaQuest on December 31, 2019 including $60.0 million of principal repayment of the notes, accrued and unpaid interest of $7.6 million, and an early redemption fee of $2.4 million.

(B) Hercules

In October 2017, the Company, its subsidiaries, as guarantors, and Hercules Capital, Inc. ("Hercules") entered into a Loan Agreement (the "Hercules Loan Agreement"), which provided up to $40.0 million principal amount of term loans (the "Term Loans"). A first tranche of $25.0 million principal amount was funded upon execution of the Hercules Loan Agreement in October 2017 and the remaining $15.0 million principal amount was funded in March 2018.

The Term Loans bore interest at a variable per annum rate at the greater of (i) the prime rate plus 4% and (ii) 8.25%. The scheduled maturity date of the Term Loans was November 1, 2021. The Company was obligated to make monthly interest payments during the Interest-only Period (through June 1, 2020), subject to certain terms and conditions, followed by monthly installments of principal and interest through the maturity date. Prepayment of the Term Loans was subject to a prepayment charge and the Company was also obligated to pay an end of term charge of 6.55% of the principal amount of the Term Loans funded under the Hercules Loan Agreement. The Company's obligations under the Hercules Loan Agreement were secured by a first lien security interest in substantially all of the Company's and its subsidiaries' respective assets (other than intellectual property). The Hercules Loan Agreement included customary affirmative and restrictive covenants and representations and warranties.

Concurrent with each funding of the Term Loans, the Company was required to issue to Hercules a warrant (the "Warrants") to purchase a number of its common shares equal to 3% of the principal amount of the relevant Term Loan funded divided by the exercise price, which was based on the lowest three-day volume-weighted average price for the three consecutive trading days prior to the funding date for such Term Loan. The Warrants may be exercised on a cashless basis and are immediately exercisable through the seventh anniversary of the applicable funding date. In connection with the first tranche funded under the Hercules Loan Agreement, the Company issued a Warrant to Hercules exercisable for an aggregate of 49,800 of its common shares at an exercise price of $15.06 per common share. Concurrent with the funding of the second tranche, the Company issued a Warrant to Hercules exercisable for an aggregate of 23,910 of its common shares at an exercise price of $18.82 per common share. The total 73,710 warrants issued to Hercules were outstanding as of March 31, 2020 and 2019.

The Company repaid all of its obligations to Hercules on December 31, 2019, including $40.0 million of principal repayment of the Term Loans, accrued and unpaid interest of $0.3 million, a prepayment penalty of $0.4 million, and an end of term charge of $2.6 million.

(C) Extinguishment of Debt

On December 27, 2019, the Company and its subsidiary, Myovant Sciences GmbH ("MSG"), entered into the Sumitomo Dainippon Pharma Loan Agreement, which is further discussed in Note 7(A). On December 30, 2019, the Company borrowed an initial amount of $113.7 million under the Sumitomo Dainippon Pharma Loan Agreement, the proceeds of which were used to repay all outstanding obligations under the NovaQuest Securities Purchase Agreement and the Hercules Loan Agreement and to satisfy certain other fees and expenses. The repayments resulted in a loss on extinguishment of debt of $4.9 million, which is included under the caption, loss on extinguishment of debt, in the Company's consolidated statements of operations for the year ended March 31, 2020. The loss on extinguishment of debt was calculated as the difference between the carrying amount of the debt and the amounts paid to retire the debt.

As of March 31, 2020, no amounts were outstanding to NovaQuest and Hercules. As of March 31, 2019, amounts outstanding to NovaQuest under the NovaQuest Securities Purchase Agreement and Hercules under the Hercules Loan Agreement consisted of the following (in thousands):

	NovaQuest	Hercules	Total
Principal amount	$ 60,000	$ 40,000	$ 100,000
End of term charge	—	2,620	2,620
Less: unamortized debt discounts and issuance costs	(756)	(2,482)	(3,238)
Loan payables less unamortized debt discounts and issuance costs	59,244	40,138	99,382
Less: current maturities	—	(6,142)	(6,142)
Long-term debt, net of current maturities and unamortized debt discounts and issuance costs	$ 59,244	$ 33,996	$ 93,240

Note 7—Related Party Transactions

(A) Sumitomo Dainippon Pharma Co., Ltd.

On October 31, 2019, the Company's former majority shareholder, Roivant, and Sumitovant, a subsidiary of Sumitomo Dainippon Pharma, entered into a Transaction Agreement (the "Sumitomo Dainippon Pharma-Roivant Agreement"), which among other things, provided for Sumitomo Dainippon Pharma to acquire all of the Company's outstanding common shares held by Roivant. In addition, on October 31, 2019, the Company and Sumitomo Dainippon Pharma entered into a letter agreement pursuant to which, among other things, the Company and Sumitomo Dainippon Pharma would enter into an investor rights agreement and loan agreement upon the closing of the transactions contemplated by the Sumitomo Dainippon Pharma-Roivant Agreement (the "Closing").

On December 27, 2019, the Closing occurred and, as a result, all of the Company's outstanding common shares held directly or indirectly by Roivant and not already held by Sumitovant were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo Dainippon Pharma, resulting in Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, owning 45,008,604 of the Company's outstanding common shares, representing approximately 50.2% 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. As of March 31, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 46,788,604 of the Company's outstanding common shares, representing approximately 52.1% of the Company's common shares outstanding on March 31, 2020.

Sumitomo Dainippon Pharma Loan Agreement

On December 27, 2019, the Company and its subsidiary, MSG, entered into a Loan Agreement with Sumitomo Dainippon Pharma (the "Sumitomo Dainippon Pharma Loan Agreement"). Pursuant to the Sumitomo Dainippon Pharma Loan Agreement, Sumitomo Dainippon Pharma agreed to make revolving loans to the Company in an aggregate principal amount of up to $400.0 million. On December 30, 2019, the Company borrowed an initial amount of $113.7 million under the Sumitomo Dainippon Pharma Loan Agreement, the proceeds of which were used to repay all outstanding obligations of the Company to Hercules and NovaQuest (See Note 6) and to satisfy certain other fees and expenses. Additional funds may be drawn down by the Company once per calendar quarter, subject to certain terms and conditions, including consent of the Company's board of directors. In addition, if Sumitomo Dainippon Pharma fails to own at least a majority of the Company's outstanding common shares, it may become unlawful under Japanese law for Sumitomo Dainippon Pharma to fund loans to the Company, in which case the Company would not be able to continue to borrow under the Sumitomo Dainippon Pharma Loan Agreement. Interest is due and payable quarterly, and the outstanding principal amounts are due and payable in full on the five-year anniversary of the closing date of the Sumitomo Dainippon Pharma Loan Agreement. Loans under the Sumitomo Dainippon Pharma Loan Agreement are prepayable at any time without premium or penalty upon 10 business days' prior written notice.

Loans under the Sumitomo Dainippon Pharma Loan Agreement bear interest at a rate per annum equal to 3-month London Interbank Offered Rate ("LIBOR") plus a margin of 3% payable on the last day of each calendar quarter. The Company's obligations under the Sumitomo Dainippon Pharma Loan Agreement are fully and unconditionally guaranteed by the Company and its subsidiaries. The loans and other obligations are senior unsecured obligations of the Company, MSG, and subsidiary guarantees. The Sumitomo Dainippon Pharma Loan Agreement includes customary representations and warranties and affirmative and negative covenants.

The Sumitomo Dainippon Pharma Loan Agreement also includes customary events of default, including payment defaults, breaches of representations and warranties, breaches of covenants following any applicable cure period, cross acceleration to certain other debt, failure to pay certain final judgments, certain events relating to bankruptcy or insolvency, failure of material provisions of the loan documents to remain in full force and effect or any contest thereto by the Company or any of its subsidiaries and certain breaches by the Company under the Investor Rights Agreement. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% will apply to the outstanding principal amount of the loans, Sumitomo Dainippon Pharma may terminate its obligations to make loans to the Company and declare the principal amount of loans to become immediately due and payable, and Sumitomo Dainippon Pharma may take such other actions as set forth in the Sumitomo Dainippon Pharma Loan Agreement. Upon the occurrence of certain bankruptcy and insolvency events, the obligations of Sumitomo Dainippon Pharma to make loans to the Company would automatically terminate and the principal amount of the loans would automatically become due and payable. In addition, if it becomes unlawful for Sumitomo Dainippon Pharma to maintain the loans under the Sumitomo Dainippon Pharma Loan Agreement or within 30 days of a change of control with respect to the Company, the Company would be required to repay the outstanding principal amount of the Loans.

As of March 31, 2020, the outstanding loan balance of $113.7 million is classified as a long-term liability on the Company's consolidated balance sheets under the caption long-term debt, less current maturities (related party). As of March 31, 2020, approximately $286.3 million of borrowing capacity remains available to the Company, subject to the terms of the Sumitomo Dainippon Pharma Loan Agreement. Interest expense under the Sumitomo Dainippon Pharma Loan Agreement was $1.4 million for the year ended March 31, 2020 and is included in interest expense (related party) in the Company's consolidated statements of operations. There was no interest expense (related party) for the years ended March 31, 2019 and 2018.

Investor Rights Agreement

On December 27, 2019, the Company entered into an Investor Rights Agreement with Sumitomo Dainippon Pharma and Sumitovant (the "Investor Rights Agreement"). Pursuant to the Investor Rights Agreement, among other things, the Company agreed, at the request of Sumitovant, to register for sale, under the Securities Act of 1933, common shares beneficially owned by Sumitovant, subject to specified conditions and limitations. In addition, the Company agreed to periodically provide Sumitovant (i) certain financial statements, projections, capitalization summaries and other information and (ii) access to the Company's books, records, facilities and employees during the Company's normal business hours as Sumitovant may reasonably request, subject to specified limitations.

The Investor Rights Agreement also contains certain protections for the Company's minority shareholders for so long as Sumitomo Dainippon Pharma or certain of its affiliates beneficially owns more than 50% of the Company's common shares. These protections include: (i) a requirement that Sumitovant vote its shares for the election of independent directors in accordance with the recommendation of the Company's board of directors (the "board") or in the same proportion as the shareholders not affiliated with Sumitovant vote their shares; (ii) a requirement that the audit committee of the Company's board be composed solely of three independent directors; (iii) a requirement that any transaction proposed by Sumitomo Dainippon Pharma or certain of its affiliates that would increase Sumitomo Dainippon Pharma's beneficial ownership to over 60% of the outstanding voting power of the Company must be approved by the Company's audit committee (if occurring prior to December 27, 2022), and be conditioned on the approval of shareholders not affiliated with Sumitovant approving the transaction by a majority of the common shares held

by such shareholders; and a requirement that any related person transactions between Sumitomo Dainippon Pharma or certain of its affiliates and the Company must be approved by the Company's audit committee.

Pursuant to the Investor Rights Agreement, the Company also agreed that at all times that Sumitomo Dainippon Pharma beneficially owns more than 50% of the Company's common shares, Sumitomo Dainippon Pharma, by purchasing common shares in the open market or from the Company in certain specified circumstances, will have the right to maintain its percentage ownership in the Company's common shares in the event of a financing event or acquisition event conducted by the Company, or specified other events, subject to specific conditions.

(B) Roivant Sciences Ltd.

As a result of the closing of the Sumitomo Dainippon Pharma-Roivant Agreement described above, on December 27, 2019 all of the Company's outstanding common shares held directly or indirectly by Roivant and not already held by Sumitovant were transferred to Sumitovant, and Roivant transferred all of the outstanding equity of Sumitovant to Sumitomo Dainippon Pharma. As a result of the transfer of these common shares, Roivant no longer beneficially owns any common shares of the Company. On December 27, 2019, in connection with the closing of the Sumitomo Dainippon Pharma-Roivant Agreement, the then existing Information Sharing and Cooperation Agreement between the Company and Roivant, the then existing Services Agreements between the Company and certain of its subsidiaries and Roivant and certain of its subsidiaries, and the then existing Option Agreement between the Company and Roivant were terminated.

Under the Services Agreements, the Company paid or reimbursed Roivant or its subsidiaries for expenses it, or third parties acting on their behalf, incurred for the Company or its subsidiaries. For any general and administrative ("G&A") and R&D activities performed by Roivant or its subsidiaries' employees for the benefit of the Company, the Company was charged based on the relative percentage of time utilized on Company matters by the respective employee. All other third-party pass through costs were billed to the Company at cost. For the years ended March 31, 2020, 2019 and 2018, the Company incurred expenses (inclusive of third-party pass through costs billed to the Company) of $0.6 million, $4.8 million, and $7.7 million respectively, inclusive of the mark-up. These amounts are included in R&D expenses and G&A expenses based on the nature of the services performed under the then existing Services Agreements. In addition, Roivant previously allocated share-based compensation expense to the Company based upon the relative percentage of time spent by Roivant and its subsidiaries' employees on the Company's matters. The Company recorded share-based compensation expense allocated from Roivant of $0.1 million, $0.6 million, and $1.0 million for the years ended March 31, 2020, 2019 and 2018, respectively.

In April 2018, the Company sold to Roivant 1,110,015 of its common shares at a purchase price of $20.27 per common share, for gross proceeds of $22.5 million, in a private placement. In addition, Roivant purchased 2,424,242 of the Company's common shares in the Company's June 4, 2019 underwritten public equity offering at the same price offered to the public of $8.25 per common share, for a total purchase price of $20.0 million. See Note 8.

(C) Amended and Restated Bye-Laws

On December 22, 2019, the Company's board of directors approved, subject to the closing of the Sumitomo Dainippon Pharma-Roivant transaction and shareholder approval and certain other conditions, the adoption of the Company's Fifth Amended and Restated Bye-Laws (the "New Bye-Laws"), which amended and restated the Company's bye-laws to, among other things, (i) remove the procedures established in June 2019 providing RSL with the power, under certain circumstances, to appoint a majority of directors on the Company's board and related powers, (ii) revises certain other aspects of the Company's corporate governance and (iii) make other minor wording changes and additions, removal and revisions of defined terms. The New Bye-Laws became effective on January 23, 2020.

Note 8—Shareholders' (Deficit) Equity

(A) Overview

The Company's Memorandum of Association, filed on February 2, 2016 in Bermuda, authorized the creation of one class of shares. As of March 31, 2020, the Company had 564,111,242 shares authorized with a par value of $0.000017727 per share.

(B) Underwritten Public Equity Offerings of Common Shares

On June 4, 2019, the Company completed an underwritten public equity offering of 17,424,243 of its common shares (including 2,272,727 common shares sold pursuant to the underwriters' exercise in full of their option to purchase additional common shares) at a public offering price of $8.25 per common share. After deducting the underwriting discounts and commissions and offering costs paid by the Company, the net proceeds to the Company in connection with the underwritten public equity offering, including from the exercise of the underwriters' option to purchase additional shares, were approximately $134.5 million.

In July and August 2018, the Company completed an underwritten public equity offering of 3,533,399 of its common shares (including 200,065 common shares issued and sold upon the partial exercise of the underwriters' option to purchase additional common shares) at a public offering price of $22.50 per common share. After deducting the underwriting discounts and commissions and offering costs paid by the Company, the net proceeds to the Company in connection with the underwritten public equity offering, including from the partial option exercise, were approximately $74.4 million.

(C) Private Placement with Former Majority Shareholder

In April 2018, the Company entered into a share purchase agreement with Roivant, its former majority shareholder, pursuant to which the Company sold to Roivant 1,110,015 of its common shares at a purchase price of $20.27 per common share, for gross proceeds of $22.5 million, in a private placement.

(D) At-the-Market Equity Offering Program

In April 2018, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") to sell its common shares having an aggregate offering price of up to $100.0 million from time to time through an "at-the-market" equity offering program under which Cowen acts as the Company's agent. During the years ended March 31, 2020 and 2019, the Company issued and sold 106,494 and 3,970,129, respectively, of its common shares under the Sales Agreement. The common shares were sold at a weighted-average price of $24.65 and $21.91, respectively, per common share for aggregate net proceeds to the Company of approximately $2.5 million and $84.1 million, respectively, after deducting underwriting commissions and offering costs paid by the Company. As of March 31, 2020, the Company had approximately $10.4 million of capacity available to it under its "at-the-market" equity offering program.

(E) Issuance of Equity Instruments to NovaQuest and Hercules

In October 2017, the Company issued and sold 138,361 common shares to NovaQuest for $2.0 million in accordance with the terms of the NovaQuest Securities Purchase Agreement. In December 2018, the Company issued and sold 1,082,977 common shares to NovaQuest for $18.0 million in accordance with the NovaQuest Securities Purchase Agreement and issued and sold 1,203,307 common shares to NovaQuest for $20.0 million in accordance with the NovaQuest Equity Purchase Agreement. In October 2017, the Company issued a Warrant to Hercules exercisable for 49,800 of its common shares at an exercise price of $15.06 per common share and in March 2018, the Company issued a Warrant to Hercules exercisable for an aggregate of 23,910 of its common shares at an exercise price of $18.82 per common share. See Note 6.

(F) Takeda Warrant Liability

In accordance with the terms of the Takeda License Agreement (see Note 4), the Company issued a warrant to Takeda to purchase an indeterminate number of capital shares. The warrant entitled Takeda, together with its affiliates, to maintain a 12% ownership interest in the Company, as determined after such exercise, through the later of (i) April 30, 2017 or (ii) the final closing of the Company's initial public offering, unless earlier terminated upon a change in control. During the year ended March 31, 2018, the Company issued and delivered 4,432 of its common shares to Takeda upon the automatic exercise of the Takeda warrant. The warrant expired on April 30, 2017.

Note 9—Income Taxes

The loss before income taxes and the related tax expense are as follows (in thousands):

	Years Ended March 31,		
	2020	2019	2018
Income (loss) before income taxes:			
United States	$ (29,509)	$ (11,246)	$ (7,229)
Switzerland	(239,666)	(247,445)	(129,261)
Bermuda	(19,054)	(14,357)	(6,513)
Other[1]	1	(27)	(39)
Total loss before income taxes	$ (288,228)	$ (273,075)	$ (143,042)
Current taxes:			
United States	$ 758	$ 473	$ 13
Switzerland	—	—	—
Bermuda	—	—	—
Other[1]	3	3	(8)
Total current tax expense	761	476	5
Deferred taxes:			
United States	—	—	208
Switzerland	—	—	—
Bermuda	—	—	—
Other[1]	—	—	—
Total deferred tax expense	—	—	208
Total income tax expense	$ 761	$ 476	$ 213

[1] Primarily United States state and local, Ireland and United Kingdom activity.

A reconciliation of income tax expense computed at the Bermuda statutory rate to income tax expense reflected in the consolidated statements of operations is as follows (dollars in thousands):

	Years Ended March 31,					
	2020		2019		2018	
Income tax expense at Bermuda statutory rate	$ —	— %	$ —	— %	$ —	— %
Foreign rate differential[2]	(40,056)	13.90	(31,252)	11.44	(14,802)	10.35
Impact of changes in enacted income tax rates	(27,150)	9.42	—	—	—	—
R&D tax credits	(4,224)	1.47	—	—	—	—
Share-based compensation deferral adjustment	4,089	(1.42)	—	—	—	—
Change in uncertain tax positions	3,016	(1.05)	—	—	—	—
Valuation allowance	65,193	(22.62)	32,335	(11.83)	13,966	(9.77)
Tax reform	—	—	—	—	1,049	(0.73)
Other	(107)	0.04	(607)	0.22	—	—
Total income tax expense	$ 761	(0.26)%	$ 476	(0.17)%	$ 213	(0.15)%

[2] Primarily related to current tax on United States operations including permanent differences as well as operations in Switzerland and the United Kingdom at rates different than the Bermuda rate.

The Company's effective tax rate for the years ended March 31, 2020, 2019, and 2018 was (0.26)%, (0.17)% and (0.15)%, respectively, and is 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 and liabilities as of March 31, 2020 and 2019 are as follows (in thousands):

	March 31,	
	2020	2019
Deferred tax assets:		
Research tax credits	$ 6,521	$ 7,224
Net operating losses	84,694	38,194
Share-based compensation	8,573	6,106
Intangibles[3]	52,922	38,673
Lease liability	2,633	—
Other	4,936	2,539
Subtotal	160,279	92,736
Valuation allowance	(157,525)	(92,330)
Deferred tax liabilities:		
Depreciation	(409)	(406)
Right-of-use assets	(2,345)	—
Total deferred tax assets	$ —	$ —

[3] In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory* ("ASU 2016-16"). ASU 2016-16 requires the income tax consequences of intra-entity transfers of assets, other than inventory, to be recognized when the transfer occurs. ASU 2016-16 was effective for the Company on April 1, 2018 and was adopted using a modified retrospective approach. The adoption of this standard resulted in the recognition of a deferred tax asset of $38.7 million with a corresponding valuation allowance of $38.7 million during the year ended March 31, 2019.

As of March 31, 2020, the Company's net operating losses in Switzerland, Ireland, and the United Kingdom were $615.9 million, $0.1 million, and $24.3 million, respectively. The Switzerland net operating losses will begin to expire on March 31, 2025. The net operating losses in Ireland and the United Kingdom can be carried forward indefinitely with annual usage limitations where applicable. As of March 31, 2020, the Company has research and development credit carryforwards in the United States in the amount of $7.6 million which will begin to expire on March 31, 2037, and in California in the amount of $1.9 million which can be carried forward indefinitely.

The Company assesses the realizability of the 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 records a valuation allowance as necessary. Due to the Company's cumulative loss position which provides significant negative evidence which is difficult to overcome, the Company has recorded a valuation allowance of $157.5 million as of March 31, 2020 representing the portion of the deferred tax asset that is not more likely than not to be realized. The amount of the deferred tax asset 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 deferred tax assets at each balance sheet date in order to determine the proper amount, if any, required for a valuation allowance.

There are outside basis differences related to the Company's 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 U.S. tax attributes may be subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986 (the "Code"), and similar state provisions if the Company experiences one or more ownership changes, which would limit the amount of the tax attributes that can be utilized to offset future taxable income. In general, an ownership change as defined by Section 382, results from the transactions increasing ownership of certain stockholders or public groups in the stock of the corporation of more than 50 percentage points over a three-year period. If a change in ownership occurs in the future, the R&D credit carryforwards could be eliminated or restricted. The Company experienced an ownership change for the purposes of Section 382 and 383 of the Code in December 2019. The ownership change did not result in the forfeiture of any credits generated prior to this date. If a change in ownership occurs in the future, the tax attributes could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The Company is subject to tax and will file income tax returns in the United Kingdom, Switzerland, Ireland, and the United States federal and certain state and local jurisdictions. The Company is subject to tax examinations for tax years ended March 31, 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 results of operations or cash flows in the period of resolution, settlement or when the statutes of limitations expire.

Activity related to unrecognized tax benefits for the year ended March 31, 2020 is as follows (in thousands):

	Amount
Unrecognized tax benefit at April 1, 2019	$ —
Gross increases — prior period tax positions	2,067
Gross decreases — prior period tax positions	—
Gross increases — current period tax positions	1,110
Unrecognized tax benefit at March 31, 2020	$ 3,177

During the tax year ended March 31, 2020, the Company's unrecognized tax benefits increased by $3.2 million, primarily associated with the Company's U.S. Federal and California R&D tax credits. As of March 31, 2020, the Company had unrecognized tax benefits of $3.2 million that if recognized would have an immaterial effect on the Company's effective tax rate. The Company had no accrual for interest or penalties on its consolidated balance sheets at March 31, 2020 and 2019, and had not recognized interest and/or penalties in its consolidated statement of operations for any of the years ended March 31, 2020, 2019 and 2018. The Company does not expect that there will be a significant change in the unrecognized tax benefits over the next twelve months. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the effective tax rate.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted on March 27, 2020 in the U.S. The CARES Act includes many measures to assist companies, including temporary changes to income-based tax laws. There were no material impacts to the Company's income taxes due to the Company's full valuation allowance. It is uncertain if and to what extent various states will conform to the CARES Act.

Note 10—Share-Based Compensation

(A) Myovant 2016 Equity Incentive Plan

In June 2016, the Company adopted its 2016 Equity Incentive Plan, as amended (the "2016 Plan"), under which 4.5 million common shares were originally reserved for issuance. Pursuant to the "evergreen" provision contained in the 2016 Plan, the number of shares reserved for issuance under the 2016 Plan automatically increases on April 1 of each year, commencing on (and including) April 1, 2017 and ending on (and including) April 1, 2026, in an amount equal to 4% of the total number of shares of capital stock outstanding on March 31 of the preceding fiscal year, or a lesser number of shares as determined by the Company's board of directors. On April 1, 2019, the number of common shares authorized for issuance increased automatically by 2.9 million shares in accordance with the evergreen provision of the 2016 Plan. As of March 31, 2020, a total of 1.5 million common shares were available for future issuance under the 2016 Plan.

The Company's employees, directors, officers and consultants are eligible to receive non-qualified and incentive stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other share awards under the 2016 Plan.

(B) Stock Option Repricing

On August 26, 2019 (the "repricing date"), the Company's board of directors approved a stock option repricing program (the "repricing") whereby certain previously granted and still outstanding vested and unvested stock options held by current employees and certain executives were repriced on a one-for-one basis to $7.78 per share, which represented the closing market price of the Company's common shares on the repricing date. To be eligible to participate in the stock option repricing program, 735,428 vested stock options to certain executives as of the repricing date are subject to a one-year exercise restriction period beginning from the repricing date. No other terms of the repriced stock options were modified, and the repriced stock options will continue to vest according to their original vesting schedules and will retain their original expiration dates. As a result of the repricing, 5,095,013 vested and unvested stock options outstanding with original exercise prices ranging from $8.82 to $24.44, and a median exercise price of $17.28 per share, were repriced under this program. The repricing resulted in one-time incremental stock-based compensation expense of $9.2 million, which will be recognized over the remaining term of the repriced stock options.

(C) Stock Options

Each option will have an exercise price equal to the fair market value of the Company's common shares on the date of grant. For grants of incentive stock options, if the grantee owns, or is deemed to own, 10% or more of the total voting power of the Company, then the exercise price shall be 110% of the fair market value of the Company's common shares on the date of grant and the option will have a five-year contractual term. Options that are forfeited or expire are available for future grants.

Stock options granted under the 2016 Plan may provide option holders, if approved by the Company's board of directors, the right to exercise their options prior to vesting. In the event that an option holder exercises the unvested portion of any option, such unvested portion will be subject to a repurchase option held by the Company at the lower of (1) the fair market value of its common shares on the date of repurchase and (2) the exercise price of the options. Any common shares underlying such unvested portion will continue to vest in accordance with the original vesting schedule of the option.

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

	Years Ended March 31,		
	2020	2019	2018
Expected common share price volatility	69.5%	71.6%	74.4%
Expected risk free interest rate	2.05%	2.78%	2.04%
Expected term, in years	6.17	6.23	6.22
Expected dividend yield	—%	—%	—%

A summary of stock option activity and data under the Company's 2016 Plan for the periods presented is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at March 31, 2017	1,525,857	$ 5.06	9.52	$ 10,255
Granted	2,338,116	$ 12.50		
Exercised	(15,195)	$ 2.38		
Forfeited	(299,373)	$ 6.64		
Options outstanding at March 31, 2018	3,549,405	$ 9.84	9.02	$ 40,557
Granted	2,246,410	$ 21.36		
Exercised	(154,494)	$ 8.41		
Forfeited	(244,856)	$ 14.59		
Options outstanding at March 31, 2019	5,396,465	$ 14.46	8.51	$ 50,878
Granted	2,992,200	$ 11.57		
Exercised	(124,097)	$ 7.59		
Forfeited	(541,266)	$ 17.60		
Options outstanding at March 31, 2020	7,723,302	$ 9.25	8.08	$ 4,146
Options vested and expected to vest at March 31, 2020	7,723,302	$ 9.25	8.08	$ 4,146
Options exercisable at March 31, 2020	3,009,080	$ 8.13	7.30	$ 3,686

The weighted-average exercise price for granted, exercised, and forfeited options during the year ended March 31, 2020, as well as prior period amounts, have not been retroactively adjusted to reflect the impact of the stock option repricing described previously. As of March 31, 2020, 2019 and 2018, there were 3,009,080, 1,581,810 and 502,361 vested options, respectively. As a result of the change in control of the Company described in Note 7(A), the vesting of 849,212 stock options was accelerated on December 27, 2019, resulting in the recognition of $11.2 million of share-based compensation expense upon the change in control.

Additional information regarding options is set forth below (in thousands, except per share data).

	Years Ended March 31,		
	2020	2019	2018
Intrinsic value of options exercised	$ 1,036	$ 2,167	$ 181
Grant date fair value of options vested	$ 2,112	$ 11,409	$ 5,831
Weighted-average grant date fair value per share of options granted	$ 11.54	$ 14.10	$ 8.35

(D) Restricted Stock Awards and Restricted Stock Units

A summary of restricted stock award ("RSA") and restricted stock unit ("RSU") activity and data under the Company's 2016 Plan for the periods presented is as follows:

	Number of shares	Weighted Average Grant Date Fair Value
Unvested balance at March 31, 2017	1,128,222	$ 5.10
Granted	579,111	$ 14.10
Vested	(493,598)	$ 5.10
Unvested balance at March 31, 2018	1,213,735	$ 9.39
Granted	29,700	$ 17.28
Vested	(287,369)	$ 5.21
Unvested balance at March 31, 2019	956,066	$ 10.90
Granted	724,554	$ 7.98
Vested	(295,090)	$ 5.56
Forfeited	(105,218)	$ 7.98
Unvested balance at March 31, 2020	1,280,312	$ 10.71

The total fair value of RSAs vested during the years ended March 31, 2020, 2019 and 2018 was $1.4 million, $1.4 million and $2.5 million, respectively. The total fair value of RSUs vested during the years ended March 31, 2020 and 2019 was $0.2 million and $0.1 million, respectively. No RSUs vested during the year ended March 31, 2018.

(E) Performance Stock Units

On August 26, 2019, the Company's board of directors granted performance stock units covering a total of 408,510 common shares, of which two-thirds of the shares (272,338 shares) subject to each performance stock unit vests based upon the passage of time, and the remaining one-third of the shares (136,172 shares) subject to each performance stock unit vests if the Company achieves certain clinical study and regulatory milestones. As of March 31, 2020, the performance conditions had not been met and were deemed not probable of being met. As a result of the change in control of the Company described in Note 7(A), the vesting of certain performance stock units covering a total of 108,640 common shares was accelerated on December 27, 2019, resulting in the recognition of $0.8 million of share-based compensation expense upon the change in control. As of March 31, 2020, performance stock units covering a total of 299,870 common shares are unvested.

(F) Share-Based Compensation Expense

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

	Years Ended March 31,		
	2020	2019	2018
Share-based compensation expense recognized as:			
R&D expenses	$ 14,524	$ 7,161	$ 3,674
G&A expenses	25,727	11,535	7,909
Total	$ 40,251	$ 18,696	$ 11,583

Share-based compensation expense is included in R&D and G&A expenses in the accompanying consolidated statements of operations consistent with the grantee's salary. Share-based compensation expense included in R&D and G&A expenses for the year ended March 31, 2020 include $1.8 million and $10.2 million, respectively, related to the acceleration of vesting of certain share-based payment awards as a result of the change in control of the Company described previously. Share-based compensation expense presented in the table above includes share-based compensation expense allocated to the Company by its former majority

shareholder (See Note 7(B)). Total unrecognized share-based compensation expense was approximately $52.3 million as of March 31, 2020 and is expected to be recognized over a weighted-average period of approximately 2.70 years.

Note 11—Defined Contribution Plan

The Company sponsors a defined contribution plan pursuant to Section 401(k) of the U.S. Internal Revenue Code that allows eligible participants to contribute up to 90% of their eligible compensation, subject to maximum deferral limits specified by the Internal Revenue Code. Beginning in February 2020, the Company implemented 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, which such matching contributions becoming fully vested immediately. For the year ended March 31, 2020, the Company recorded total expense for matching contributions of $0.2 million. There were no matching contributions for the years ended March 31, 2019 and 2018.

Note 12—Leases

As described in Note 2, the Company adopted ASU 2016-2, *Leases*, (Topic 842) as of April 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with historical accounting under Topic 840.

The Company leases 40,232 square feet of office space located in Brisbane, California pursuant to a lease agreement, as amended, that expires in May 2026. The Company has the option to extend the lease term for an additional seven years but is not reasonably certain that it will exercise the option and has therefore excluded it from the lease term. The lease agreement, as amended, required the Company to deliver an irrevocable standby letter of credit in the amount of $0.5 million to the landlord, the amount of which is subject to reduction to approximately $0.2 million if certain conditions are met.

During October 2019, the Company entered into a Sublease Agreement ("sublease") for an additional 20,116 square feet of office space within the same building as its current corporate office space located in Brisbane, California. The sublease term expires in February 2024. The sublease required the Company to deliver an irrevocable standby letter of credit to the sublessor for the duration of the lease in the amount of $0.2 million.

The Company currently has no other significant operating, financing, or short-term leases.

The Company recognizes rent expense on a straight-line basis over the noncancelable term of its operating leases. Prior to the adoption of Topic 842, under Topic 840, rent expense was $2.1 million and $0.9 million for the years ended March 31, 2019 and 2018, respectively. For the year ended March 31, 2020, the components of operating lease expense for the Company's Brisbane, California office space were as follows (in thousands):

	Amount
Operating lease cost	$ 2,496
Variable lease cost [1]	225
Total operating lease cost	$ 2,721

[1] Variable lease cost includes common area maintenance and utilities costs which are not included in operating lease liabilities and which are expensed as incurred.

Certain information related to the Company's operating lease right-of-use assets and operating lease liabilities for its Brisbane, California office space was as follows for the year ended March 31, 2020 (in thousands):

	Amount
Cash paid for operating lease liabilities	$ 2,289
Operating lease right-of-use assets obtained in exchange for new operating lease liabilities	$ 12,237

As of March 31, 2020, the Company's operating leases for its Brisbane, California office space had a weighted average remaining lease term of 5.7 years and a weighted average discount rate of 12.3%.

As of March 31, 2020, maturities of operating lease liabilities for the Company's Brisbane, California office space were as follows (in thousands):

Years Ended March 31,		
2021	$	2,939
2022		3,028
2023		3,127
2024		3,053
2025		2,409
Thereafter		2,898
Total lease payments		17,454
Less imputed interest [(1)]		(4,942)
Present value of future minimum lease payments		12,512
Less operating lease liability, current portion		(1,516)
Operating lease liability, long-term portion	$	10,996

[(1)] The Company's lease agreements do not provide an implicit rate. The imputed interest was determined using the Company's incremental borrowing rate, which represents an estimated rate of interest that it would have to pay to borrow equivalent funds on a collateralized basis over a similar term at the lease inception date.

Note 13—Development and Commercialization Agreement

On March 30, 2020, the Company entered an exclusive license agreement for Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand. Under the agreement, the Company received an upfront payment of $40.0 million on March 31, 2020, which is included in current deferred revenue on the consolidated balance sheet, and is eligible to receive up to $40.0 million in regulatory milestone payments (of which $10.0 million was received in April 2020) and $107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval. Under the terms of the agreement, the Company will continue to lead global development of relugolix combination tablet. The Company has also agreed to assist Richter in transferring manufacturing technology from the Company's contract manufacturing organizations to Richter to enable Richter to manufacture relugolix combination tablet. If requested by Richter, the Company has agreed to supply Richter with quantities of relugolix combination tablet for its territories pursuant to the Company's agreements with its contract manufacturing organizations. Richter will be responsible for local clinical development, manufacturing, and all commercialization activities for its territories. The Company has also granted Richter an option to collaborate with the Company on relugolix combination tablet for future indications in women's health other than fertility.

The Company concluded that Richter represented a customer and applied relevant guidance from ASC 606 to evaluate the appropriate accounting under the Development and Commercialization Agreement. In accordance with this guidance, the Company identified one material combined performance obligation to grant a license to Richter to certain of its intellectual property and the delivery of certain clinical and regulatory data packages for uterine fibroids and endometriosis. The Company determined that its grant of a license to Richter to certain of its intellectual property was not distinct from the delivery of certain clinical and regulatory data packages. The Company concluded that the combined performance obligation had not been satisfied as of March 31, 2020, and as a result has included the $40.0 million upfront payment as current deferred revenue on the consolidated balance sheet.

The Company determined that the initial transaction price under the Richter Development and Commercialization Agreement totaled $50.0 million, consisting of the upfront payment of $40.0 million received on March 31, 2020 and the $10.0 million regulatory milestone payment received in April 2020. The Company will recognize the transaction price as revenue when the combined performance obligation is satisfied. The Company has not assigned a transaction price to any other regulatory milestones, sales-related milestones, or royalties on net sales following regulatory approval given the substantial uncertainty related to their achievement.

Note 14—Commitments and Contingencies

(A) Indemnification Agreements

The Company has agreed to indemnify its officers and directors for certain events or occurrences, subject to certain limits, while the officer or director was serving at the Company's request in such capacity. The maximum amount of potential future indemnification liability is unlimited; however, the Company holds directors' and officers' liability insurance which limits the Company's exposure and may enable it to recover a portion of any future amounts paid. In the normal course of business, the

Company also enters into contracts and agreements with service providers and other parties with which it conducts business that contain indemnification provisions pursuant to which the Company has agreed to indemnify the party against certain types of third-party claims. The Company has agreed to indemnify Sumitomo Dainippon Pharma against certain losses, claims, liabilities, and related expenses incurred by Sumitomo Dainippon Pharma, subject to the terms of the Sumitomo Dainippon Pharma Loan Agreement (See Note 7(A)). The Company has not experienced any material losses related to these indemnification obligations, and no material claims with respect thereto were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related accruals have been established.

(B) Contract Service Providers

In the normal course of business, the Company enters into agreements with contract service providers to assist in the performance of its R&D and clinical and commercial manufacturing activities. Subject to required notice periods and the Company's 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 collaborative research, contract research, clinical and commercial manufacturing, and supplier agreements in the future, which may require upfront payments and long-term commitments of capital resources.

(C) Legal Contingencies

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. The Company is currently not involved in any material legal proceedings.

Note 15—Selected Quarterly Financial Data (Unaudited)

The following table presents selected unaudited quarterly financial data of the Company for the years ended March 31, 2020 and 2019 (in thousands, except share and per share data). The unaudited quarterly financial data is prepared on the same basis as the audited consolidated financial statements, and in the opinion of management, includes all recurring adjustments necessary for a fair statement of such information. The Company's operating results for any quarter are not necessarily indicative of the operating results for any future quarters or a full year. The net loss per common share amounts for the quarterly periods have been computed separately. Therefore, the sum of quarterly net loss per common share amounts may not equal annual net loss per common share amounts.

	Fiscal 2020 Quarter Ended			
	June 30, 2019	September 30, 2019	December 31, 2019	March 31, 2020
Total operating expenses	$ 65,269	$ 67,406	$ 78,069	$ 64,143
Net loss	$ (67,904)	$ (70,568)	$ (85,604)	$ (64,913)
Net loss per common share — basic and diluted	$ (0.89)	$ (0.79)	$ (0.96)	$ (0.73)
Weighted average common shares outstanding — basic and diluted	76,468,347	88,798,398	88,893,579	89,130,806

	Fiscal 2019 Quarter Ended			
	June 30, 2018	September 30, 2018	December 31, 2018	March 31, 2019
Total operating expenses	$ 60,083	$ 64,123	$ 69,120	$ 71,500
Net loss	$ (62,134)	$ (65,770)	$ (70,633)	$ (75,014)
Net loss per common share — basic and diluted	$ (0.98)	$ (0.99)	$ (1.04)	$ (1.07)
Weighted average common shares outstanding — basic and diluted	63,310,177	66,666,876	67,616,419	70,076,475

Note 16—Subsequent Events

(A) Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Loan Agreement

Pursuant to the terms of the Sumitomo Dainippon Pharma Loan Agreement (see Note 7(A)), the Company is permitted to draw down funds once per calendar quarter, subject to certain conditions. In April 2020, the Company borrowed $80.0 million under the Sumitomo Dainippon Pharma Loan Agreement. Subsequent to this draw, approximately $206.3 million of borrowing capacity remains available to the Company.

Common Share Purchases by Majority Shareholder

During the period from April 1, 2020 through May 14, 2020, Sumitovant purchased a total of 1,679,868 of the Company's common shares on the open market. As of May 14, 2020, Sumitovant directly, and Sumitomo Dainippon Pharma indirectly, own 48,468,472 of the Company's outstanding common shares, representing approximately 53.9% of the Company's common shares outstanding on May 14, 2020.

(B) Gedeon Richter Plc. Development and Commercialization Agreement

In April 2020, the Company received a $10.0 million milestone payment from Richter pursuant to the Development and Commercialization Agreement. The milestone payment related to the Company's Marketing Authorisation Application submission to the European Medicines Agency for relugolix combination tablet for the treatment of women with moderate to severe symptoms associated with uterine fibroids. See Note 13.

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

None.

Item 9A. Controls and Procedures

(1) Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(2) 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, 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. Our internal control over financial reporting includes those policies and procedures that:

- pertain to 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 our assets that could have a material effect on the financial statements.

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

Our management 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) (COSO). 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.

(3) Attestation Report of the Registered Public Accounting Firm

Our independent registered public accounting firm was not required to and did not express an opinion on the effectiveness of our internal control over financial reporting as of March 31, 2020.

(4) Changes in Internal Control over Financial Reporting

We continuously seek to improve the efficiency and effectiveness of our internal controls. 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

On May 18, 2020, we and Sumitovant, our majority shareholder, entered into a consulting agreement pursuant to which Sumitovant will provide consulting services to us to support us in commercial planning, commercial launch activities and implementation. Adele Gulfo, Sumitovant's Chief Business and Commercial Development Officer and a member of our board of directors, will provide the services to us on behalf of Sumitovant under the agreement. The term of engagement will continue through November 11, 2020, or such earlier time as we hire a permanent Chief Commercial Officer, and may be renewed upon the mutual written consent of the parties. Either we or Sumitovant may terminate the engagement under the agreement at any time for any reason by giving not less than 15 days prior written notice thereof to the other party. The consulting services will be provided with the aggregate fees not to exceed a total of $120,000 without our prior written approval.

PART III.

We intend to file a definitive proxy statement for our 2020 Annual General Meeting of Shareholders ("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 under 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 the Board of Directors and Corporate Governance," "Executive Officers" and, if applicable, "Delinquent Section 16(a) Reports" and is incorporated herein by reference.

Item 11. Executive Compensation

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

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

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 Accounting Fees and Services

The information required by this item will be contained in our 2020 Proxy Statement under the caption "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.

PART IV. FINANCIAL INFORMATION

Item 15. Exhibits, Financial Statement Schedules

(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:

(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.

(3) Exhibits.

Exhibit Index

Exhibit No.		Description of Document	Schedule / Form	File No.	Exhibit No.	Filing Date
3.1		Certificate of Incorporation.	S-1	333-213891	3.1	09/30/2016
3.2		Memorandum of Association.	S-1	333-213891	3.2	09/30/2016
3.3		Fifth Amended and Restated Bye-Laws.	10-Q	001-37929	3.3	02/10/2020
4.1	†	Description of Common Shares.				
4.2		See Exhibits 3.1 - 3.3.				
10.1		Letter Agreement, dated October 31, 2019, by and between the Registrant and Sumitomo Dainippon Pharma Co., Ltd.	10-Q	001-37929	10.1	02/10/2020
10.2		Loan Agreement, dated as of December 27, 2019, by and among Sumitomo Dainippon Pharma Co., Ltd., as the Lender, the Registrant, as the Parent, and Myovant Sciences GmbH, as the Borrower.	10-Q	001-37929	10.2	02/10/2020
10.3		Investor Rights Agreement, dated as of December 27, 2019, by and among the Registrant, Sumitovant Biopharma Ltd. and Sumitomo Dainippon Pharma Co., Ltd.	10-Q	001-37929	10.3	02/10/2020
10.4	†*	License Agreement, dated April 29, 2016, by and between the Registrant and Takeda Pharmaceuticals International AG and Amendment No. 1 dated August 30, 2016.				
10.5	†*	Amendment No. 2 to License Agreement, dated March 3, 2020, by and between the Registrant and Takeda Pharmaceuticals International AG.				
10.6	†*	Agreement for the Manufacture and Supply of Clinical Trial Material, dated June 7, 2016, by and between the Registrant and Takeda Pharmaceuticals Company Limited, as amended.				

10.7	*	Commercial Manufacturing & Supply Agreement, effective as of May 30, 2018, by and between Myovant Sciences GmbH and Takeda Pharmaceutical Company Limited.	10-Q/A	001-37929	10.5	09/17/2018
10.8		Sales Agreement, dated as of April 2, 2018, between Myovant Sciences Ltd. and Cowen and Company, LLC.	8-K	001-37929	1.1	04/03/2018
10.9	+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Lynn Seely, M.D. and Myovant Sciences, Inc.	10-Q	001-37929	10.1	11/08/2018
10.10	+	Restricted Stock Award Agreement, dated May 31, 2017, by and between Myovant Sciences Ltd. and Lynn Seely.	10-K	001-37929	10.21	05/24/2019
10.11	+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Frank Karbe and Myovant Sciences, Inc.	10-Q	001-37929	10.2	11/08/2018
10.12	+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Matt Lang and Myovant Sciences, Inc.	10-Q	001-37929	10.3	11/08/2018
10.13	+	Amended and Restated Employment Agreement, dated as of November 7, 2018, by and between Juan Camilo Arjona Ferreira, M.D. and Myovant Sciences, Inc.	10-Q	001-37929	10.4	11/08/2018
10.14	+	Employment Agreement, dated as of November 1, 2018, by and between Kim Sablich and Myovant Sciences, Inc.	10-Q	001-37929	10.6	02/07/2019
10.15	+	Form of Indemnification Agreement with directors and executive officers.	S-1	333-213891	10.8	09/30/2016
10.16	+	2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.5	10/20/2016
10.17	+	Forms of Option Grant Notice and Option Agreement under 2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.6	09/30/2016
10.18	+	Form of Amendment No.1 to the Stock Option Grant Notice and Option Agreement under 2016 Equity Incentive Plan, as amended.	10-Q	001-37929	10.1	11/12/2019
10.19	+	Form of Early Exercise Stock Purchase Agreement under 2016 Equity Incentive Plan, as amended.	S-1	333-213891	10.7	09/30/2016
10.20	+	Form of Restricted Stock Unit Grant Notice and Award Agreement under 2016 Equity Incentive Plan, as amended.	10-K	001-37929	10.30	05/24/2019
10.21	+	Form of Restricted Stock Unit Grant Notice and Award Agreement under 2016 Equity Incentive Plan, as amended (2019 Form).	10-Q	001-37929	10.2	11/12/2019
10.22	+	Form of Restricted Stock Award Agreement under 2016 Equity Incentive Plan, as amended.	10-K	001-37929	10.31	05/24/2019
10.23	+	2020 Incentive Bonus Arrangements with Executive Officers.	10-Q	001-37929	Part II -Item 5	02/10/2020
10.24	†+	Non-Employee Director Compensation Policy.				
21.1	†	Subsidiaries of the Registrant.				
23.1	†	Consent of independent registered public accounting firm.				
31.1	†	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	†	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				

32.1	**	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.
32.2	**	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.
101.INS		Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH		Inline XBRL Taxonomy Extension Schema
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF		Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase
104		Cover Page Interactive Data File- the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

† Filed herewith.

+ 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.

MYOVANT SCIENCES LTD.

By: /s/ Lynn Seely

Lynn Seely
(Principal Executive Officer and Director)

Date: May 18, 2020

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Lynn Seely and Frank Karbe, 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 Myovant 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, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Lynn Seely Lynn Seely	Principal Executive Officer and Director	May 18, 2020
/s/ Frank Karbe Frank Karbe	Principal Financial and Accounting Officer	May 18, 2020
/s/ Myrtle Potter Myrtle Potter	Chairman and Director	May 18, 2020
/s/ Terrie Curran Terrie Curran	Director	May 18, 2020
/s/ Mark Guinan Mark Guinan	Director	May 18, 2020
/s/ Adele Gulfo Adele Gulfo	Director	May 18, 2020
/s/ Hiroshi Nomura Hiroshi Nomura	Director	May 18, 2020
/s/ Kathleen Sebelius Kathleen Sebelius	Director	May 18, 2020

Exhibit 4.1

DESCRIPTION OF COMMON SHARES

The following description of our share capital and provisions of our memorandum of association and amended and restated bye-laws is a summary and is qualified entirely by reference to the applicable provisions of our memorandum of association, amended and restated bye-laws and the Bermuda Companies Act 1981, as amended, or the Companies Act. Our memorandum of association and amended and restated bye-laws are exhibits to the Form 10-K and Form 10-Q filings we make with the U.S. Securities and Exchange Commission which are available at www.sec.gov.

General

We are an exempted company limited by shares incorporated under the laws of Bermuda on February 2, 2016, under the name Roivant Endocrinology Ltd. We changed our name to Myovant Sciences Ltd. in May 2016. The objects of our business are unrestricted, and Myovant Sciences Ltd. has the capacity of a natural person. We can therefore undertake activities without restriction on our capacity.

Since our incorporation, other than a subdivision of our authorized and issued share capital and our initial public offering of common shares in November 2016, 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. There have been no public takeover offers by third parties for our shares nor any public takeover offers by us for the shares of another company that have occurred during the last or current financial years.

Share Capital

Our authorized share capital consists of 564,111,242 common shares, $0.000017727 par value per common share. All of our issued and outstanding common shares are fully paid. Pursuant to our amended and restated bye-laws, subject to the requirements of the NYSE 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 on such terms and conditions as it may determine. 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 (as defined in the Companies Act), which includes the NYSE.

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. Unless a different majority is required by law or by our amended and restated bye-laws, resolutions to be approved by holders of common shares require approval by a majority of votes cast at a general meeting at which a quorum is present.

In the event of our liquidation, dissolution or winding up, the holders of common shares are entitled to share equally and ratably in our assets, if any, remaining after the payment of all of our debts and liabilities, subject to any liquidation preference on any issued and outstanding preference shares.

Preference Shares

Pursuant to Bermuda law and our amended and restated bye-laws, our board of directors may, by resolution, establish one or more series of preference shares having such number of shares, designations, dividend rates, relative voting rights, conversion or exchange rights, redemption rights, liquidation rights, rights to elect or appoint directors 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. Additionally, the issuance of preference shares may have the effect of decreasing the market price of the common shares and may adversely affect the voting power of holders of common shares and reduce the likelihood that common shareholders will receive dividend payments and payments upon liquidation.

Dividend Rights

Under 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.

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 majority of the votes cast at a general meeting of the relevant class of shareholders at which a quorum consisting of at least two persons holding or representing one-third or more of the issued shares of the relevant class is present. Our amended and restated bye-laws specify that the creation or issue of shares ranking equally with existing shares will not, unless expressly provided by the terms of issue of existing shares, vary the rights attached to existing shares. In addition, the creation or issue of preference shares ranking prior to common shares will not 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. We shall not vary or alter the rights attaching to any class of shares if our board of directors determines in its sole discretion that any non de minimis adverse tax, regulatory or legal consequences to our company, any subsidiary of our company, or any direct or indirect holders of shares or our affiliates (as defined in our amended and restated bye-laws) may result from such variation.

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 or unless all applicable consents, authorizations and permissions of any governmental agency or body in Bermuda have been obtained or if it appears to our board of directors that any non-de minimis adverse tax, regulatory or legal consequences for us, any subsidiary of ours, holders of our common shares or our affiliates (as defined in our amended and restated bye-laws) would result from the transfer. Subject to these restrictions, a holder of common shares may transfer the title to all or any of his common shares by completing a form of transfer in the form set out in our amended and restated bye-laws (or as near thereto as circumstances admit) or in such other common form as our board of directors may accept. 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. Any class of our shares that are listed or admitted to trading on an appointed stock exchange (such as the New York Stock Exchange) may be transferred in accordance with the rules and regulations of such exchange.

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. While Bermuda law permits the shareholders to waive the requirement to hold an annual general meeting by resolution (either for a specific year or a period of time or indefinitely), our amended and restated bye-laws provide that, notwithstanding, an annual general meeting shall be held in each year.

Bermuda law provides that a special general meeting of shareholders may be called by the board of directors of a company and must be called upon the request of shareholders holding not less than 10% of the paid-up capital of the company carrying the right to vote at general meetings. Bermuda law also requires that shareholders be given at least five days' advance notice of a general meeting, but the accidental omission to give notice to any person does not invalidate the proceedings at a meeting. Our amended and restated bye-laws provide that our principal executive officer or the chairman or any two directors or any director and the secretary or our board of directors may convene an annual general meeting and our principal executive officer or the chairman or any two directors or any director and the secretary or our board of directors may convene a special general meeting. Under our amended and restated bye-laws, at least 14 days' notice of an annual general meeting or ten days' notice of a special general meeting must be given to each shareholder entitled to vote at such meeting. This notice requirement is subject to the ability to hold such meetings on shorter notice if such notice is agreed: (1) in the case of an annual general meeting by all of the shareholders entitled to attend and vote at such meeting; or (2) in the case of a special general meeting by a majority in number of the shareholders entitled to attend and vote at the meeting holding not less than 95% in nominal value of the shares entitled to vote at such meeting. Subject to the rules of the NYSE, the quorum required for a general meeting of shareholders is

two or more persons present in person at the start of the meeting and representing in person or by proxy in excess of 50% of the total voting shares in our company.

Access to Books and Records and Dissemination of Information

Members of the general public have a right to inspect the public documents of a company available at the office of the Registrar of Companies in Bermuda. These documents include a company's memorandum of association, including its objects and powers, and certain alterations to the amended and restated memorandum of association. The shareholders have the additional right to inspect the bye-laws of the company, minutes of general meetings and the company's audited financial statements, which must be presented in the annual general meeting. The register of members of a company is also open to inspection by shareholders and by members of the general public without charge. The register of members is required to be open for inspection for not less than two hours in any business day (subject to the ability of a company to close the register of members for not more than thirty days in a year). A company is required to maintain its share register in Bermuda but may, subject to the provisions of the Companies Act establish a branch register outside of Bermuda. A company is required to keep at its registered office a register of directors and officers that is open for inspection for not less than two hours in any business day by members of the public without charge. Bermuda law does not, however, provide a general right for shareholders to inspect or obtain copies of any other corporate records.

Election and Removal of Directors

Our amended and restated bye-laws provide that our board of directors shall consist of a single class of directors of such number of directors as the Nominating and Corporate Governance Committee of the board of directors may determine. Each director shall hold office until the next annual general meeting at which his or her successor is elected or appointed or if earlier, the next special general meeting called for the purpose of ending the term of such director and replacing that director, in each case, subject to his or her office being vacated sooner.

Nominations of persons for election as a director or the proposal of other business to be transacted by the shareholders may be made at an annual general meeting or special meeting only (1) by or at the direction of the board of directors, or (2) subject to any applicable law, by any Eligible Member of record at the time of giving of notice who complies with the notice procedures set forth in our amended and restated bye-laws. In the case of a special meeting, nominations may also be made pursuant to our notice of meeting or any supplement thereto. An "Eligible Member" is a shareholder that, together with the common shares held by its affiliates (as defined in our amended and restated bye-laws), owns of record shares that constitute five percent or more of the voting power of all issued shares that are eligible to vote at a general meeting and who has held such shares for at least three years.

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 (or 60 days in the case of our Audit Committee's proposal of a director) 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, 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.

A director may be removed, only with cause, by the shareholders, provided notice of the shareholders meeting convened to remove the director is given to the director. The notice must contain a statement of the intention to remove the director and must be served on the director not less than 14 days before the meeting. The director is entitled to attend the meeting and be heard on the motion for his removal. The term of a director may also be ended by an annual general meeting, or by a special general meeting called for the purpose of ending the term of such director and replacing that director, and the director's office is deemed vacated if the director is not re-elected.

Proceedings of Board of Directors

Our amended and restated bye-laws provide that our business is to be managed and conducted by our board of directors. Bermuda law permits individual and corporate directors and there is no requirement in our amended and restated bye-laws or Bermuda law that directors hold any of our shares. There is also no requirement in our amended and restated bye-laws or Bermuda law that our directors must retire at a certain age.

The compensation of our directors will be determined by the board of directors, and there is no requirement that a specified number or percentage of "independent" directors must approve any such determination. Our directors may also be paid all travel, hotel and other reasonable out-of-pocket expenses properly incurred by them in connection with our business or their duties as directors.

A director who discloses a direct or indirect interest in any contract or arrangement with us as required by Bermuda law will not be entitled to vote in respect of any such contract or arrangement in which he or she is interested unless the chairman of the relevant meeting of our board of directors determines that such director is not disqualified from voting.

Contractual Limitations on Board Actions and Matters

We have entered into an the Investor Rights Agreement, dated as of December 27, 2019, with Sumitomo Dainippon Pharma Co., Ltd. and Sumitovant Biopharma Ltd. (collectively "***Sumitomo***") pursuant to which, among other things, we have agreed as to certain limitations on actions that our board of directors and various committees of the board of directors may take, as well as the composition of our board of directors and various committees of the board of directors, for so long as Sumitomo continues to hold more than 50% of the total voting power of our equity securities.

Indemnification of Directors and Officers

Section 98 of the Companies Act provides generally that a Bermuda company may indemnify its directors, officers and auditors against any liability which by virtue of any rule of law would otherwise be imposed on them in respect of any negligence, default, breach of duty or breach of trust, except in cases where such liability arises from fraud or dishonesty of which such director, officer or auditor may be guilty in relation to the company. Section 98 further provides that a Bermuda company may indemnify its directors, officers and auditors against any liability incurred by them in defending any proceedings, whether civil or criminal, in which judgment is awarded in their favor or in which they are acquitted or granted relief by the Supreme Court of Bermuda pursuant to Section 281 of the Companies Act.

Our amended and restated bye-laws provide that we shall indemnify our officers and directors in respect of their actions and omissions, except in respect of their fraud or dishonesty, and that we may advance funds to our officers and directors for expenses incurred in their defense upon receipt of an undertaking to repay the funds if any allegation of fraud or dishonesty is proved. Our amended and restated bye-laws provide that the shareholders waive all claims or rights of action that they might have, individually or in right of the company, against any of the company's directors or officers for any act or failure to act in the performance of such director's or officer's duties, except in respect of any fraud or dishonesty of such director or officer. Section 98A of the Companies Act permits us to purchase and maintain insurance for the benefit of any officer or director in respect of any loss or liability attaching to him in respect of any negligence, default, breach of duty or breach of trust, whether or not we may otherwise indemnify such officer or director. We have purchased and maintain a directors' and officers' liability policy for such purpose.

Amendment of Memorandum of Association and Bye-laws

Bermuda law provides that the memorandum of association of a company may be amended by a resolution passed at a general meeting of shareholders. Our amended and restated bye-laws provide that no bye-law shall be rescinded, altered or amended, and no new bye-law shall be made, unless it shall have been approved by a resolution of our board of directors and by a resolution of our shareholders.

Under Bermuda law, the holders of an aggregate of not less than 20% in par value of a company's issued share capital or any class thereof have the right to apply to the Supreme Court of Bermuda for an annulment of any amendment of the memorandum of association adopted by shareholders at any general meeting, other than an amendment that alters or reduces a company's share capital as provided in the Companies Act. Where such an application is made, the amendment becomes effective only to the extent that it is confirmed by the Supreme Court of Bermuda. An application for an annulment of an amendment of the memorandum of association must be made within 21 days after the date on which the resolution altering the company's memorandum of association is passed and may be made on behalf of persons entitled to make the application by one or more of their number as they may appoint in writing for the purpose. No application may be made by shareholders voting in favor of the amendment.

Amalgamations and Mergers

The amalgamation or merger of a Bermuda company with another company or corporation (other than certain affiliated companies) requires the amalgamation or merger agreement to be approved by the company's board of directors and by its

shareholders. Unless the company's bye-laws provide otherwise, the approval of 75% of the shareholders voting at such meeting is required to approve the amalgamation or merger agreement, and the quorum for such meeting must be two or more persons holding or representing more than one-third of the issued shares of the company. Our amended and restated bye-laws provide that the approval of a simple majority of shareholders voting at a meeting to approve the amalgamation or merger agreement shall be sufficient (except for an amalgamation or merger that is a "business combination"), and the quorum for such meeting shall be two or more persons holding or representing more than 50% of the total voting shares in the company.

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, excluding for the purposes of determining the number of shares issued and outstanding those shares owned (1) by persons who are directors and also officers and (2) employee share plans in which employee participants do not have the right to determine whether shares held subject to the plan will be tendered in a tender or exchange offer; 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 or special general meeting of shareholders by the affirmative vote of at least 66 2/3% of our issued and outstanding voting shares that are not owned by the interested shareholder.

For purposes of these provisions, a "business combination" includes recapitalizations, mergers, amalgamations, consolidations, exchanges, asset sales, leases, certain issues or transfers of shares or other securities and other transactions resulting in a financial benefit to the interested shareholder. An "interested shareholder" is any person or entity that beneficially owns 15% or more of our issued and outstanding voting shares and any person or entity affiliated with or controlling or controlled by that person or entity.

Shareholder Suits

Class actions and derivative actions are generally not available to shareholders under Bermuda law. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or 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 amended and restated bye-laws contain a provision by virtue of which our shareholders waive any claim or right of action that they have, both individually and on our behalf, against any director or officer in relation to any action or failure to take action by such director or officer, except in respect of any fraud or dishonesty of such director or officer. We have been advised

by the SEC that in the opinion of the SEC, the operation of this provision as a waiver of the right to sue for violations of federal securities laws would likely be unenforceable in U.S. courts.

Capitalization of Profits and Reserves

Pursuant to our amended and restated 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 amended and restated 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 enquires have failed to establish the shareholder's new address. This entitlement conferred on the company in respect of the foregoing, 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 any of our shares, warrants and other securities 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 the NYSE. Approvals or permissions given by the Bermuda Monetary Authority do not constitute a guarantee by the Bermuda Monetary Authority as to our performance or our creditworthiness. Accordingly, in giving such consent or permissions, neither the Bermuda Monetary Authority nor the Registrar of Companies in Bermuda shall be liable for the financial soundness, performance or default of our business or for the correctness of any opinions or statements expressed in this prospectus. Certain issues and transfers of common shares involving persons deemed resident in Bermuda for exchange control purposes require the specific consent of the Bermuda Monetary Authority. We have sought and have obtained a specific permission from the Bermuda Monetary Authority for the issue and transfer of our common shares up to the amount of our authorized capital from time to time, and options, warrants, depository receipts, rights, loan notes, debt instruments and our other securities to persons resident and non-resident for exchange control purposes with the need for prior approval of such issue or transfer.

In accordance with Bermuda law, share certificates are only issued in the names of companies, partnerships or individuals. In the case of a shareholder acting in a special capacity (for example as a trustee), certificates may, at the request of the shareholder, record the capacity in which the shareholder is acting. Notwithstanding such recording of any special capacity, we are not bound to investigate or see to the execution of any such trust.

Transfer Agent and Registrar

A register of holders of the common shares will be maintained by Conyers Corporate Services (Bermuda) Limited in Bermuda, and a branch register will be maintained in the United States by American Stock Transfer & Trust Company, LLC, which also serves as transfer agent. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

The transfer agent for any series of preference shares that we may offer under this prospectus will be named and described in the prospectus supplement for that series.

Listing

Our common shares are listed on the NYSE under the trading symbol "MYOV."

Bermuda Taxation Impacts on U.S. Holders of our Common Shares

At the present time, there is no Bermuda income or profits tax, withholding tax, capital gains tax, capital transfer tax, estate duty or inheritance tax payable by us or by our shareholders in respect of our shares. We have obtained an assurance from the Minister of Finance of Bermuda under the Exempted Undertakings Tax Protection Act 1966 that, in the event that any legislation is enacted in Bermuda imposing any tax computed on profits or income, or computed on any capital asset, gain or appreciation or any tax in the nature of estate duty or inheritance tax, such tax shall not, until March 31,2035, be applicable to us or to any of our operations or to our shares, debentures or other obligations except insofar as such tax applies to persons ordinarily resident in Bermuda or is payable by us in respect of real property owned or leased by us in Bermuda.

U.K. Taxation Impacts on U.S. Holders of our Common Shares

The discussion below is intended as a general guide to certain aspects of U.K. tax law and HM Revenue & Customs, or HMRC, published practice applying as at the date of this filing (both of which are subject to change at any time, possibly with retrospective effect) which relate to our common shares. It does not constitute legal or tax advice and does not purport to be a complete analysis of all U.K. tax considerations relating to the holding of our common shares. In particular it should be noted that special rules may apply to certain persons such as market makers, brokers, dealers or intermediaries.

Dividends

Withholding Tax

Dividends paid by the company are not subject to any withholding or deduction for or on account of U.K. tax.

Stamp Duty and Stamp Duty Reserve Tax

No UK stamp duty or UK stamp duty reserve tax, or SDRT, will be payable on the issue or transfer of, or agreement to transfer, our common shares, subject to the comments below.

UK stamp duty will in principle be payable on any instrument of transfer of our common shares (where the amount or value of the consideration is more than £1,000) that is executed in the United Kingdom or that relates to any property situated, or to any matter or thing done or to be done, in the United Kingdom. No UK stamp duty should be payable on the transfer of our common shares, provided that any transfer documents are executed and retained outside the United Kingdom. Holders of common shares should be aware that, even where an instrument of transfer is in principle subject to UK stamp duty, UK stamp duty is not required to be paid unless it is necessary to rely on the instrument for legal purposes, for example to register a change of ownership by updating a share register held in the United Kingdom or in litigation in a UK court.

Provided that our common shares are not registered in any register maintained in the United Kingdom by us or on our behalf and are not paired with any shares or securities issued by a UK incorporated company, any agreement to transfer common shares will not be subject to SDRT.

Our common shares are not paired with any shares or securities issued by a UK incorporated company and we do not intend that any register of common shares will be maintained in the United Kingdom by us or on our behalf.

Exhibit 10.4

CERTAIN Information Identified by "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

EXECUTION VERSION

LICENSE AGREEMENT

by and between

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

and

ROIVANT ENDOCRINOLOGY LTD.

Dated as of April 29, 2016

TABLE OF CONTENTS

LICENSE AGREEMENT

This License Agreement (this "Agreement") is made effective as of April 29, 2016 (the "Effective Date") by and between Takeda Pharmaceuticals International AG a company incorporated under the laws of Switzerland having its principal place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon Zurich, Switzerland ("Takeda") and Roivant Endocrinology Ltd., an exempted limited company incorporated under the laws of Bermuda, a having its registered office at 2 Church Street, Hamilton, Bermuda ("Licensee"). Licensee and Takeda are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Takeda is a pharmaceutical company engaged in the research, development, and commercialization of products useful in the amelioration, treatment, or prevention of human diseases and conditions;

WHEREAS, Licensee is a pharmaceutical company engaged in the development and commercialization of treatments for endocrine-related Men's Health and Women's Health diseases or disorders;

WHEREAS, Licensee wishes to obtain, and Takeda desires to grant, a license under certain patents, patent applications, know-how, and other proprietary information Controlled by Takeda for the Development and Commercialization of the Licensed Compounds and Licensed Products in the Licensee Territory; and

WHEREAS, Takeda wishes to obtain, and Licensee desires to grant, a license under certain patents, patent applications, know-how, and other proprietary information Controlled by Licensee for Development and Commercialization of the Licensed Compounds and Licensed Products in the Takeda Territory.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1. "Accounting Standards" means GAAP in the case of Licensee and IFRS in the case of Takeda.

1.2. "Adverse Event" or "AE" has the meaning set forth in 21 C.F.R. § 312.32 and generally means any untoward medical occurrence associated with the use of a product in human subjects, whether or not considered related to such product. An AE does not necessarily have a causal relationship with a product, that is, an AE can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of such product.

1.3. "Affiliate" means, with respect to a particular person or entity, a Person that controls, is controlled by, or is under common control with such person or entity, other than any Excluded Affiliate (with respect to Licensee). For the purposes of this definition, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

1.4. "Applicable Law" means any applicable federal, state, local, municipal, foreign, or other law, statute, legislation, constitution, principle of common law, code, treaty ordinance, regulation, rule, or order of any kind whatsoever put into place under the authority of any Governmental Authority, including the FFDCA, Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), all as amended from time to time, together with any

rules, regulations, and compliance guidance promulgated thereunder. "Applicable Law" will include the applicable regulations and guidance of the FDA and European Union (and national implementations thereof) that constitute Good Laboratory Practices, Good Manufacturing Practices, and Good Clinical Practices (and, if and as appropriate under the circumstances, ICH guidance or other comparable regulation and guidance of any applicable Governmental Authority).

1.5. "Assigned Regulatory Materials" has the meaning set forth in Section 4.3.1 (Licensed Product INDs).

1.6. "Bankruptcy Laws" has the meaning set forth in Section 13.14 (Rights in Bankruptcy).

1.7. "[***].

1.8. "Breaching Party" has the meaning set forth in Section 13.3.1 (Cure Periods).

1.9. "Business Day" means a day other than Saturday, Sunday, or any other day on which commercial banks located in the State of New York, U.S., Zurich, Switzerland, Bermuda, or Japan, are authorized or obligated by Applicable Law to close.

1.10. "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31; *provided*, *however*, that (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the first complete Calendar Quarter thereafter and (b) the last Calendar Quarter of the Term will end upon the expiration or termination of this Agreement.

1.11. "Calendar Year" means the twelve (12) month period ending on December 31; *provided*, *however*, that (a) the first Calendar Year of the Term will begin on the Effective Date and end on December 31, 2016 and (b) the last Calendar Year of the Term will end upon the expiration or termination of this Agreement.

1.12. "Cash-on-Hand" has the meaning set forth in Section 11.4.2 (Cash-on-Hand).

1.13. "Change of Control" means the consummation of: (a) any transaction in which any Third Party acquires directly or indirectly the beneficial ownership of any voting security of Licensee, or if the percentage ownership of such person or entity in the voting securities of Licensee is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty percent (50%) of the total voting power of all of the then-outstanding voting securities of Licensee; (b) any merger, consolidation, recapitalization, or reorganization of Licensee, other than any such transaction which would result in stockholders or equity holders of Licensee, or an Affiliate of Licensee, immediately prior to such transaction owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; and (c) the sale or other transfer to a Third Party of all or substantially all of Licensee's assets which relate to this Agreement.

1.14. "Claim" has the meaning set forth in Section 15.1 (Indemnification by Licensee).

1.15. "Clinical Trial" means any clinical trial in humans that is conducted in accordance with Good Clinical Practices and is designed to generate data in support or maintenance of an IND or NDA, or other similar marketing application, including any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Phase IIIb Clinical Trial, or any post-approval clinical trial in humans.

1.16. "CMC" means chemistry, manufacturing, and controls.

1.17. "Combination Product" means any Licensed Product comprising: (a) a Licensed Compound and (b) at least one other active compound or ingredient.

1.18. "Commercial Manufacturing and Supply Agreement" has the meaning set forth in Section 8.1.3 (Commercial Supply).

1.19. "Commercial Viability Termination" has the meaning set forth in Section 13.5.1 (Commercial Viability Termination).

1.20. "Commercialization" means all activities undertaken by or on behalf of a Party to promote, market, sell, and distribute a Licensed Product, including: (a) sales force efforts, detailing, advertising, marketing, the creation and approval of promotional materials, sales or distribution, pricing, customer and government contracting, and medical affairs, including medical education, medical information, clinical science liaison activities, and health economics and outcomes research; (b) product security activities that may include enhancing supply chain security, implementing brand protection technologies, intelligence gathering, forensic analysis, customs recordation, and anti-counterfeiting enforcement action, such as taking Internet countermeasures, collaborating with law enforcement and seeking criminal restitution; (c) management of any risk evaluation and mitigation strategies (REMS) programs; (d) importing, exporting, transporting, customs clearance, warehousing, invoicing, handling, and delivering the Licensed Products to customers; and (e) other similar activities relating to the Licensed Products. When used as a verb, "Commercialize" means to engage in Commercialization activities.

1.21. "Commercialization Diligence Obligations" has the meaning set forth in Section 7.2 (Commercialization Diligence Obligations).

1.22. "Commercialization Plan" has the meaning set forth in Section 7.3 (Commercial Plan).

1.23. "Commercially Reasonable Efforts" means, with respect to the efforts to be expended, or considerations to be undertaken, by Licensee or its Affiliate with respect to any objective, activity or decision to be undertaken under this Agreement with respect to the Licensed Compounds or Licensed Products, the level of efforts and resources commonly dedicated by a similarly situated pharmaceutical company to accomplish such objective, activity, or decision with respect to a product of similar commercial potential at a similar stage in its lifecycle taking into account [***]. Any other pharmaceutical product Licensee is then discovering, researching, developing, manufacturing, commercializing, or otherwise exploiting, alone or with one or more collaborators, will not be taken into account so as to reduce, diminish, or limit Commercially Reasonable Efforts.

1.24. "Competing Product" means: (a) any small molecule oral GnRH receptor antagonist (other than a TAK-385 Licensed Product) for the treatment, prevention, cure, or control of symptoms associated with Uterine Fibroids, Endometriosis, or prostate cancer, and (b) any TAK-448 Licensed Product, but solely with respect to the treatment, prevent, cure or control of symptoms associated with prostate cancer in the Takeda Territory.

1.25. "Complementary Product" means: (a) any pharmaceutical or biopharmaceutical product, other than a TAK-385 Licensed Product, for the treatment, prevention, cure, or control of symptoms associated with Uterine Fibroids or Endometriosis or (b) any pharmaceutical or biopharmaceutical product, other than a TAK-385 Licensed Product, for the treatment, prevention, cure, or control of symptoms associated with prostate cancer.

1.26. "Confidential Information" means all non-public or proprietary Information disclosed by a Party to the other Party under this Agreement, which may include ideas, inventions, discoveries, concepts, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, inventories, machines, techniques, development, designs, drawings, computer programs, skill, experience, documents, apparatus, results, clinical and regulatory strategies, regulatory documentation, information and submissions pertaining to or made in association with Regulatory Materials, data (including pharmacological, toxicological, and clinical data, raw data, analytical and quality control data, manufacturing data and descriptions, patent and legal data, market data, financial data or

descriptions), devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, without regard as to whether any of the foregoing is marked "confidential" or "proprietary," or disclosed in oral, written, graphic, or electronic form. Confidential Information will include the terms and conditions of this Agreement.

1.27. "Contact Person" has the meaning set forth in Section 2.5 (Contact Persons).

1.28. "Contract Manufacturing Organization" or "CMO" means a Third Party contract manufacturing organization.

1.29. "Control" means, with respect to any Information, Patent Right, Trademark or other Intellectual Property Right, ownership or possession by a Party, including its Affiliates, of the ability (without taking into account any rights granted by one Party to the other Party under the terms of this Agreement) to grant access, a license, or a sublicense to such Information, Patent Right, Trademark or other Intellectual Property Right without (a) violating the terms of any agreement or other arrangement with, (b) being required to make any payment to, or (c) necessitating the consent of, in each case ((a) - (c)), any Third Party, at such time that the Party would be first required under this Agreement to grant the other Party such access, license, or sublicense.

1.30. "Cover" or "Covered" or "Covering" means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of the subject matter would fall within the scope of a claim in the Patent Right.

1.31. "Cure Period" has the meaning set forth in Section 13.3.1 (Cure Periods).

1.32. "Development" means all non-clinical and clinical research and drug development activities undertaken by or on behalf of a Party, including toxicology, pharmacology, and other non-clinical efforts, statistical analysis, the performance of Clinical Trials, CMC development, or other activities reasonably necessary in order to obtain or maintain Regulatory Approval of a Licensed Product. When used as a verb, "Develop" means to engage in Development activities.

1.33. "Development Milestone Events" means those Development milestone events to be achieved by Licensee in connection with the performance of its Development activities with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products, as set forth in the TAK-385 Development Plan.

1.34. "Diligent Efforts" means, with respect to a TAK-385 Licensed Product in the Men's Health Field in the Takeda Territory, the commercially reasonable efforts, expertise, and resources commonly used by Takeda for a product owned by it or to which it has exclusive rights in the Takeda Territory, which, as compared with a TAK-385 Licensed Product, is of similar market potential, at a similar stage in its development or product life, and involves similar risks, all as measured based upon the facts and circumstances at the time such efforts are due, [***].

1.35. "Disclosing Party" has the meaning set forth in Section 12.1 (Nondisclosure and Non-Use).

1.36. "Dispute" or "Disputes" has the meaning set forth in Section 14.1 (Exclusive Dispute Resolution Mechanism).

1.37. "EMA" means the European Medicines Agency, or any successor thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems, and devices in the European Union.

1.38. "Endometriosis" means a condition resulting from the presence of endometrial tissue outside the uterus.

1.39. "Excluded Affiliate" means (a) any Parent Affiliate or (b) any direct or indirect subsidiary of a Parent Affiliate that (i) is controlled (as defined in Section 1.3 (Affiliate)) by such Parent Affiliate but is not controlled by Licensee and (ii) is established for the development and commercialization of compounds and products other than the Licensed Compounds and Licensed Products.

1.40. "Executive Officer" has the meaning set forth in Section 14.2 (Resolution by Executive Officers).

1.41. "Exploit" or "Exploitation" means to Develop, Manufacture, and Commercialize. When used as a verb, "Exploit" and "Exploiting" means to engage in Exploitation and "Exploited" has a corresponding meaning.

1.42. "FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.43. "FFDCA" means the Federal Food, Drug and Cosmetic Act under United States Code, Title 21, as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.44. "Field" means the treatment, prevention, cure, or control of any human disease, disorder, illness, or condition, including the Men's Health Field and the Women's Health Field.

1.45. "First Commercial Sale" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the first sale of a Licensed Product by Licensee, its Affiliates, or its Sublicensees to an end user or prescriber for use, consumption, or resale of a Licensed Product in a country where Regulatory Approval of the Licensed Product has been obtained.

1.46. "FTE" means the equivalent of the work of one duly qualified employee of Licensee full time for one year (consisting of a total of [***] hours per year) carrying out scientific or technical work under this Agreement. Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. The portion of an FTE billable by Licensee for one individual during a given accounting period will be determined by dividing the number of hours worked directly by said individual on the work to be conducted under this Agreement during such accounting period and the number of FTE hours applicable for such accounting period based on [***] working hours per Calendar Year.

1.47. "FTE Rate" means the amount of [***] for an FTE per Calendar Year.

1.48. "GAAP" means generally accepted accounting principles current in the United States, as consistently applied.

1.49. "Generic Competition Percentage" means, on a Licensed Product-by-Licensed Product and country-by-country basis, total aggregate sales of the applicable Generic Licensed Products in a Calendar Quarter in such country divided by the sum of: (a) total aggregate sales of a Licensed Product sold in such Calendar Quarter in such country and (b) total aggregate sales of the Generic Licensed Product in such Calendar Quarter in such country, where, in each case ((a) and (b)), the total aggregate sales of a Licensed Product and each Generic Licensed Product will be based on the average of the monthly data provided by IMS Health Incorporated, Fairfield, Connecticut (or IMS-equivalent data if IMS data is not available).

1.50. "Generic Licensed Product" means, on a Licensed Product-by-Licensed Product (including Combination Product-by-Combination Product) and country-by-country basis, any pharmaceutical product sold by a Third Party in such country, other than as a Sublicensee under this Agreement that: (a) contains the same active ingredient or active ingredients as the applicable Licensed Product in the same dosage form (*e.g.*, oral, injectable, or intranasal) as the applicable Licensed Product and (b) is categorized by the applicable Regulatory Authority in such country to be therapeutically equivalent to, or interchangeable with, such Licensed Product, such that the pharmaceutical product may be substituted for the Licensed Product at the point of dispensing without any intervention by the prescribing physician in such country.

1.51. "Good Clinical Practices" or "GCP" means the then-current standards, practices, and procedures for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including (a) those promulgated or endorsed by the FDA as set forth in the guidelines adopted by the ICH, titled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance" (or any successor document) including related regulatory requirements imposed by the FDA, as they may be updated from time to time, (b) the Declaration of Helsinki (2013), as amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, § 50 (Protection of Human Subjects), § 56 (Institutional Review Boards) and § 312 (Investigational New Drug Application), and (d) the equivalent Applicable Laws in any relevant country, in each case ((a)-(d)), that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of Clinical Trial subjects.

1.52. "Good Laboratory Practices" or "GLP" means the then-current standards, practices, and procedures for laboratory activities of pharmaceuticals (promulgated or endorsed by the FDA as set forth in 21 C.F.R. § 58 (or any successor statute or regulation) or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development (OECD)), including: (a) related regulatory requirements imposed by the FDA, as they may be updated from time to time; (b) applicable guidelines promulgated under the ICH; and (c) such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which the studies of a pharmaceutical product are conducted to the extent such standards are no less stringent than United States Good Laboratory Practice.

1.53. "Good Manufacturing Practices" or "GMP" means all applicable then-current standards for Manufacturing, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. §§ 201, 211, 600 and 610 and all applicable FDA guidelines and requirements, (b) the principles detailed in European Directive 2003/94/EC for medicines and investigational medicines for human use and the applicable guidelines stated in the Eudralex guidelines, (c) the principles detailed in the applicable ICH guidelines, (d) the principles detailed in the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time, and (e) cooperation with the conduct of any inspection by qualified persons to ensure compliance with the foregoing standards.

1.54. "Governmental Authority" means any multi-national, national, federal, state, local, provincial, municipal, or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court, or other tribunal).

1.55. "Hatch-Waxman Act" means rights conferred in the U.S. under the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. §355, as amended (or any successor statute or regulation).

1.56. "ICH" means International Conference on Harmonization.

1.57. "IFRS" means the International Financial Reporting Standards as promulgated by the International Standards Accounting Board, as consistently applied.

1.58. "IND" means an Investigational New Drug application as defined in the FFDCA, or a clinical trial authorization application for a pharmaceutical product filed with a Regulatory Authority in any other regulatory jurisdiction outside the U.S., the filing of which is necessary to commence or conduct clinical testing of such pharmaceutical product in humans in such jurisdiction.

1.59. "IND Transfer Date" has the meaning set forth in Section 4.3.1 (Licensed Product INDs).

1.60. "Indemnifying Party" has the meaning set forth in Section 15.3.1 (Notice).

1.61. "Indemnitee" has the meaning set forth in Section 15.3.1 (Notice).

1.62. "Indication" means the use of a Licensed Product for the treatment, prevention, cure, or control of a specific human disease, disorder, illness, or condition.

1.63. "Information" means information, discoveries, compounds, compositions, formulations, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, techniques, designs, drawings, correspondence, computer programs, documents, apparatus, results, strategies, regulatory documentation, information and submissions pertaining to, or made in association with, filings with any Government Authority or Patent Office, data, including pharmacological, toxicological, non-clinical and clinical data, raw data, analytical and quality control data, manufacturing data and descriptions, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, material, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable, and any copyrights therein.

1.64. "Initial Clinical Supply" has the meaning set forth in Section 8.1.1 (Clinical Supply).

1.65. "Initial Development Activities" means those activities to be performed in furtherance of the following Clinical Trials: [***], each of which ((a) - (c)) is separately described in the TAK-385 Development Plan.

1.66. "Intellectual Property Rights" means all rights in Patent Rights, Trademarks, copyrights, design rights, database rights, moral rights, Information, Inventions, and any and all other intellectual property or proprietary rights (whether registered or unregistered) now known or hereafter recognized in any jurisdiction, and all applications and rights to apply for any of them, anywhere in the world.

1.67. "Inventions" means any and all inventions, improvements, discoveries, and developments, whether or not patentable, made, conceived, or reduced to practice in the course of performance of this Agreement whether made, conceived or reduced to practice solely by, or on behalf of, Takeda, Licensee, the Parties jointly, or any Affiliate of either Party.

1.68. "JNDA" means a Japanese new drug application and any other applicable submission to the PMDA for pharmaceutical, biologic, or device approval.

1.69. "Joint Inventions" has the meaning set forth in Section 10.1 (Ownership of Inventions).

1.70. "Joint Know-How" means all Information and Inventions jointly generated by Licensee and Takeda during the Term that pertain to the Exploitation of the Licensed Compounds or Licensed Products in the Field in the Territory. Joint Know-How excludes any Information contained within or Inventions Covered by a published Joint Patent Right.

1.71. "Joint Patent Rights" means all Patent Rights Covering Joint Inventions.

1.72. "Joint Technology" means, collectively, Joint Know-How and Joint Patent Rights.

1.73. "JRC" has the meaning set forth in Section 2.2.1 (Establishment; Responsibilities).

1.74. "Knowledge" means the first hand and actual knowledge of (a) [***], with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products and (b) [***], with respect to the TAK-448 Licensed Compound and TAK-448 Licensed Products, in each case ((a) and (b)), without any inquiry or investigation.

1.75. "Labeling" means the healthcare professional information or patient information used in the Territory that is part of an NDA for a Licensed Product including the package insert, medication guides, company core safety information ("CCSI"), and company core data sheet ("CCDS").

1.76. "Licensed Compound" means a TAK-385 Licensed Compound or a TAK-448 Licensed Compound.

1.77. "Licensed Product" means any TAK-385 Licensed Product or TAK-448 Licensed Product.

1.78. "Licensed Product IND" means any IND filed related to a Licensed Product, whether in existence as of the Effective Date or filed by a Party with a Regulatory Authority during the Term, including any supplements or amendments thereto. The Licensed Product INDs as of the Effective Date are set forth on Schedule 1.78(a) (TAK-385 Licensed Product INDs) and Schedule 1.78(b) (TAK-448 Licensed Product INDs).

1.79. "Licensed Product Infringement" has the meaning set forth in Section 10.6.2(a) (Licensee's Right).

1.80. "Licensee Development Activities" has the meaning set forth in Section 5.1.1 (Licensee Development).

1.81. "Licensee Diligence Obligations" means the obligations of Licensee set forth in Section 5.2 (Development Diligence Obligations) and Section 7.2.1 (Commercialization Diligence Obligations; Of Licensee).

1.82. "Licensee Indemnitee" has the meaning set forth in Section 15.2 (Indemnification by Takeda).

1.83. "Licensee Know-How" means all Information and Inventions Controlled by Licensee or its Affiliates (other than the Takeda Know-How and Joint Know-How) during the Term that are necessary to Exploit a Licensed Compound or a Licensed Product. Licensee Know-How excludes any Information contained within or Inventions Covered by a published Licensee Patent Right.

1.84. "Licensee Obligations" has the meaning set forth in Section 16.8 ([***]).

1.85. "Licensee Patent Rights" means all Patent Rights Controlled by Licensee or its Affiliates (other than the Takeda Patent Rights and Joint Patent Rights) as of the Effective Date or during the Term that Cover a Licensed Compound or any Licensed Product or are otherwise necessary to Exploit a Licensed Compound or a Licensed Product.

1.86. "Licensee Product Trademarks" has the meaning set forth in Section 10.9 (Trademarks).

1.87. "Licensee Regulatory Materials" means any Regulatory Materials related to (a) a Licensed Compound or a Licensed Product in the Field in the Licensee Territory or (b) the TAK-385 Licensed Compound or TAK-385 Licensed Product in the Men's Health Field in the Takeda Territory, in each case ((a) and (b)), Controlled by Licensee during the Term, including the Assigned Regulatory Materials.

1.88. "Licensee Royalties" has the meaning set forth in Section 9.2.1 (a) (Licensee Royalty Obligation).

1.89. "Licensee Technology" means, collectively, Licensee Know-How and Licensee Patent Rights.

1.90. "Licensee Territory" means (a) with respect to the TAK-385 Licensed Compound or a TAK-385 Licensed Product, worldwide excluding the Takeda Territory and (b) with respect to the TAK-448 Licensed Compound or a TAK-448 Licensed Product, worldwide.

1.91. "Losses" has the meaning set forth in Section 15.1 (Indemnification by Licensee).

1.92. "MAA" means an application for Regulatory Approval (but excluding any application for approval of pricing or reimbursement for a Licensed Product by any Governmental Authority) filed with the EMA.

1.93. "Major Market Country" means each of [***].

1.94. "Manufacture" or "Manufacturing" means all activities by or on behalf of a Party related to the manufacturing of a Licensed Compound or a Licensed Product, or any ingredient thereof, including test

method development and stability testing, formulation, manufacturing scale-up, manufacturing for Development or Commercialization, labeling, filling, processing, packaging, in-process and finished Licensed Product testing, shipping, storing, or release of a Licensed Compound or a Licensed Product or any ingredient thereof, quality assurance and quality control activities related to manufacturing and release of a Licensed Compound or a Licensed Product, ongoing stability tests, and regulatory activities related to any of the foregoing. When used as a noun, "Manufacture" or "Manufacturing" means any and all activities involved in Manufacturing.

1.95. "Manufacturing and Supply Agreement" means the Takeda Clinical Manufacturing and Supply Agreement or the Commercial Manufacturing and Supply Agreement (if any), as applicable.

1.96. "Manufacturing Arbitration Draft" has the meaning set forth in Section 8.2.2 (Arbitration Drafts).

1.97. "Men's Health Field" means the treatment, prevention, cure, or control of symptoms associated with prostate cancer.

1.98. "NDA" means a (a) New Drug Application or supplemental New Drug Application as contemplated by Section 505(b) of the FFDCA, submitted to the FDA pursuant to 21 C.F.R. § 314, including any amendments thereto or (b) any comparable applications filed in or for countries or jurisdictions outside of the United States to obtain Regulatory Approval to Commercialize a Licensed Product in that country or jurisdiction. References to "NDA" herein will refer to a JNDA or MAA as applicable.

1.99. "Net Sales" means, with respect to any Licensed Product, the gross amounts invoiced or received (whichever first occurs) by Licensee, its Affiliates, and Sublicensees (other than Third Party Distributors) for sales of such Licensed Product to Third Parties (including Third Party Distributors), less the following deductions, to the extent such deductions are paid, incurred, or otherwise taken, reasonable and customary, provided to Third Parties, and actually allowed with respect to such sales:

1.99.1 [***];

1.99.2 [***];

1.99.3 [***];

1.99.4 [***];

1.99.5 [***];

1.99.6 [***]; or

1.99.7 [***].

All such discounts, allowances, credits, rebates, and other deductions will be fairly and equitably allocated between such Licensed Product and other products of Licensee and its Affiliates and its Sublicensees such that such Licensed Product does not bear a disproportionate portion of such deductions. Notwithstanding the foregoing, amounts received or invoiced by Licensee or its Affiliates or its Sublicensees (other than Third Party Distributors) for the sale of such Licensed Product among Licensee or its Affiliates or its Sublicensees (other than Third Party Distributors) for resale will not be included in the computation of Net Sales hereunder. In any event, any amounts received or invoiced by Licensee or its Affiliates or its Sublicensees will be accounted for only once. For purposes of determining Net Sales, a Licensed Product will be deemed to be sold when invoiced. Net Sales will be accounted for in accordance with the applicable Accounting Standards. A particular deduction may only be accounted for once in the calculation of Net Sales. Net Sales will exclude any samples of a Licensed Product transferred or disposed of at no cost, or

cost below a Party's cost of goods for such Licensed Product, for promotional, Development, or educational purposes.

In the event that a Licensed Product is sold as part of a Combination Product, then Net Sales for such product shall be determined by multiplying the net sales of the Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition) by the fraction, A / (A+B) where A is the weighted average sale price of such Licensed Product when sold separately in finished form, and B is the weighted average sale price of the other active compound or ingredient in the Combination Product sold separately in finished form.

In the event that the weighted average sale price of a Licensed Product can be determined but the weighted average sale price of the other active compound or ingredient in the Combination Product cannot be determined, then Net Sales for such product shall be calculated by multiplying the net sales of the Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition) by the fraction A / C where A is the weighted average sale price of such Licensed Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of the other active compounds or ingredients in the Combination Product can be determined but the weighted average sale price of such Licensed Product cannot be determined, Net Sales for such product shall be calculated by multiplying the net sales of the Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition) by the following formula: one (1) minus B / C where B is the weighted average sale price of the other active compound or ingredient in the Combination Product when sold separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of both a Licensed Product and the other active compound or ingredient in the Combination Product cannot be determined, then Net Sales for such product shall be equal to [***] of the net sales of the Combination Product (as calculated in accordance with analogous criteria as set forth above for the "Net Sales" definition).

1.100. "Neutral Expert" has the meaning set forth in Section 8.2.1 (Notice; Experts).

1.101. "Non-Breaching Party" has the meaning set forth in Section 13.3.1 (Cure Periods).

1.102. "Notifying Party" has the meaning set forth in Section 6.2.4(b) (Meetings).

1.103. "[***]" means [***].

1.104. "[***]" means the Co-Development Agreement dated June 30, 2015 between Takeda and [***].

1.105. "On-Going Clinical Trials" means: (a) with respect to TAK-385, the Clinical Trials identified internally by Takeda as C27002, C27003, and TB-AK160108, and (b) with respect to TAK-448, the Clinical Trials identified internally by Takeda as TAK-448-2001 and TAK-448-2002.

1.106. "Parent Affiliate" means any Person that controls (as defined in Section 1.3 (Affiliate)) Licensee, including RSL.

1.107. "Patent Office" means a Governmental Authority that administers and regulates patents, such as the Japan Patent Office, United States Patent and Trademark Office, or other similar Governmental Authority.

1.108. "Patent Rights" means all: (a) patents, including any utility or design patent; (b) patent applications, including provisionals, non-provisionals, substitutions, divisionals, continuations, continuations in-part or renewals; (c) patents of addition, restorations, extensions, supplementary protection certificates, registration or confirmation patents, patents resulting from post-grant proceedings, re-issues, and re-examinations; (d)

other patents or patent applications claiming priority directly or indirectly to: (i) any such specified patent or patent application specified in (a) through (c), or (ii) any patent or patent application from which a patent or patent application specified in (a) through (c) claim direct or indirect priority; (e) inventor's certificates; (f) other rights issued from a Governmental Authority similar to any of the foregoing specified in (a) through (e); and (g) in each of (a) through (f), whether such patent, patent application or other right arises in the U.S. or any other jurisdiction in the world.

1.109. "PCT" has the meaning set forth in Section 10.4.4 (Pending PCT Application).

1.110. "Pending PCT Application" has the meaning set forth in Section 10.4.4 (Pending PCT Application).

1.111. "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.112. "Pharmacovigilance Agreement" has the meaning set forth in Section 6.3.1 (Pharmacovigilance Agreement).

1.113. "Phase III Clinical Trial" means a pivotal clinical trial of a pharmaceutical product, with a defined dose or a set of defined doses, which trial is designed to ascertain efficacy and safety of such product, for the purpose of enabling the preparation and submission of an NDA with the applicable Regulatory Authority and to provide an adequate basis for physician labeling, as described in 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

1.114. "PMDA" means the Japanese Pharmaceuticals and Medical Devices Agency and any successor entity.

1.115. "Product Trademarks" has the meaning set forth in Section 10.9 (Trademarks).

1.116. "Prosecution" or "Prosecute" means, with respect to a Patent Right, all communication and other interaction with any Patent Office or patent authority having jurisdiction over a patent application in connection with pre-grant proceedings.

1.117. "[***].

1.118. "Recall" means a Party's removal or correction of a Licensed Product following (a) notice or request of any Regulatory Authority or (b) the good faith determination by such Party that an event, incident, or circumstance has occurred that required such a recall of such Licensed Product. A Recall does not include a market withdrawal or a stock recovery.

1.119. "Receiving Party" has the meaning set forth in Section 12.1 (Nondisclosure and Non-Use).

1.120. "Regulatory Approval" means any approval (including any supplement, amendment, or pre- and post-approval), license, registration, or authorization of any national, regional, state, or local regulatory authority, department, bureau, commission, council or other Government Authority, that is necessary for the Commercialization of a pharmaceutical product in a country or regulatory jurisdiction (including, where required, approval of any application for pricing or reimbursement for such pharmaceutical product by any regulatory authority).

1.121. "Regulatory Authority" means any applicable Governmental Authority involved in granting Regulatory Approval or issuing a Recall for a Licensed Product in the Territory, including in the U.S. the FDA, in the E.U. the EMA, and in Japan the PMDA.

1.122. "Regulatory Exclusivity" means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a Licensed Product in a country or jurisdiction in the Territory, other than a Patent Right, including orphan drug exclusivity, pediatric exclusivity, and rights conferred in the U.S. under the Hatch-Waxman Act.

1.123. "Regulatory Materials" means regulatory applications, filings, submissions, notifications, registrations, Regulatory Approvals, or other submissions, including any written correspondence or meeting minutes, made to, made with, or received from any Regulatory Authority submitted to a Regulatory Authority in any country for the purpose of obtaining Regulatory Approval from that Regulatory Authority (including all INDs, NDAs, and associated common technical documents) and any amendments and supplements thereto, and all data and other information contained in, and Regulatory Authority correspondence relating to, any of the foregoing. Regulatory Materials include the Licensed Product INDs, and amendments and supplements thereto.

1.124. "Reimbursed Expenses" has the meaning set forth in Section 13.9.2(b)(i) (Clinical Trial Completion).

1.125. "ROFN Notice Period" has the meaning set forth in Section 3.7 (Right of First Negotiation).

1.126. "ROFN Period" has the meaning set forth in Section 3.7 (Right of First Negotiation).

1.127. "Royalties" has the meaning set forth in Section 9.2.1 (Royalty Rates).

1.128. "Royalty Report" has the meaning set forth in Section 9.3 (Manner of Payment; Royalty Reports).

1.129. "Royalty Term" means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period commencing on the First Commercial Sale of a Licensed Product in such country and continuing until the later of:

(a) the expiration of the last to expire Valid Claim in a Licensee Patent Right (with respect to Takeda Royalties) or a Takeda Patent Right (with respect to Licensee Royalties), as applicable, Covering such Licensed Product in such country;

(b) the expiration of the applicable Regulatory Exclusivity for such Licensed Product in such country; or

(c) ten (10) years after the First Commercial Sale of such Licensed Product in such country.

1.130. RSL" means Roivant Sciences Ltd., a Bermuda exempt limited company.

1.131. "RSL Collaboration Agreement" means any agreement entered into by RSL (a) alone or with others, to research (or fund any research), develop, make, use, sell, offer for sale, or import any Complementary Product in the Licensee Territory or Takeda Territory or (b) with any Third Party with respect to a license or other acquisition of rights relating to any Complementary Product in the Licensee Territory or Takeda Territory.

1.132. "Safety Termination" has the meaning set forth in Section 13.4.1 (Termination by Licensee for Safety Reasons).

1.133. "Selected Third Party Agreements" means, with respect to a Terminated Compound or Terminated Product, any agreement entered into by and between Licensee or any of its Affiliates or its Sublicensees, on the one hand, and one or more Third Parties, on the other hand, that is necessary or reasonably useful for Exploiting such Terminated Compound or Terminated Product in the Field in the Territory and does not relate to any compound or product other than the Terminated Compounds or Terminated Product, including (a) any agreement pursuant to which Licensee, its Affiliates, or its Sublicensees receives any license or other rights to Exploit such Terminated Compound or Terminated Product, (ii) supply agreements pursuant to which

Licensee, its Affiliates, or its Sublicensees obtain or may obtain quantities of such Terminated Compound or Terminated Product, (iii) clinical trial agreements, (iv) contract research organization agreements, and (v) any technical service agreements.

1.134. "Serious Adverse Event" or "SAE" has the meaning set forth in 21 C.F.R. § 312.32, and generally means any Adverse Event that (a) results in death, (b) is life-threatening, (c) requires inpatient hospitalization or prolongation of existing hospitalization, (d) results in persistent or significant disability or incapacity, (e) is a congenital anomaly or birth defect, or (f) based upon appropriate medical judgment is considered an important medical event that may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

1.135. "Sole Inventions" has the meaning set forth in Section 10.1 (Ownership of Inventions).

1.136. "Subcontractor" has the meaning set forth in Section 3.4 (Subcontractors).

1.137. "Sublicensee" has the meaning set forth in Section 3.3.1 (Right to Sublicense).

1.138. "TAK-385 Development Plan" means the Development Plan setting forth the Development activities to be conducted by Licensee with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products attached as Schedule 5.3 (TAK-385 Development Plan), as may be amended in accordance with Section 5.3 (Development Plans).

1.139. "TAK-385 Licensed Compound" means: (a) the chemical compound coded by Takeda as TAK-385 and the structure of which is set forth on Schedule 1.138 (TAK-385 Licensed Compound); (b) any compound other than TAK-385 that is Covered by any Takeda Patent Right set forth on Schedule 1.151 (Takeda Patent Rights) that also Covers TAK-385; and (c) any [***] of any compound described in clause (a).

1.140. "TAK-385 Licensed Product" means any pharmaceutical product, including all forms, presentations, strengths, doses, and formulations (including any method of delivery) containing a TAK-385 Licensed Compound.

1.141. "TAK-448 Licensed Compound" means: (a) the oligopeptide coded by Takeda as TAK-448 and the structure of which is set forth on Schedule 1.141 (TAK-448 Licensed Compound); (c) any oligopeptide other than TAK-448 that is Covered by any Takeda Patent Right set forth on Schedule 1.151 (Takeda Patent Rights) that also Covers TAK-448; and (d) any [***] of any compound described in clause (a).

1.142. "TAK-448 Licensed Product" means any pharmaceutical product, including all forms, presentations, strengths, doses, and formulations (including any method of delivery) containing a TAK-448 Licensed Compound.

1.143. "Takeda Clinical Manufacturing and Supply Agreement" has the meaning set forth in Section 8.1.1 (Clinical Supply).

1.144. "Takeda Commercialization Plan" has the meaning set forth in Section 7.3.2 (Takeda Commercialization Plans).

1.145. "Takeda Diligence Obligations" has the meaning set forth in Section 7.2.2 (Commercialization Diligence Obligations; Of Takeda).

1.146. "Takeda Indemnitee" has the meaning set forth in Section 15.1 (Indemnification by Licensee).

1.147. "Takeda Know-How" means (a) all Information and Inventions Controlled by Takeda or its Affiliates as of the Effective Date that are necessary or reasonably useful to Exploit a Licensed Compound or a Licensed Product and (b) all Information and Inventions developed after the Effective Date and Controlled by Takeda

or its Affiliates (other than Licensee Know-How and Joint Know-How) during the Term that are necessary to Exploit a Licensed Compound or a Licensed Product. Takeda Know-How excludes any Information contained within or Inventions Covered by, a published Takeda Patent Right.

1.148. "Takeda Licensed Product Infringement" has the meaning set forth in Section 10.6.3 (Infringement Actions in the Takeda Territory).

1.149. "Takeda Manufacturing Know-How" has the meaning set forth in Section 4.2 (Technology Transfer).

1.150. "Takeda Materials" has the meaning set forth in Section 4.2 (Technology Transfer).

1.151. "Takeda Patent Rights" means (a) those Patent Rights set forth on Schedule 1.151 part (a) (TAK-385 Patent Rights), (b) those Patent Rights set forth on Schedule 1.151 part (b) (TAK-448 Patent Rights), and (c) all Patent Rights (other than Licensee Patent Rights and Joint Patent Rights) Controlled by Takeda during the Term that Cover any Invention made by or on behalf of Takeda after the Effective Date that Covers a Licensed Compound or any Licensed Product or is otherwise necessary to Exploit any Licensed Compound or Licensed Product.

1.152. "Takeda Product Trademarks" has the meaning set forth in Section 10.9 (Trademarks).

1.153. "Takeda Regulatory Materials" means any Regulatory Materials related to a Licensed Product in the Field in the Takeda Territory owned or Controlled by Takeda as of the Effective Date or during the Term.

1.154. "Takeda Royalties" has the meaning set forth in Section 9.2.1 (b) (Takeda Royalty Obligation).

1.155. "Takeda Technology" means, collectively, Takeda Know-How and Takeda Patent Rights.

1.156. "Takeda Territory" means, solely related to the TAK-385 Licensed Compound and TAK-385 Licensed Products, Japan, China Hong Kong, Indonesia, Korea, Malaysia, Philippines, Singapore, Taiwan, Thailand, and Vietnam, including, in each case, the territories and possession of each of the foregoing.

1.157. "Term" has the meaning set forth in Section 13.1 (Term).

1.158. "Terminated Compound" has the meaning set forth in Section 13.9.1 (All Termination Events).

1.159. "Terminated Field" has the meaning set forth in Section 13.9.1 (All Termination Events).

1.160. "Terminated Product" has the meaning set forth in Section 13.9.1 (All Termination Events).

1.161. "Territory" means the Licensee Territory and the Takeda Territory. When used to refer to a Party's Territory, "Territory" means the Licensee Territory with respect to Licensee and the Takeda Territory with respect to Takeda.

1.162. "Third Party" means a Person other than Takeda or Licensee or their respective Affiliates. For clarity, "Third Party" includes Excluded Affiliates.

1.163. "Third Party Distributor" means any Third Party appointed by Licensee or any of its Affiliates to distribute, market, and sell any Licensed Product, with or without packaging rights, in one or more countries in the Licensee Territory, in circumstances where such Third Party purchases Licensed Product from Licensee or its Affiliates for resale but does not make any royalty or profit share payment to Licensee or its Affiliates with respect to its resale of such Licensed Product.

1.164. "Third Party IP Claim" has the meaning set forth in Section 10.7.1 (Notice).

1.165. "Trademark" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

1.166. "Transaction Agreements" means this Agreement, the Investor Rights Agreement, the Right of First Refusal and Co-Sale Agreement, the Subscription Agreement, the Warrant to Purchase Common Shares, and the Right of First Option Agreement.

1.167. "Transition Plan" has the meaning set forth in Section 4.1 (Transfer Working Group).

1.168. "Transition Services" has the meaning set forth in Section 4.2.1 (Transition Services).

1.169. "United States Good Laboratory Practice" means the then-current U.S. GLP and any GLP of another jurisdiction other than the U.S. that is more stringent than the U.S. GLP.

1.170. "Uterine Fibroids" means the condition in which a non-cancerous tumor originates from the uterus.

1.171. "Valid Claim" means (a) a claim of an issued and unexpired Patent Right to the extent such claim has not been revoked, held invalid or unenforceable by a Patent Office, court or other governmental agency of competent jurisdiction in a final order, from which no further appeal can be or is taken, and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; or (b) a claim within a patent application that has not been pending for more than [***] years from the earliest filing date to which such claim or the applicable patent application is entitled to claim priority and which claim has not been revoked, cancelled, withdrawn, held invalid, or abandoned; *provided*, *however*, that if a claim is issued after such [***] year period, such claim will, after issuance, be considered a Valid Claim in accordance with subsection (a) above.

1.172. "Withdrawal Notices" has the meaning set forth in Section 2.4 (Withdrawal from Committees).

1.173. "Women's Health Field" means the treatment, prevention, cure, or control of symptoms associated with Uterine Fibroids or Endometriosis.

ARTICLE 2
GOVERNANCE

2.1. **[***]**

2.2. **Joint Review Committee**.

2.2.1 Establishment; Responsibilities. Promptly after the Effective Date, the Parties agree to establish and convene a Joint Review Committee (or "JRC") to provide a forum for discussing Licensee's ongoing Development and Commercialization activities with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products pursuant to this Agreement and the coordination of such Licensee activities with Takeda's Development and Commercialization of the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Takeda Territory (where applicable). The JRC will consist of representatives and operate by the procedures in accordance with this Section 2.2 (Joint Review Committee). Except as otherwise provided herein, the role of the JRC will be:

(a) to coordinate the transfer of all Assigned Regulatory Materials to be assigned to Licensee pursuant to Section 4.3.1 (Licensed Product INDs) and Section 4.3.2 (Other Assigned Regulatory Materials);

(b) to review, discuss, and solely with respect to any Development activities in the Takeda Territory set forth therein, approve, any proposed material amendments or revisions to the TAK-385 Development Plan;

(c) to review and discuss the initial TAK-385 Commercialization Plan, and any proposed material amendments or revisions to such Commercialization Plan;

(d) to review and discuss Licensee's activities and progress under the TAK-385 Development Plan, including to review and discuss the Development reports described in Section 5.4 (Development Reporting);

(e) to review and discuss Takeda's activities and progress with respect to the Development of the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Men's Health Field and the Women's Health Field in the Takeda Territory;

(f) to review and discuss Licensee's activities and progress against the Commercialization Plan, including to review and discuss the Commercialization reports described in Section 7.4 (Commercialization Reporting);

(g) to review and discuss Takeda's activities in the Men's Health Field and its progress against the Takeda Commercialization Plan with respect to activities in the Men's Health Field, including to review and discuss the Commercialization reports described in Section 7.4 (Commercialization Reporting);

(h) to discuss and coordinate Licensee's Development activities with Takeda's Development and Commercialization of the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Takeda Territory (where appropriate);

(i) to discuss the selection of the Product Trademarks to be used by each Party in connection with the Commercialization of the TAK-385 Licensed Products, subject to Section 10.9 (Trademarks); and

(j) subject to Section 2.2.2 (JRC Decisions), to attempt to resolve any matters in dispute arising between the Parties.

2.2.2 JRC Decisions. The JRC will use good faith efforts to reach unanimous agreement with respect to all matters within the JRC's authority. The Party with final decision making authority over a matter within the JRC's authority shall consider in good faith any comments received by the other Party with respect to such matter. Should the JRC not be able to reach agreement with respect to such matter at a duly called meeting of the JRC, then beginning on the [***] Business Day after the date on which the matter is referred to the Executive Officers (unless a longer period is agreed to by the Parties), the decision regarding such matter may be finally determined as follows (to the extent such matter is within the JRC's authority):

(a) *Licensee Decision Making*. Licensee will have the sole right to make any final decisions related to the Exploitation of the Licensed Compounds or Licensed Products by or on behalf of Licensee in the Field and for the Licensee Territory; and

(b) *Takeda Decision Making*. Takeda will have the sole right to make any final decisions related to the Exploitation of the TAK-385 Licensed Compound or TAK-385 Licensed Products by or on behalf of Takeda in and for the Field in the Takeda Territory;

provided that neither Party will be entitled to exercise its final decision-making authority or otherwise act with respect to any Licensed Compound or Licensed Product:

(i) in a manner that excuses such Party from any obligation specifically enumerated under this Agreement;

(ii) in a manner that would require a Party to increase its spending on Development activities in excess of the amount required to satisfy its Development diligence obligations set forth under Section 5.2 (Development Diligence Obligations);

(iii) in a manner that negates any consent right or other right specifically allocated to the other Party under this Agreement;

(iv) to resolve any dispute involving the breach or alleged breach of this Agreement or to amend or modify this Agreement or any of the Parties' respective rights and obligations hereunder;

(v) to resolve a matter if the provisions of this Agreement specify that unanimous or agreement of the Parties, including mutual consent, is required for such matter;

(vi) to resolve a matter in a manner that would require a Party to be in breach of any of its obligations under any written agreement with a Third Party with respect to a Licensed Compound or Licensed Product; or

(vii) in a manner that would require a Party to perform any act that would cause such Party to breach any of its obligations hereunder.

2.2.3 JRC Membership and Procedures.

(a) *Membership*. Promptly after the Effective Date, each Party will designate two (2) representatives for the JRC and provide the other Party with written notice of such representatives, each of which representatives will be of the seniority and experience appropriate for service on the JRC in light of the functions, responsibilities, and authority of the JRC and the status of Development or Commercialization of the TAK-385 Licensed Compound and TAK-385 Licensed Products being pursued hereunder from time to time. The JRC may elect to vary the number of representatives from time to time during the Term; *provided that* unless otherwise agreed in writing by the JRC, the JRC will maintain an equal number of representatives from each Party at all times. Either Party may designate substitutes for its JRC representatives if one or more of such Party's designated representatives is unable to be present at a meeting. From time to time each Party may replace its JRC representatives by written notice to the other Party specifying the prior representative and their replacement.

(b) *Chairperson.* A designated representative of Licensee will be the chairperson of the JRC during the Term. The chairperson will be responsible for calling and convening meetings, but will have no special authority over the other members of the JRC, and will have no additional voting rights. The chairperson (or its designee) will: (i) prepare and circulate an agenda reasonably in advance of each upcoming meeting; and (ii) prepare and issue written minutes of each JRC meeting within [***] days thereafter. Such minutes will not be finalized until each JRC representative reviews and approves such minutes in writing; *provided that* any minutes will be deemed approved unless a member of such JRC objects to the accuracy of such minutes within [***] days after the circulation of the minutes. The minutes, including all drafts thereof, will be the Confidential Information of both Parties.

2.3. **Meetings**.

2.3.1 JRC Meetings. Unless otherwise agreed by the JRC, the JRC will meet at least [***] each Calendar Year until the First Commercial Sale of the first TAK-385 Licensed Product; *provided that* the JRC will hold an in-person meeting to establish the JRC's operating procedures no more than [***] days after the Effective Date. During the period commencing on such First Commercial Sale of the first TAK-385 Licensed Product and thereafter during the Term, unless otherwise agreed by the JRC, the JRC will meet no less than [***] per Calendar Year during the Term. Additional meetings of the JRC may be held with the consent of each Party (such consent not to be unreasonably withheld, conditioned, or delayed). In the case of any dispute referred to the JRC, such meeting will be held within [***] Business Days following referral to the JRC, or as soon as reasonably possible. Meetings of the JRC will be effective only if a majority of representatives of each Party are present or participating. Other than the initial JRC meeting, the JRC may meet either (a) in person at either Party's facilities or at such locations as the Parties may otherwise agree or (b) by teleconference or videoconference. Additional non-members of the JRC having relevant experience may from time to time be invited to participate in a JRC meeting, *provided that* such participants will have no voting rights or powers. Non-member employees of a Party or its Affiliates will only be allowed to attend if: (i) the other Party's representatives have consented to the attendance (such consent not to be unreasonably withheld, conditioned, or delayed); and (ii) such non-employee participant is subject to written confidentiality and non-use obligations substantially similar as those set forth in this Agreement.

2.3.2 Expenses. Each Party will be responsible for all of its own expenses incurred in connection with participating in any such JRC meetings, including all travel and all expenses associated therewith. The Parties will share equally any Third Party expenses incurred in connection with an off-site JRC meeting (e.g., meeting room fees).

2.4. **Withdrawal from the JRC**. At any time during the Term and for any reason, Takeda will have the right to withdraw from participation in the JRC upon written notice to Licensee, which notice will be effective immediately upon receipt ("Withdrawal Notice"). Following the issuance of a Withdrawal Notice and subject to this Section 2.4 (Withdrawal from JRC), Takeda's representatives to the JRC will not participate in any meetings of the JRC, nor will Takeda have any right to vote on decisions within the authority of the JRC; *provided that* Licensee make not make any decisions with respect to matters reserved for Takeda's final decision-making pursuant to Section 2.2.2(b) (Takeda Decision Making). If, at any time following of the issuance of a Withdrawal Notice, Takeda wishes to resume participating in the JRC, then Takeda will provide Licensee with [***] days prior written notice and, following such notice period, Takeda representatives to the JRC will be entitled to attend any subsequent meeting of the JRC and to participate in the activities of, and decision-making by, the JRC as provided in this Article 2 (Governance) as if a Withdrawal Notice had not been issued by Takeda pursuant to this Section 2.4 (Withdrawal from JRC). Following Takeda's issuance of a Withdrawal Notice pursuant to this Section 2.4 (Withdrawal from JRC), unless and until Takeda resumes participation in the JRC in accordance with this Section 2.4 (Withdrawal from JRC), Licensee will have the right to make the final decision on all matters within the scope of authority of the JRC, other than those matters reserved for Takeda's final decision-making pursuant to Section 2.2.2(b) (Takeda Decision Making), which shall be submitted to Takeda for approval through the Contact Person established through Section 2.5 (Contact Persons). Notwithstanding anything to the contrary set forth herein, the withdrawal by Takeda under this Section 2.4 (Withdrawal from JRC) will only limit Takeda's rights, authority, and obligations under this Article 2 (Governance) with respect to participation on the JRC, and will not limit any other rights, authority, or obligations of Takeda under this Agreement, including Takeda's right to receive the reports described in Section 5.4 (Development Reporting) and Section 7.4 (Commercialization Reporting).

2.5. **Contact Persons**. Each Party will appoint a person who will oversee contact between the Parties for all matters relating to this Agreement (each, a "Contact Person"), which person may be replaced at any time upon written notice to the other Party. Each Contact Person will work together to manage and facilitate the communication between the Parties under this Agreement. The Contact Persons will not have decision-making authority with respect to any matter under this Agreement.

ARTICLE 3
LICENSE GRANTS

3.1. **Takeda License Grants; Right of Reference**.

3.1.1 Exclusive License Grant. Subject to the terms and conditions of this Agreement (including Section 3.5.1 (Takeda Retained Rights)), Takeda hereby grants to Licensee an exclusive, sublicensable (subject to Section 3.3 (Sublicensing)), royalty-bearing right and license under the Takeda Technology and Takeda's interest in the Joint Technology to Exploit the Licensed Compounds and Licensed Products in the Field in the Licensee Territory.

3.1.2 Non-Exclusive License Grant. Subject to the terms and conditions of this Agreement, Takeda hereby grants to Licensee a non-exclusive, sublicensable (subject to Section 3.3 (Sublicensing)) right and license under the Takeda Technology and Takeda's interest in the Joint Technology to: (a) Develop the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Men's Health Field in the Takeda Territory solely for the purpose of Exploiting such Licensed Products in the Field in the Licensee Territory, or as required in order for Licensee to comply with its diligence obligations set forth in Section 5.2 (Development Diligence Obligations) and (b) Manufacture the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Takeda Territory.

3.1.3 Licensee's Right of Reference. Subject to the terms and conditions of this Agreement and without expanding any of the rights granted to Licensee under Section 3.1.1 (Exclusive License Grant) and Section 3.1.2 (Non-Exclusive License Grant), Takeda hereby grants to Licensee (or its Affiliates or its Sublicensees) access to, and a right of reference with respect to, any Takeda Regulatory Materials and corresponding documentation to the extent Controlled by Takeda at any time during the Term, solely for the purposes of (a) Exploiting the Licensed Compounds and Licensed Products in the Field in the Licensee Territory, (b) Developing the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Men's Health Field in the Takeda Territory, and (c) Manufacturing the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Takeda Territory. Takeda agrees to execute, acknowledge, and deliver any further documents or instruments and to perform all such other acts as may be necessary or appropriate in order to effect such right of reference.

3.2. **Licensee License Grants; Right of Reference**.

3.2.1 Exclusive License Grant. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Takeda an exclusive, sublicensable (subject to Section 3.3 (Sublicensing)), royalty-bearing right and license under the Licensee Technology and Licensee's interest in the Joint Technology to Exploit the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Field in the Takeda Territory.

3.2.2 Non-Exclusive License Grant. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Takeda a non-exclusive, sublicensable (subject to Section 3.3 (Sublicensing)) right and license under the Licensee Technology and Licensee's interest in the Joint Technology to: (a) Develop the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Women's Health Field in the Licensee Territory solely for the purpose of Exploiting such TAK-385 Licensed Products in the Field in the Takeda Territory, (b) Manufacture the Licensed Compounds and Licensed Products in the Licensee Territory, and (c) perform its obligations under this Agreement with respect to the Licensed Compounds and Licensed Products in the Field in the Licensee Territory (if any).

3.2.3 Takeda's Right of Reference. Subject to the terms and conditions of this Agreement and without expanding any of the rights granted to Takeda under Section 3.2.1 (Exclusive License Grant) and Section 3.2.2 (Non-Exclusive License Grant), Licensee hereby grants to Takeda and its Affiliates

and its Sublicensees, access to, and a right of reference with respect to, any Licensee Regulatory Materials and corresponding documentation to the extent Controlled by Licensee at any time during the Term, solely for the purposes of (a) Exploiting the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Field in the Takeda Territory, (b) Manufacturing the Licensed Compounds and Licensed Products, (c) completing the On-Going Clinical Trials and (d) performing Takeda's obligations under this Agreement with respect to the Licensed Compounds and Licensed Products in the Field in the Licensee Territory. Licensee agrees to execute, acknowledge, and deliver any further documents or instruments and to perform all such other acts as may be necessary or appropriate in order to effect such right of reference.

3.3. **Sublicensing**.

3.3.1 Right to Sublicense. Each Party will have the right to grant sublicenses, through multiple tiers, of the rights granted to such Party under Section 3.1 (Takeda License Grants; Right of Reference) and Section 3.2 (Licensee License Grants; Right of Reference) (as applicable), to Third Parties (each, a "Sublicensee") and to its Affiliates upon written notice to the other Party; [***]. In no event will any sublicense relieve either Party of any of its obligations under this Agreement.

3.3.2 Sublicense Requirements. Each Party will cause any sublicense agreement to include provisions regarding Intellectual Property Rights as are necessary to permit a Party to license or sublicense to the other Party any Patent Rights, Information, or Inventions developed in the course of performance of activities pursuant to such sublicense agreement that are necessary or useful for such other Party to Exploit the Licensed Compounds and Licensed Products in the applicable Territory in accordance with this Agreement. Further, each Party will use Commercially Reasonable Efforts to include in any such sublicense agreement a good faith obligation on such Sublicensee to participate in discussions with Licensee and Takeda at least [***] to facilitate information sharing and the global coordination of the Exploitation of the Licensed Compounds and Licensed Products. Each Party will remain responsible for the performance of this Agreement and the performance of its Affiliates and Sublicensees under their sublicensed rights to the same extent as if such activities were conducted by such Party. Each sublicense to a Sublicensee of the rights granted to such Party under Section 3.1 (Takeda License Grants; Right of Reference) and Section 3.2 (Licensee License Grants; Right of Reference) (as applicable) will be in writing and will refer to, be subordinate to, and be consistent with this Agreement in all material respects. Licensee shall include provisions in each sublicense agreement requiring that, upon Takeda's request following termination of this Agreement by Licensee for any reason other than by Licensee pursuant to Section 13.3 (Termination for Material Breach), the Sublicensee enter into a direct license agreement with Takeda under the Takeda Technology or Takeda's interest in the Joint Technology that is sublicensed to such Sublicensee on substantially the same terms as set forth in such sublicense agreement between Licensee and such Sublicensee, so that such Sublicensee is under the same obligations to perform as it was prior to this Agreement being terminated; *provided*, *however*, that (a) such direct license agreement would not impose on Takeda any obligations over and above its obligations under this Agreement and (b) as consideration for such direct license, [***]. No sublicense or subcontract will diminish, reduce, or eliminate any obligation of either Party under this Agreement.

3.3.3 Performance by Licensee Sublicensees. Any sublicense agreement entered into by Licensee or Takeda and a Sublicensee will (a) require each Sublicensee to comply with the applicable terms and conditions of this Agreement (including the Royalty reporting obligations set forth under Section 9.3 (Royalty Reports; Royalty Payments) and the record keeping and audit requirements set forth under Section 9.6 (Audit)) and (b) [***].

3.3.4 [***] Sublicensing Terms. Notwithstanding anything to the contrary set forth herein, Takeda may grant a sublicense to [***] pursuant to the [***] Agreement, and the terms and conditions set forth under [***] to the [***] Agreement. Takeda will [***] of the [***] Agreement applicable to the

grant of such sublicense and the sharing of information pursuant to [***], including the confidentiality provisions set forth in the [***] Agreement, against [***] or its successors-in-interest to the [***] Agreement as necessary to protect Licensee's rights [***].

3.4. **Subcontractors**. In performing its activities under this Agreement, each Party may engage any consultant, subcontractor, distributor, co-promotion partner, or other vendor to conduct its obligations thereunder or hereunder (each, a "Subcontractor"); *provided that* (a) such Party remains responsible for (i) the management of its Subcontractors, (ii) fulfillment by its Subcontractors of all obligations set forth under this Agreement as if the Subcontractor were a party hereto, and (iii) any uncured material breach of this Agreement by a Subcontractor and (b) such Party will [***]. Without limitation, such contracts entered into with Subcontractors will contain provisions, including those relating to Intellectual Property Rights, confidentiality, and non-use that are no less restrictive than those set forth in this Agreement. The engagement of any Subcontractor in compliance with this Section 3.4 (Subcontractors) will not relieve either Party of its obligations under this Agreement or the TAK-385 Development Plan.

3.5. **Retained Rights**.

3.5.1 Takeda Retained Rights. Any rights of Takeda not expressly granted to Licensee under the provisions of this Agreement will be retained by Takeda (and may be exercised by Takeda itself or through its Affiliates or Third Parties in its sole discretion), including, in each case, (a) the right to use, make, have made, import, sell, offer for sale, have sold, research, develop, commercialize, or otherwise exploit in any field (i) products and technologies practicing the Takeda Technology, other than the Licensed Compounds or Licensed Products and (ii) any active pharmaceutical ingredient, compound or product that may be contained in a Licensed Product, other than the Licensed Compounds and (b) the right to exploit or license the Takeda Technology other than for the purposes of Exploiting a Licensed Compound or Licensed Product in the Licensee Territory. In addition, notwithstanding the exclusive license granted by Takeda to Licensee in this Agreement in the Licensee Territory under Section 3.1.1 (Exclusive License Grant), Takeda retains the non-exclusive right under the Takeda Technology and Takeda's interest in the Joint Technology (which may be exercised by Takeda itself or through its Affiliates or Third Parties in its sole discretion) to (A) Develop the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Women's Health Field in the Licensee Territory solely for the purpose of Commercializing such Licensed Products in the Field in the Takeda Territory, (B) Manufacture the Licensed Compounds and the Licensed Products in the Licensee Territory, (C) complete the On-Going Clinical Trials and (D) perform its obligations under this Agreement with respect to the Licensed Compounds and Licensed Products in the Field in the Licensee Territory (if any). Licensee will not exploit or sublicense the Takeda Technology except as expressly licensed in this Agreement. Without limiting the generality of the foregoing, Licensee will not Exploit the TAK-385 Licensed Compound or any TAK-385 Licensed Product in the Women's Health Field in the Takeda Territory. In addition, Licensee will not [***].

3.5.2 Licensee Retained Rights. Any rights of Licensee not expressly granted to Takeda under the provisions of this Agreement will be retained by Licensee (and may be exercised by Licensee itself or through its Affiliates or Third Parties in its sole discretion). In addition, notwithstanding the exclusive license granted by Licensee to Takeda in this Agreement in the Takeda Territory under Section 3.1.2 (Non-Exclusive License Grant), Licensee retains the non-exclusive right under the Licensee Technology and Licensee's interest in the Joint Technology (which may be exercised by Licensee itself or through its Affiliates or Third Parties in its sole discretion) to (a) Develop the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Men's Health Field in the Takeda Territory solely for the purpose of Commercializing such TAK-385 Licensed Products in the Field in the Licensee Territory, and (b) Manufacture the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Takeda Territory.

3.6. **No Implied Licenses**. No license or other right is or will be created or granted hereunder by implication, estoppel, or otherwise. All licenses and rights are or will be granted only as expressly provided in this Agreement.

3.7. **Right of First Negotiation**. If Takeda, in its sole discretion, makes a final determination not to seek Regulatory Approval for or Commercialize TAK-385 Licensed Products in any country within the Takeda Territory, then it shall so notify Licensee in writing. If Licensee provides a written notice to Takeda during the [***] day period following Licensee's receipt of such notice from Takeda (the "ROFN Notice Period") indicating Licensee's interest in negotiating with Takeda regarding such rights in such country, then the Parties will exclusively negotiate in good faith regarding the terms and conditions under which Licensee might obtain rights to seek Regulatory Approval for and Commercialize, TAK-385 Licensed Products in such country for a period of [***] days commencing upon Takeda's receipt of such written notice from Licensee (the "ROFN Period"). If (a) Licensee does not deliver notice to Takeda during the ROFN Notice Period indicating its interest in negotiating with Takeda or (b) the Parties are unable to reach terms on a definitive agreement during the ROFN Period, then in either case ((a) or (b)), Licensee's right of first negotiation under this Section 3.7 (Right of First Negotiation) will terminate as to such country, and [***].

ARTICLE 4
TRANSITION AND TRANSFER

4.1. **Transfer Working Group**. Promptly after the Effective Date, the Parties, via the JRC, will establish a transition regulatory and CMC/manufacturing working group to manage the transition to Licensee of regulatory and Manufacturing activities under this Agreement. For a period of [***] months following the Effective Date, or such longer period as the Parties may agree, the transition working group will meet at least [***] and may meet more frequently if agreed by the Parties. The transition working group will develop and agree upon an orderly plan for the transition of regulatory and Manufacturing activities from Takeda to Licensee (the "Transition Plan"). The Transition Plan will be consistent with Section 4.2 (Technology Transfer) and Section 4.3 (Transfer of Regulatory Materials and Other Data).

4.2. **Technology Transfer**. In accordance with the Transition Plan, Takeda will use reasonable efforts to make available to Licensee all Takeda Know-How (including all historical process or analytical information (i.e., all experimentally or literature-derived data used to Manufacture the Licensed Compounds and Licensed Products)) that is necessary or useful to enable the Manufacture of the Licensed Compounds and Licensed Products by or on behalf of Licensee (the "Takeda Manufacturing Know-How"), by providing copies or samples of relevant documentation, materials, and other embodiments of such Takeda Know-How, including data within reports, notebooks, and electronic files. Takeda will be permitted to make such Takeda Manufacturing Know-How available in such form as Takeda will determine, including, if Takeda so elects, in the form such Takeda Manufacturing Know-How is maintained by Takeda. If requested by Licensee, Takeda will translate any Takeda Manufacturing Know-How into English as part of the Transition Services to be performed by Takeda in accordance with Section 4.2.1 (Transition Services). Any materials provided by Takeda in connection with the transfer of the Takeda Manufacturing Know-How (the "Takeda Materials") will remain the sole property of Takeda. Licensee will (a) itself retain control of all such Takeda Materials, (b) use such Takeda Materials only in the fulfillment of obligations or exercise of rights under this Agreement, (c) not use such Takeda Materials or deliver the same to, or for the benefit of, any Third Party (other than a Sublicensee), without Takeda's prior written consent, and (d) not use such Takeda Materials in research or testing involving human subjects except as expressly provided under this Agreement.

4.2.1 Transition Services. Takeda will perform certain services to facilitate the technology transfer described in Section 4.2 (Technology Transfer) in accordance with the Transition Plan (the "Transition Services"). Licensee will reimburse Takeda for [***], in each case, incurred by Takeda in connection with any Transition Services requested by Licensee and agreed to by Takeda. Licensee shall be responsible for [***] in connection with the Transition Services. Takeda will

invoice Licensee for any reimbursement for any Transition Services to which it is entitled under this Section 4.2.1 (Transition Services) within [***] days after the end of each [***], and Licensee will pay all invoices submitted by Takeda within [***] days of the date of receipt of the invoice. Licensee stipulates that such cooperation will not require Takeda to conduct any research or Development activities or generate any information or materials.

4.2.2 Takeda Materials Disclaimer. Licensee stipulates that compounds, reagents, and other materials supplied by Takeda hereunder (including the Takeda Materials) are experimental in nature and are provided as is, without any warranties as to merchantability or fitness for a particular purpose. Licensee further stipulates that all of such materials' properties or characteristics are not known, and agrees that it will use such materials with reasonable care and will assume responsibility for any losses or injuries incurred by it or its Affiliates or Sublicensees through use of such materials. Notwithstanding the foregoing, the disclaimers set forth in this Section 4.2.2 (Takeda Materials Disclaimer) will not negate any express warranties made by Takeda in the Takeda Clinical Manufacturing and Supply Agreement.

4.3. **Transfer of Regulatory Materials and Other Data**.

4.3.1 Licensed Product INDs. Within [***] days of the Effective Date, unless otherwise agreed by the Parties, Takeda will assign to Licensee all rights, title, and interests in and to each Licensed Product IND filed in the Field in the Licensee Territory, and will transfer to Licensee copies (in electronic or other format) of those Regulatory Materials owned by Takeda or its Affiliates as of the Effective Date that are necessary to assign such Licensed Product INDs to Licensee. The date of such transfer will be the "IND Transfer Date".

4.3.2 Other Assigned Regulatory Materials. After the IND Transfer Date, Takeda will transfer to Licensee copies (in electronic or other format) of other Regulatory Materials Controlled by Takeda as of the Effective Date and not transferred to Licensee pursuant to Section 4.3.1 (Licensed Product INDs) to the extent (a) such materials relate to the Development or Manufacture of the Licensed Compounds and Licensed Products in the Field in the Licensee Territory and (b) do not relate to or are not necessary for the Exploitation of the TAK-385 Licensed Compound or TAK-385 Licensed Products in the Field in the Takeda Territory (collectively, with the Regulatory Materials transferred to Licensee pursuant to Section 4.3.1 (Licensed Product INDs) the "Assigned Regulatory Materials"). Without limiting Section 4.3.1 (Licensed Product INDs), the transfer to Licensee of all Assigned Regulatory Materials will be accomplished in accordance with the timing and the process set forth in the Transition Plan.

4.3.3 Other Regulatory Materials. If any Regulatory Materials Controlled by Takeda as of the Effective Date relate to the Development or Manufacture of the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Field in the Licensee Territory and also relate to and are necessary for the Exploitation of the TAK-385 Licensed Compound or TAK-385 Licensed Products in the Field in the Takeda Territory, then, after the IND Transfer Date and in accordance with the Transition Plan, Takeda will provide copies of such material to Licensee, but such materials will not be Assigned Regulatory Materials for purposes of this Agreement and will not be assigned to Licensee pursuant to this Agreement.

4.3.4 Clinical Trial Data. In connection with the transfer of Regulatory Materials provided for in Section 4.3.1 (Licensed Product INDs) and Section 4.3.2 (Other Assigned Regulatory Materials), and in accordance with the Transition Plan, Takeda will provide to Licensee separate copies (in electronic or other format) of the study reports that are owned or Controlled by Takeda (to the extent not previously provided to Licensee) from all non-clinical trials and Clinical Trials for the Licensed Compounds and Licensed Products in the Field in the Licensee Territory, in each case, whether such studies are completed as of the Effective Date or then in-progress. In addition, Takeda will be responsible, at its own expense, for completing the On-Going Clinical Trials and will remain the

sponsor of the On-Going Clinical Trials. Takeda will, at its own expense, prepare the final study reports for the On-Going Clinical Trials upon completion thereof and thereafter promptly provide Licensee a copy of such final study reports.

4.3.5 Costs and Cooperation. Licensee will bear [***] in connection with the transfer and assignment of all Assigned Regulatory Materials, and any other copies of Regulatory Materials provided to Licensee pursuant to Section 4.3.1 (Licensed Product INDs) through Section 4.3.3 (Other Regulatory Materials). Subject to the terms and conditions of this Agreement, upon Licensee's written request, Takeda will execute and deliver, or will cause to be executed and delivered, to Licensee such endorsements, assignments, and other documents as may be reasonably necessary to assign, convey, transfer, and deliver to Licensee all of Takeda's rights, title, and interests in and to the Assigned Regulatory Materials, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with copy to Licensee) notifying such Regulatory Authority of the transfer of ownership of each Licensed Product IND assigned to Licensee pursuant to Section 4.3.1 (Licensed Product INDs).

ARTICLE 5
DEVELOPMENT

5.1. **Development Activities**.

5.1.1 Licensee Development. Licensee will conduct its Development activities with respect to each Licensed Compound and Licensed Product in a manner so as to seek and maintain Regulatory Approvals that include an appropriate label in each applicable Indication in light of available clinical data. As between the Parties, Licensee will be solely responsible for: (a) all activities related to the Development of the Licensed Compounds and Licensed Products in the Field in the Licensee Territory; (b) all activities related to the Development of the TAK-385 Licensed Compound and TAK-385 Licensed Products through the receipt of Regulatory Approval in the Men's Health Field in the Takeda Territory ((a) and (b), the "Licensee Development Activities"); and (c) all expenses, including Third Party expenses, related to such Development activities in (a), (b), and (c).

5.1.2 Initial Development Activities. Licensee will be solely responsible for the conduct of all Initial Development Activities and all expenses, including Third Party expenses, related to such Initial Development Activities. Notwithstanding anything to the contrary set forth herein, Licensee will complete all such Initial Development Activities and provide to Takeda all data, reports, and other Information generated in the performance thereof on or prior to [***].

5.1.3 Takeda Development. As between the Parties, Takeda will be solely responsible for all activities related to the Development of the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Women's Health Field in the Takeda Territory and all expenses, including Third Party expenses, related to such Development activities.

5.2. **Development Diligence Obligations**. During the Term, Licensee will (a) use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval of a TAK-385 Licensed Product in the Women's Health Field in the United States [***], (b) use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval of a TAK-385 Licensed Product in the Men's Health Field in Japan and the United States, (c) use Commercially Reasonable Efforts to [***] set forth in the TAK-385 Development Plan, (d) use Commercially Reasonable Efforts to [***], and (e) [***]. In addition, during the Term, Licensee will use Commercially Reasonable Efforts to Develop and obtain Regulatory Approval of a TAK-448 Licensed Product in the Field in one country or jurisdiction in the Licensee Territory.

5.3. **Development Plans**. During the Term, Licensee will conduct all Development activities in connection with the TAK-385 Licensed Compound or any TAK-385 Licensed Product in accordance with the terms and conditions set forth in this Article 5 (Development) and the plan for Development activities with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products (as such plan may be amended from time to time pursuant to this Section 5.3 (Development Plans) (with respect to the TAK-385 Development Plan), a "TAK-385 Development Plan"). [***]. The TAK-385 Development Plan will include reasonably detailed descriptions of: (a) all material Development activities reasonably anticipated to be undertaken by Licensee to obtain Regulatory Approval of the one or more TAK-385 Licensed Products in the Field in the Licensee Territory and in the Men's Health Field in the Takeda Territory, (b) all Licensee Development Activities in the Takeda Territory, (c) all Initial Development Activities, (d) estimated dates on which Licensee expects to achieve each Development Milestone Event, including the filing of an NDA in each country in the Licensee Territory in which Licensee is Developing a TAK-385 Licensed Product, and (e) an estimate of costs and expenses associated with the activities set forth in the TAK-385 Development Plan. The initial TAK-385 Development Plan is attached hereto as Schedule 5.3 (TAK-385 Development Plan). Without limiting the foregoing, the TAK-385 Development Plan will provide that Licensee conduct (i) [***]; and (ii) [***], in each case consistent with the activities described in the initial TAK-385 Development Plan attached hereto as Schedule 5.3 (TAK-385 Development Plan). Licensee will prepare an update to the TAK-385 Development Plan at least annually. Licensee may amend the TAK-385 Development Plan as reasonable or necessary at any time during the Term; *provided that* all annual updates and any material amendments must be reviewed, discussed, and, solely with respect to any Development activities in the Takeda Territory, approved, by the JRC in accordance with Section 2.2.2(a) (Establishment; Responsibilities), and *provided*, *further*, that all such updates or material amendments to the TAK-385 Development Plan must be in accordance with the requirements of this Article 5 (Development). No update or amendment to the TAK-385 Development Plan related to Development activities in the Takeda Territory will be effective unless approved by the JRC in accordance with Article 2 (Governance). Licensee will provide Takeda with a copy of all updates or amendments to the TAK-385 Development Plan.

5.4. **Development Reporting**.

5.4.1 General Reporting.

(a) *TAK-385*. Within [***] days following the end of each Calendar Quarter during which Licensee is performing activities under the TAK-385 Development Plan or is Manufacturing or having Manufactured any supplies of the TAK-385 Licensed Compound or TAK-385 Licensed Products for Development purposes, Licensee will provide Takeda with [***] written reports of the material Development and material Manufacturing activities it has performed, or caused to be performed, since the preceding report, its material Development and material Manufacturing activities in process, and the future activities it expects to initiate. [***].

(b) *TAK-448*. No later than [***] of each Calendar Year during which Licensee is performing any Development activities with respect to the TAK-448 Licensed Compound or TAK-448 Licensed Products, or is Manufacturing or having Manufactured any supplies of the TAK-448 Licensed Compound or TAK-448 Licensed Products for Development purposes, Licensee will provide Takeda with [***] written reports of the material Development and material Manufacturing activities it has performed, or caused to be performed, since the preceding report, its material Development and material Manufacturing activities in process, and the future activities it expects to initiate. [***].

5.4.2 [***] Agreement. Upon Takeda's reasonable request, Licensee will provide to Takeda any Information related to the Development of the TAK-385 Licensed Compound and TAK-385 Licensed Products by Licensee to the extent such Information is required by Takeda to comply with its obligations under the [***] Agreement.

5.5. **Exclusivity; Option**.

5.5.1 Exclusivity Covenants.

(a) *Competing Products*. Subject to Section 5.6 (Competing Product Acquisitions), during the period commencing on the Effective Date and ending two (2) years after the First Commercial Sale of a TAK-385 Licensed Product in a Major Market Country, each of Licensee and RSL will not, directly or indirectly, and will cause all of Licensee's Affiliates and Excluded Affiliates (other than any such Excluded Affiliate that is a public company) not to, (a) alone or with others, research (or fund any research), develop, make, use, sell, offer for sale, or import any Competing Product in the Licensee Territory or Takeda Territory or (b) enter into any agreement with any Third Party with respect to a license or other acquisition of rights relating to any Competing Product in the Licensee Territory or Takeda Territory.

(b) [***].

5.5.2 Excluded Affiliate Divestitures. If RSL divests any other Excluded Affiliate in a transaction that causes such Excluded Affiliate to cease to be controlled (as defined in Section 1.3 (Affiliate)) by a Parent Affiliate, then upon the consummation of such transaction, such Person will no longer be bound by the terms of Section 5.5.1 (Exclusivity Covenants).

5.5.3 Licensee Right of First Option. Promptly, but in no less than thirty (30) days after the Effective Date, RSL and Licensee will enter into an agreement in a form approved by Takeda pursuant to which RSL grants Licensee an option, exercisable at any time during the period commencing upon [***] and ending two (2) years after the First Commercial Sale of a TAK-385 Licensed Product in a Major Market Country, to require RSL or any other Excluded Affiliate that is not a public company to transfer and assign to Licensee all rights Controlled by it under Patent Rights, Know-How, and other intellectual property relating to any Complementary Product (other than a Competing Product). If Licensee exercises such option, in consideration for such assignment and transfer Licensee will pay to RSL one hundred ten percent (110%) of such Excluded Affiliate's cost of acquiring of such rights under such RSL Collaboration Agreement.

5.6. **Competing Product Acquisitions**.

5.6.1 Options. If, (a) during the period commencing on the Effective Date and ending [***] years after the First Commercial Sale of a TAK-385 Licensed Product in [***], Licensee, any Affiliate controlled by Licensee, or any Excluded Affiliate acquires, or is acquired by, a Third Party (whether such acquisition occurs by way of a purchase of assets, merger, consolidation, or similar transaction), and where such Third Party is developing or commercializing a Competing Product or is otherwise engaged in activities that would otherwise constitute a breach of 5.5.1(a) (Competing Products) or (b) [***], then in each case ((a) and (b)), unless the Parties agree otherwise in writing, then Licensee, such Affiliate controlled by Licensee, or such Excluded Affiliate will (with respect to the applicable Competing Product or [***]), at its option and no later than [***] days following the date of consummation of the relevant merger, consolidation, or acquisition, notify Takeda in writing of its determination to either:

(a) divest, or cause the relevant Excluded Affiliate to divest, whether by license or otherwise, its interest in the Competing Product or [***] (as applicable), to the extent necessary to be in compliance with 5.5.1 (Exclusivity Covenants); or

(b) terminate the development or commercialization of the Competing Product or [***] (as applicable).

5.6.2 Divestiture or Termination. If Licensee notifies Takeda in writing that it or its relevant Affiliate or Excluded Affiliate intends to divest such Competing Product or [***] (as applicable) or terminate the development or commercialization of the Competing Product or [***] (as applicable) as provided in Section 5.6.1 (Options), then Licensee or its relevant Affiliate or Excluded Affiliate will effect the consummation of such divestiture within [***] months or effect such termination within [***] days, subject to compliance with Applicable Law (as applicable), after the consummation of the relevant merger, consolidation, or acquisition contemplated in Section 5.6.1 (Options), and will confirm to Takeda in writing when such divestiture or termination has been completed. Licensee will keep Takeda reasonably informed of its efforts and progress in effecting such divestiture or termination until it is completed. Prior to such divestiture or termination, Licensee or its relevant Affiliate or Excluded Affiliate will take all reasonable steps to limit data access and sharing between its personnel working on the TAK-385 Licensed Compound or any TAK-385 Licensed Product or having access to data from activities performed under this Agreement and Confidential Information of Takeda and personnel working on such Competing Product or [***] (as applicable).

5.7. **Records; Disclosure of Data and Results**. In conformity with standard pharmaceutical industry practices and the terms and conditions of this Agreement, Licensee will prepare and maintain, or will cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports, and data with respect to activities conducted pursuant to the TAK-385 Development Plan for a minimum of [***] years following the end of the Calendar Year to which such plan pertains and, upon Takeda's written request, will send legible copies of the aforesaid to Takeda throughout the Term and for a minimum of [***] months following the Term.

5.8. **Clinical Trial Transparency**. Each Party will maintain compliance with all Applicable Laws related to Clinical Trial transparency for the Licensed Products, as well as any industry guidelines or codes of conduct, or other internal transparency policies that may apply to either the sponsor of any Clinical Trial for the Licensed Products or the owner of any Regulatory Approval for the Licensed Products. Without limiting the foregoing: (a) for Clinical Trial transparency activities associated with Clinical Trial sponsorship, each Party: (i) will perform registration (e.g., posting and maintaining protocol information) and summary results posting and maintenance activities on public registries or websites as required by Applicable law for all Clinical Trials of Licensed Products, whether before or after the Effective Date, (ii) may register and post summary results for any Clinical Trials of Licensed Products commenced after the Effective Date in accordance with such Party's individual registration transparency policies for Clinical Trials that such Party sponsors, and (iii) [***]; and (b) each Party will retain responsibility for Clinical Trial transparency activities and requirements applicable to such Party as the owner of an NDA. The Parties will cooperate with each other as reasonably requested so that each Party may satisfy its Clinical Trial transparency and data sharing requirements consistent with this Section 5.8 (Clinical Trial Transparency).

ARTICLE 6
REGULATORY

6.1. **Regulatory Materials and Regulatory Approvals**.

6.1.1 Licensee Ownership. Following the IND Transfer Date, Licensee or its relevant Affiliates will have the sole right to file and hold all Regulatory Materials (including any Assigned Regulatory Materials) for the Licensed Compounds and Licensed Products in the Field in the Licensee Territory.

6.1.2 Takeda Ownership. Takeda or its relevant Affiliates will have the sole right to file and hold all Regulatory Materials for the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Field in the Takeda Territory.

6.2. **Regulatory Cooperation**.

6.2.1 Licensee Responsibilities. Subject to Applicable Law and this Section 6.2 (Regulatory Cooperation), Licensee will, at its sole expense, oversee, monitor, and manage all regulatory interactions, communications, and filings with, and submissions to, Regulatory Authorities with respect to the Licensed Compounds and Licensed Products in the Field in the Licensee Territory; *provided that* Licensee will provide Takeda with a copy of all proposed material Regulatory Materials filed with or submitted to any Regulatory Authority for Takeda's review and comment sufficiently in advance of Licensee's filing or submission thereof, and Licensee will reasonably consider incorporating any reasonable comments received from Takeda into such Regulatory Materials. Licensee will have final decision making authority regarding all regulatory activities, including the Labeling strategy and the content of submissions within the Licensee Territory, subject to the terms and conditions of this Agreement. For the avoidance of doubt, to the extent any such Regulatory Materials are not prepared in English by Licensee in the normal course of business, Licensee shall not be required to translate any such Regulatory Materials into English for the purposes of this Section 6.2.1 (Licensee Responsibilities).

6.2.2 Takeda Responsibilities. Subject to Applicable Law and this Section 6.2 (Regulatory Cooperation), Takeda will, at is sole expense, oversee, monitor, and manage all regulatory interactions, communications, and filings with, and submissions to, the PMDA with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Field in the Takeda Territory; *provided that* Takeda will provide Licensee with a copy of all proposed material Regulatory Materials filed with or submitted to any Regulatory Authority for Licensee's review and comment sufficiently in advance of Takeda's filing or submission thereof, and Takeda will reasonably consider incorporating any reasonable comments received from Licensee into such Regulatory Materials. Subject to Section 6.5 (Labeling Information Exchange), Takeda will have final decision making authority regarding all regulatory activities, including the Labeling strategy and the content of submissions within the Takeda Territory, subject to the terms and conditions of this Agreement. For the avoidance of doubt, to the extent any such Regulatory Materials are not prepared in English by Takeda in the normal course of business, Takeda shall not be required to translate any such Regulatory Materials into English for the purposes of this Section 6.2.2 (Takeda Responsibilities).

6.2.3 Common Technical Documents. In addition, the Party that first files an NDA with respect to a Licensed Product shall be responsible for preparing, and shall make available to the other Party, the common technical document for each Indication for which such Party files such NDA. Thereafter, Licensee shall be responsible for preparing, at its own expense, and shall make available to Takeda, the common technical document for each Indication for which Licensee files an NDA with respect to a Licensed Product in each country within the Licensee Territory and Takeda shall be responsible for preparing, at its own expense, and shall make available to Licensee, the common technical document for each Indication for which Takeda files an NDA with respect to a Licensed Product in each country within the Takeda Territory.

6.2.4 Cooperation, Meetings and Sharing Final Materials.

(a) Ongoing Cooperation. The Parties will cooperate with each other to achieve the regulatory objectives contemplated herein in a timely, accurate, and responsive manner, including using reasonable efforts to coordinate the regulatory strategy in the Women's Health Field and Men's Health Field such that it is consistent with the overall objective of facilitating Regulatory Approvals of one or more TAK-385 Licensed Products in the Women's Health Field and Men's Health Field in both the Licensee Territory and the Takeda Territory. Each Party will assist the other Party, as is reasonably necessary, in order for such Party to obtain and maintain each applicable IND and NDA for the TAK-385 Licensed Compound and TAK-385 Licensed Products for which such Party

bears responsibility under this Agreement, including in connection with the preparation and filing of such Party's Regulatory Materials. Each Party will assist the other Party as reasonably requested in connection with CMC data and the preparation and filing of Regulatory Materials related to the Manufacture of the Licensed Compounds and Licensed Products in the Territory.

(b) Meetings. Each Party (the "Notifying Party") shall promptly notify the other Party of any request for a meeting or substantive telephone conference call with a Regulatory Authority with respect to any TAK-385 Licensed Compound or TAK-385 Licensed Product in the Notifying Party's Territory. Upon such other Party's written request, the Notifying Party shall request that the Regulatory Authority permit at least [***] from such other Party with relevant regulatory experience to observe and participate in any such meeting or conference call;

provided that Licensee's right to observe and participate in such meetings or calls will be limited to activities related to the Men's Health Field. To the extent permitted by such Regulatory Authority and Applicable Law, such other Party shall have the right to observe and, as applicable, participate in any such meeting or conference call. The foregoing rights and obligations will apply with respect to meetings or conferences initiated by the Notifying Party or by a Regulatory Authority. The Notifying Party shall promptly furnish the other Party with copies of all substantive contact reports concerning substantive conversations or minutes from any substantive meetings with a Regulatory Authority with respect to any IND related to a TAK-385 Licensed Product.

(c) Ongoing Assistance; Sharing of Submitted Regulatory Materials. Upon a Party's reasonable request, the other Party shall provide or otherwise make available to the requesting Party relevant internal regulatory documents, such as notes and preparation materials, and any materials documenting any clarifications (whether orally or otherwise) regarding any Regulatory Materials transferred to the requesting Party from the other Party hereunder or with respect to which the requesting Party has a right of reference. Each Party will provide to the other Party copies of all finalized material Regulatory Materials filed with, and submissions to, Regulatory Authorities by or on behalf of a Party with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products. For the avoidance of doubt, to the extent any such Regulatory Materials are not prepared in English by a Party in the normal course of business, such Party shall not be required to translate any such Regulatory Materials into English for the purposes of this Section 6.2.4(c) (Ongoing Assistance; Sharing of Submitted Regulatory Materials).

6.3. **Pharmacovigilance Agreement and Safety Data Exchange**.

6.3.1 Pharmacovigilance Agreement. Not later than [***] days following the Effective Date, the Parties will execute a pharmacovigilance agreement on reasonable and customary terms that will provide, among other things, guidelines and responsibilities for (a) the receipt, investigation, recording, review, communication, reporting, and exchange between the Parties of Adverse Event reports and other safety information relating to the Licensed Compounds and Licensed Products, (b) appropriate reconciliation procedures to ensure adequate and compliant exchange of safety data, (c) contact with Regulatory Authorities with respect to the foregoing, and (d) the maintenance of a global safety database with respect to the Licensed Compounds and Licensed Products, in each case ((a) - (d)), in accordance with Applicable Law (the "Pharmacovigilance Agreement"). The Pharmacovigilance Agreement will contain terms no less stringent than those required by ICH or other applicable guidelines in order to allow the Parties to meet the applicable regulatory and legal requirements regarding the management of safety data in their respective territories.

6.3.2 Safety Data Exchange. Until the Pharmacovigilance Agreement is entered into by the Parties, the Parties will exchange any and all relevant safety data relating to the Licensed Compounds and Licensed Products within appropriate timeframes and in an appropriate format to ensure compliance with the reporting requirements of all applicable Regulatory Authorities on a worldwide basis. Without limiting the generality of the foregoing, each Party will provide written notification to the other Party within [***] days for Serious Adverse Events, within [***] days for Serious Adverse Events, and within [***] days for non-Serious Adverse Events. In addition, to the extent requested by a Party, the other Party will promptly provide to such Party any other information or materials that such Party may require to provide to any Regulatory Authority with respect to any such Serious Adverse Event or Adverse Event.

6.4. **Clinical Trial Holds; Recalls**.

6.4.1 Clinical Trial Holds. Each Party will promptly (but in any event within [***]) inform the other Party in the event that any Clinical Trial for a TAK-385 Licensed Product is suspended, put on hold, or terminated in its respective Territory prior to completion as a result of any action by a Regulatory Authority or such Party voluntarily.

6.4.2 Recalls. Each Party will promptly notify the other Party upon its determination that any event, incident, or circumstance has occurred that may result in the need for a Recall, market withdrawal or stock recovery of a Licensed Product (but in no event later than [***] and in all cases prior to the execution of such Recall, market withdrawal, or stock recovery). For all such Recalls, the Parties will reasonably consult with each other with respect to the actions to be taken to address such Recall. Subject to the foregoing, (a) for all Recalls, market withdrawals, and stock recoveries that are taken in the Licensee Territory with respect to any Licensed Product, Licensee will be responsible for execution, and Takeda will take such actions as reasonably requested by Licensee in connection therewith and otherwise reasonably cooperate in all such efforts and (b) for all Recalls, market withdrawals, and stock recoveries that are taken in the Takeda Territory with respect to any TAK-385 Licensed Product, Takeda will be responsible for execution, and Licensee will take such actions as reasonably requested by Takeda in connection therewith and otherwise reasonably cooperate in all such efforts. All expenses incurred in connection with any Recall (including expenses for notification, destruction, and return of the affected Licensed Product and any refund to customers of amounts paid for such Licensed Product) in the Licensee Territory will be the sole responsibility of Licensee, and all such expenses incurred in connection with any such Recall (including expenses for notification, destruction, and return of the affected TAK-385 Licensed Product and any refund to customers of amounts paid for such TAK-385 Licensed Product) in the Takeda Territory will be the sole responsibility of Takeda.

6.5. **Labeling Information Exchange**. The Parties will cooperate to develop methods and procedures for sharing information related to Labeling for each TAK-385 Licensed Product in the Licensee Territory (which may include, upon agreement of the Parties, entering into a labeling agreement); *provided that* Licensee will have final decision making authority with respect to the development and management of Labeling information for each Licensed Product in the Licensee Territory at its expense and Takeda will have final decision making authority with respect to the development and management of Labeling information for each TAK-385 Licensed Product in the Takeda Territory at its expense. Each Party will provide to the other Party all reasonably requested assistance with respect to such Labeling activities for each TAK-385 Licensed Product in such Party's Territory.

ARTICLE 7
COMMERCIALIZATION

7.1. **Commercialization Responsibilities**.

7.1.1 In the Licensee Territory. Licensee will be solely responsible, at its expense, for Commercializing all Licensed Products in the Field in the Licensee Territory.

7.1.2 In the Takeda Territory. Takeda will be solely responsible, at its cost and expense, for Commercializing all TAK-385 Licensed Products in the Field in the Takeda Territory.

7.2. **Commercialization Diligence Obligations**.

7.2.1 Of Licensee. During the Term, Licensee will use [***] to Commercialize each Licensed Product in each Indication and in each country in the Licensee Territory for which Regulatory Approval has been obtained.

7.2.2 Of Takeda. During the Term, upon the receipt of Regulatory Approval in the Takeda Territory for a TAK-385 Licensed Product in the Men's Health Field, Takeda will use [***] to Commercialize each TAK-385 Licensed Product in the Men's Health Field in the Takeda Territory (the "Takeda Diligence Obligations").

7.3. **Commercialization Plans**.

7.3.1 Licensee Commercialization Plans. Licensee will perform all Commercialization activities in accordance with the terms and conditions set forth in this Article 7 (Commercialization), and, subject to the last sentence of this Section 7.3.1 (Licensee Commercialization Plans), the Commercialization Plan. Licensee will prepare a plan for the Commercialization of the TAK-385 Licensed Products in the Licensee Territory for the commercial launch of and the first [***] years after the First Commercial Sale of the first TAK-385 Licensed Product in a Major Market Country, which plan must include in reasonable detail: (a) principal strategies with respect to marketing and promoting the TAK-385 Licensed Products during such time period; (b) the material activities to be conducted by Licensee in connection with the Commercialization of the TAK-385 Licensed Products during such time period (which will include all pre-Commercialization activities); and (c) [***] set forth in such Commercialization Plan (as each such plan may be amended from time to time pursuant to this Section 7.3 (Commercialization Plans), a "Commercialization Plan"). Licensee will submit the initial Commercialization Plan to the JRC for review and discussion no less than [***] months prior to the anticipated date of the first Regulatory Approval of a TAK-385 Licensed Product in the Licensee Territory. Thereafter, for the first [***] years after the First Commercial Sale of a TAK-385 Licensed Product in a Major Market Country, Licensee will submit an updated Commercialization Plan for each TAK-385 Licensed Product to the JRC for review and discussion at least [***] each Calendar Year. Licensee will provide Takeda with a copy of all finalized updates to the Commercialization Plan. Following the [***] anniversary of the First Commercial Sale of the first TAK-385 Licensed Product in a Major Market Country, Licensee's obligation to perform all Commercialization activities in accordance with the Commercialization Plan, and to update and provide such plan as set forth in this Section 7.3 (Commercialization Plans), will end.

7.3.2 Takeda Commercialization Plans. Takeda will perform all Commercialization activities in accordance with the terms and conditions set forth in this Article 7 (Commercialization), and, subject to the last sentence of this Section 7.3.2 (Takeda Commercialization Plans), the Takeda Commercialization Plan. Takeda will prepare a plan for the Commercialization of the TAK-385 Licensed Products in the Men's Health Field in the Takeda Territory for the commercial launch of and the first [***] years after the First Commercial Sale of the first TAK-385 Licensed Product in the Takeda Territory, which plan must include in reasonable detail: (a) principal strategies with respect to marketing and promoting the TAK-385 Licensed Products in the Men's Health Field during such time period; (b) the material activities to be conducted by Takeda in connection with the Commercialization of the TAK-385 Licensed Products in the Men's Health Field during such time period (which will include all pre-Commercialization activities); and (c) [***] set forth in

such Commercialization Plan (as each such plan may be amended from time to time pursuant to this Section 7.3 (Commercialization Plans), a "Takeda Commercialization Plan"). Takeda will submit the initial Takeda Commercialization Plan to the JRC for review and discussion no less than [***] months prior to the anticipated date of the first Regulatory Approval of a TAK-385 Licensed Product in the Takeda Territory. Thereafter, for the first [***] years after the First Commercial Sale of a TAK-385 Licensed Product in the Men's Health Field in the Takeda Territory, Takeda will submit an updated Takeda Commercialization Plan for each TAK-385 Licensed Product to the JRC for review and discussion at least [***] each Calendar Year. Takeda will provide Licensee with a copy of all finalized updates to the Takeda Commercialization Plan. Following the [***] anniversary of the First Commercial Sale of the first TAK-385 Licensed Product in the Men's Health Field in the Takeda Territory, Takeda's obligation to perform all Commercialization activities in accordance with the Takeda Commercialization Plan, and to update and provide such plan as set forth in this Section 7.3 (Commercialization Plans), will end.

7.4. **Commercialization Reporting**.

7.4.1 Licensee Obligations. No later than [***] of each Calendar Year, Licensee will provide to Takeda a reasonably detailed written report of the material Commercialization activities it has performed, or caused to be performed, since the preceding report, its Commercialization activities performed and the future activities it expects to initiate. Each such report will contain sufficient detail to enable Takeda to assess Licensee's compliance with its obligations set forth in Section 7.2 (Commercialization Diligence Obligations) and will include a rolling [***] year forecast of estimated Net Sales for TAK-385 Licensed Products.

7.4.2 Takeda Obligations. No later than [***] of each Calendar Year, Takeda will provide to Licensee a reasonably detailed written report of the material Commercialization activities it has performed, or caused to be performed, since the preceding report, its Commercialization activities performed and the future activities it expects to initiate with respect to any TAK-385 Licensed Product. Each such report will contain sufficient detail to enable Licensee to assess Takeda's compliance with its obligations set forth in Section 7.2 (Commercialization Diligence Obligations) and will include a rolling [***] year forecast of estimated Net Sales for TAK-385 Licensed Products.

ARTICLE 8
MANUFACTURING

8.1. **Manufacturing Responsibility**.

8.1.1 Clinical Supply. Takeda will provide to Licensee[***] the amount of TAK-385 Licensed Compound or TAK-385 Licensed Products needed by Licensee to complete all Clinical Trials contemplated by the TAK-385 Development Plan (estimated by Licensee as of the Effective Date to be [***]), solely to the extent that Takeda can supply such TAK-385 Licensed Compound or TAK-385 Licensed Products (a) from its supply of TAK-385 Licensed Compound or TAK-385 Licensed Products in existence as of the Effective Date and which supply can be used for its intended purposes without further re-processing (the "Initial Clinical Supply") and (b) after retaining the amount needed by Takeda for Clinical Trials in the Takeda Territory. Takeda will also provide to Licensee, at [***] any additional supplies of TAK-385 Licensed Compound or TAK-385 Licensed Products in excess of the Initial Clinical Supply needed by Licensee to complete all Clinical Trials contemplated by the TAK-385 Development Plan. Within [***] days after the Effective Date, the Parties will enter into a manufacturing and supply agreement (the "Takeda Clinical Manufacturing and Supply Agreement"), which will govern the terms and conditions of the Manufacturing and supply of the TAK-385 Licensed Compound and TAK-385 Licensed Products (including the Initial Clinical Supply) by Takeda to Licensee for Development purposes, including the exact quantities and the timelines for delivery. The Parties will negotiate

the terms and conditions of such Takeda Clinical Manufacturing and Supply Agreement in good faith for a period of [***] days (as may be extended upon agreement of the Parties). As part of the negotiation related to the Takeda Clinical Manufacturing and Supply Agreement, the Parties shall discuss in good faith the ability of Takeda to supply to Licensee [***]. If the Parties have not entered into a definitive agreement within such negotiation period, then the final terms and conditions of such agreement will be resolved in accordance with Section 8.2 (Arbitration for Failure to Agree).

8.1.2 Commercial Supply. Following the Effective Date the Parties will mutually agree as to which of the Parties will be responsible for the Manufacture and supply to the other Party the TAK-385 Licensed Compound or TAK-385 Licensed Products for the purposes of Commercialization in the Field in the applicable Territory. If the Parties agree that one Party will Manufacture and supply the TAK-385 Licensed Compound or TAK-385 Licensed Products to the other Party for purposes of Commercialization in such other Party's Territory, the Parties will negotiate and enter into a commercial supply agreement prior to the first submission of an NDA for the first TAK-385 Licensed Product that will set forth the terms and conditions of such supply by the applicable Party, including the quantities, forecasting, and the timelines for delivery (the "Commercial Manufacturing and Supply Agreement"). The Parties will negotiate the terms and conditions of such Commercial Manufacturing and Supply Agreement in good faith for a period of [***] days (as may be extended upon agreement of the Parties, but in any event such agreement will be entered into prior to the first submission of a NDA for the first TAK-385 Licensed Product). If the Parties have not entered into a definitive agreement within such negotiation period, then the final terms and conditions of such agreement will be resolved in accordance with Section 8.2 (Arbitration for Failure to Agree). For clarity, the Parties may agree that neither Party will supply the other Party with the TAK-385 Licensed Compound or TAK-385 Licensed Products for the purposes of Commercialization in the Field in the applicable Territory.

8.1.3 Licensee CMO Engagement. If either Party will satisfy any obligations to Manufacture and supply the TAK-385 Licensed Compound and TAK-385 Licensed Products under this Agreement through the engagement of a CMO, such CMO (a) shall be comparable in expense to other CMOs in the industry performing similar manufacturing work and (b) will have been (at the time of engagement) inspected by the FDA and the applicable Regulatory Authority in the EU or by a Qualified Person in the EU authorized to sign the required certificate (as required by Clinical Directive 2001/20/EC and Annex 13 to the European GMP Guide) and, in any such case, found to be in material compliance with all Applicable Laws, including GMP.

8.2. **Arbitration for Failure to Agree**. If the Parties cannot reach agreement and enter into a Manufacturing and Supply Agreement within the applicable period set forth in Section 8.1 (Manufacturing Responsibility), then the following binding abbreviated dispute resolution procedure shall apply to determine the final terms and conditions of such Manufacturing and Supply Agreement:

8.2.1 Notice; Experts. After expiration of the applicable negotiation period set forth in Section 8.1.1 (Clinical Supply) or Section 8.1.2 (Commercial Supply), either Party may send the other Party written notice that it wishes to determine the final terms and conditions of such Manufacturing and Supply Agreement using a Neutral Expert. Within [***] days of a Party's receipt of such notice, the Parties shall jointly appoint a neutral Third Party who is an expert with at least [***] years of experience in area of manufacturing and supply (the "Neutral Expert") within [***] Business Days.

8.2.2 Arbitration Drafts. Within [***] Business Days after the appointment of the Neutral Expert, each Party will (a) prepare a draft of such Manufacturing and Supply Agreement to be used in such arbitration proceeding (each, a "Manufacturing Arbitration Draft") and (b) submit its Manufacturing Arbitration Draft to the other Party, along with a written summary regarding its position as to why the Neutral Expert should adopt its Manufacturing Arbitration Draft. Within

[***] days of such submissions, the Parties will meet to determine whether they agree to enter into either Party's Manufacturing Arbitration Draft or a modified version thereof as such Manufacturing and Supply Agreement.

8.2.3 Arbitration Proceedings. If the Parties do not agree to enter into either Party's Manufacturing Arbitration Draft or a modified version thereof as such Manufacturing and Supply Agreement in accordance with Section 8.2.2 (Arbitration Drafts), then within [***] Business Days of such meeting, each Party may submit an opposition statement of no more than [***] pages in length to the Neutral Expert. Neither Party will be allowed to conduct any discovery. Neither Party may have any communications (either written or oral) with the Neutral Expert other than for the sole purpose of engaging the Neutral Expert or as expressly permitted in this Section 8.2.3 (Arbitration Proceedings). The Neutral Expert may consult in writing with either Party regarding the submissions made by either Party; *provided that* both Parties receive such request for consultation and are provided with an opportunity to respond. In evaluating each Party's written submissions, the Neutral Expert shall, within [***] Business Days of receipt of the written opposition statement, select one of the Parties' Manufacturing Arbitration Drafts that it determines to contain the most fair, balanced and customary terms. Such decision shall be final, binding and conclusive upon both Parties and their Affiliates, and such Manufacturing Arbitration Draft will be the applicable Manufacturing and Supply Agreement, and the Parties will execute the same.

8.2.4 Expenses. [***].

8.3. **TAK-448 Manufacturing Responsibility**. Within [***] days after the Effective Date, the Parties shall agree in writing on the allocation of responsibilities between the Parties related to the Manufacture and supply of the TAK-448 Licensed Compound and TAK-448 Licensed Products, which may include providing access to existing quantities of such compounds or products, performing a Manufacturing technology transfer, or facilitating Licensee's entry into a supply arrangement with any existing manufacturer of the TAK-448 Licensed Compound and TAK-448 Licensed Products, including Takeda.

ARTICLE 9
PAYMENT; FINANCIAL TERMS

9.1. **Equity in Licensee**. Upon the Effective Date, (a) the Parties shall enter into a separate subscription or purchase agreement in the form attached hereto as Schedule 9.1(a) (Subscription Agreement) pursuant to which Licensee will issue to Takeda that number of Licensee's common shares equal to twelve percent (12%) of Licensee's fully-diluted shares immediately following and after giving effect to such issuance, and (b) Licensee shall issue to Takeda a warrant in the form attached hereto as Schedule 9.1(b) (Takeda Warrant) to purchase Licensee's capital stock (the "Warrant").

9.2. **Royalties**.

9.2.1 Royalty Rates. In further consideration of the licenses and rights granted to each Party hereunder, with respect to Net Sales of the Licensed Products in the Territory during the applicable Royalty Term, on a Licensed Product-by-Licensed Product and country-by-country basis each Party will pay to the other Party the following amounts (collectively, "Royalties").

(a) *Licensee Royalty Obligation*. For each Licensed Product, during the applicable Royalty Term in a particular country in the Licensee Territory, Licensee will pay to Takeda a running royalty of [***] of the aggregate Net Sales of such Licensed Product in the Field in the Licensee Territory ("Licensee Royalties").

(b) *Takeda Royalty Obligation*. Following Regulatory Approval of a TAK-385 Licensed Product in the Men's Health Field in the Takeda Territory, during the applicable Royalty

Term, Takeda will pay to Licensee a running royalty of [***] of the aggregate Net Sales of such TAK-385 Licensed Product in the Takeda Territory in the Men's Health Field ("Takeda Royalties"). Takeda shall adopt an appropriate process to track, with reasonable accuracy, those Net Sales by Takeda or its Affiliates or its Sublicensees in a given period during the applicable Royalty Term that are attributable to sales of the TAK-385 Licensed Products in the Men's Health Field in the Takeda Territory and such systems shall be subject to reasonable audit by Licensee as provided in Section 9.6 (Audit).

9.2.2 Royalty Term. A Party's obligation to pay Royalties under Section 9.2.1 (Royalty Rates) will continue on a Licensed Product-by-Licensed Product and country-by-country basis commencing on the First Commercial Sale of such Licensed Product in such country in the Licensee Territory or Takeda Territory (as applicable) until the expiration of the Royalty Term for such Licensed Product in such country (at which time sales in such country will be excluded from all calculations of aggregate Net Sales hereunder).

9.2.3 Royalty Reductions.

(a) *Third Party IP*. If a Party cannot Commercialize a particular Licensed Product without infringing a Third Party's Intellectual Property Rights and if such Party pays a royalty to a Third Party for the right to Commercialize such Licensed Product under such Third Party's Intellectual Property Rights, then, subject to Section 9.2.3(d) (Cumulative Reductions Floor), such Party may credit [***] of such royalty payments to Third Parties for sales of such Licensed Product in a given Calendar Quarter against the Royalties owed and payable by such Party to the other Party on the Net Sales for such Licensed Product made in the same Calendar Quarter. Licensee will have the exclusive right to negotiate for and obtain rights under any such required Intellectual Property Rights of a Third Party in the Licensee Territory, and Takeda will have the exclusive right to negotiate for and obtain rights under any required Intellectual Property Rights of a Third Party relating to a TAK-385 Licensed Compound or a TAK-385 Licensed Product in the Takeda Territory; *provided*, *however*, that, where practical, each Party shall provide written notice to the other Party at least [***] days prior to commencing negotiations with such a Third Party.

(b) *Expiration of Valid Claims*. Subject to Section 9.2.3(d) (Cumulative Reductions Floor), if during the Royalty Term for a given Licensed Product in the United States there is no Valid Claim of a Takeda Patent Right Covering the Exploitation of such Licensed Product (or the Licensed Compound contained therein) in the United States, then, as from the first Calendar Quarter this Section 9.2.3(b) (Expiration of Valid Claims) applies, and thereafter for so long as this Section 9.2.3(b) (Expiration of Valid Claims) applies, the Licensee Royalty will be reduced by [***] for Net Sales in the United States.

(c) *Generic Competition*. Subject to Section 9.2.3(d) (Cumulative Reductions Floor), if during any Calendar Quarter during the Royalty Term for a given Licensed Product in a country the Generic Competition Percentage in such country is (i) greater than or equal to [***], but less than [***], then the Royalties owed with respect to Net Sales of such Licensed Product in such country in such Calendar Quarter will be reduced by [***]; or (ii) greater than or equal to [***], then the Royalties owed with respect to Net Sales of such Licensed Product in such country in such Calendar Quarter will be reduced by [***].

(d) *Cumulative Reductions Floor*. In no event will the aggregate Royalty amount due to a Party in any given Calendar Quarter during the Royalty Term for any Licensed Product be reduced by more than [***] of the amount that otherwise would have been due and

payable to such Party in such Calendar Quarter for such Licensed Product but for the reductions set forth in Section 9.2.3(a) through Section 9.2.3(c) (Royalty Reductions).

9.3. **Royalty Reports; Royalty Payments**. [***]. Within [***] Business Days following the end of each Calendar Quarter after the First Commercial Sale of a Licensed Product in the Licensee Territory or the Takeda Territory, as applicable, the Royalty-paying Party will provide the other Party with a Royalty report in respect of such Calendar Quarter for the other Party's review and confirmation within [***] Business Days from receipt, which report (each, a "Royalty Report") will include (a) the amount of gross sales (in U.S. dollars) of the Licensed Products in the Licensee Territory or the Takeda Territory (as applicable), (b) an itemized calculation of Net Sales in the Licensee Territory or Takeda Territory (as applicable) showing deductions, to the extent practicable, provided for in the definition of "Net Sales", (c) a calculation of the Royalty payment due on such sales by such Party, (d) an accounting of the number of units and prices for the Licensed Products sold by such Party, (e) the application of the reductions, if any, made pursuant to Section 9.2.3 (Royalty Reductions), and (f) any additional Information reasonably required by the other Party for the purpose of calculating Royalties. [***]. Within [***] Business Days following the written confirmation of the applicable quarterly Royalty Report, a Party will pay all amounts due to other Party pursuant to Section 9.2 (Royalties) and set forth in such Royalty Reports with respect to Net Sales for such Calendar Quarter.

9.4. **Exchange Rate**. With respect to sales of Licensed Products invoiced in U.S. dollars, the gross sales, Net Sales, and Royalties payable shall be expressed in U.S. dollars. With respect to sales of Licensed Products invoiced in a currency other than U.S. dollars, the gross sales, Net Sales and Royalties payable shall be expressed in the currency of the invoice issued by the selling Party (or its Affiliate or Sublicensee) together with the U.S. dollars equivalent of the Royalty due, calculated using the average quarter-end rate of exchange for a given Calendar Quarter published in the Wall Street Journal East Coast Edition.

9.5. **Taxes**.

9.5.1 Payment of Tax. A Party receiving a payment pursuant to this Article 9 (Payment; Financial Terms) will pay any and all taxes levied on such payment. A Party making a payment pursuant to this Article 9 (Payment; Financial Terms) will make a reasonable effort to obtain the lowest tax rate under Applicable Law for taxes required to be deducted and withheld from such payment. If Applicable Law requires that taxes be deducted and withheld from a payment made pursuant to this Article 9 (Payment; Financial Terms), after a Party making a payment makes a reasonable effort to obtain the lowest tax rate, the remitting Party will: (a) deduct those taxes from the payment; (b) pay the taxes to the proper taxing authority; and (c) send evidence of the obligation together with proof of payment to the other Party within [***] days following that payment.

9.5.2 Tax Residence Certificate. A Party receiving a payment pursuant to this Article 9 (Payment; Financial Terms) will provide the remitting Party appropriate certification from relevant revenue authorities that such Party is a tax resident of that jurisdiction, if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes will be made at the appropriate treaty tax rate.

9.5.3 Assessment. Either Party may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties with respect to amounts paid pursuant to this Article 9 (Payment; Financial Terms) or seek a refund of such amounts paid if permitted to do so by Applicable Law. The Parties will cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for a Party to pursue such protest.

9.5.4 Assignment. If Licensee or Takeda assigns its rights and obligations hereunder to an Affiliate or Third Party in compliance with Section 16.3 (Assignment) and if such Affiliate or Third Party shall be required by Applicable Law to withhold any additional taxes from or in respect of any

amount payable under this Agreement as a result of such assignment, then any such amount payable under this Agreement shall be increased to take into account the additional taxes withheld as may be necessary so that, after making all required withholdings, Takeda or Licensee receives an amount equal to the sum it would have received had no such assignment been made. The foregoing sentence shall not apply to any additional taxes withheld for which Takeda or Licensee may obtain a foreign tax credit.

9.6. **Audit**. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of Royalties and other payments under this Agreement. Upon reasonable prior notice, at a mutually convenient time, such records will be available during regular business hours for a period of [***] years from the end of the Calendar Year to which they pertain for examination at the expense of the requesting Party, and not more often than [***] each Calendar Year, by an independent certified public accountant selected by the requesting Party and reasonably acceptable to the other Party, for the sole purpose of verifying the accuracy of the Royalty Reports furnished by the other Party pursuant to this Agreement. Any such auditor will not disclose the other Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the Royalty Reports furnished by the other Party or the amount of payments due by the other Party under this Agreement during the prior [***] months. In the event such auditor determines that there has been a discrepancy, the requesting Party shall provide to the other Party a copy of the accountant's report. Any amounts shown to be owed but unpaid will be paid within [***] days after the date of receipt by the paying Party of the accountant's report, plus interest (as set forth in Section 9.7 (Manner of Payment; Late Payment)) from the original due date. Any amounts shown to have been overpaid will be refunded within [***] days after the date of receipt by the refunding Party of the accountant's report. The requesting Party will bear the full cost of such audit unless such audit discloses an underpayment by the other Party of more than [***] of the amount due, in which case the other Party will bear the full expense of such audit. [***].

9.7. **Manner of Payment; Late Payment**. All payments due to a Party hereunder will be made in U.S. Dollars by wire transfer of immediately available funds into an account designated by such Party from time to time. If a Party does not receive payment of any sum due to it on or before the due date, simple interest will thereafter accrue on the sum due to until the date of payment at the per annum rate of [***] over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by Applicable Law, whichever is lower.

9.8. **Licensee Financial Statements**. During the period commencing on the Effective Date and continuing until the earliest of (a) an initial public offering of Licensee's common shares; (b) a Change of Control of Licensee; or (c) the expiration of the Takeda Warrants, Licensee will provide Takeda with a copy of Licensee's reviewed quarterly reports and audited annual financial statements no later than [***] days after the end of each preceding Calendar Quarter and Calendar Year. Licensee will cause the financial statements provided to Takeda to be prepared under applicable Accounting Standards and reviewed and audited by qualified independent auditors.

9.9. **Reporting of Takeda Financial Information**. From and after the Effective Date, Takeda shall (a) cooperate with Licensee or its Affiliates and their respective accountants and auditors by providing access to information, books, and records related to the Licensed Compounds and Licensed Products as Licensee may reasonably request in connection with the preparation by Licensee or its Affiliates of historical and pro forma financial statements related to the Licensed Compounds and Licensed Products as may be required to be included in any filing made by Licensee or any of its Affiliates under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, and the regulations promulgated thereunder, including Regulation S-X and (b) without limiting the foregoing, shall provide Licensee with such information as is required for Licensee or its Affiliates to prepare audited "carve out" financial statements related to the Licensed Compounds and Licensed Products, for the [***] fiscal years prior to the Effective Date (or such shorter period as agreed to by Licensee) and information requested by Licensee and reasonably necessary to prepare any applicable pro forma financial information required to be filed by Licensee with the U.S. Securities and Exchange Commission. Such cooperation shall include, as

applicable, (i) the signing of management representation letters to the extent required in connection with any such audit performed by Licensee's auditors, (ii) providing Licensee or its Affiliates and their respective accountants and auditors with access to management representation letters provided by Takeda to Takeda's accountants and auditors, and (iii) causing Takeda's accountants, auditors, and counsel to cooperate with Licensee or its Affiliates and its accountants, auditors, and counsel in connection with the preparation and audit of any financial information to be provided under this Section 9.8 (Reporting of Takeda Financial Information). If Takeda elects to provide Licensee with the audited financial statements contemplated hereunder, the selection of an external audit firm will be at the discretion of Takeda. Such financial statements shall be derived from Takeda's historical financial statements, and accurately present in all material respects the financial position of the Licensed Compounds and Licensed Products as of the dates thereof. Takeda hereby consents to the inclusion or incorporation by reference of any financial statements provided to Licensee under this Section 9.8 (Reporting of Takeda Financial Information) in any filing by Licensee or its Affiliates with the U.S. Securities and Exchange Commission and, upon request therefor of Licensee, agrees to request that any auditor of Takeda that audits any financial statements provided to Licensee or its Affiliates under this Section 9.8 (Reporting of Takeda Financial Information) consent to the inclusion or incorporation by reference of its audit opinion with respect to such financial statements in any filing by Licensee or its Affiliates with the U.S. Securities and Exchange Commission. Licensee will be responsible for all costs incurred by Takeda or its Affiliates in connection with the generation of financial information as set forth herein, including external "carve out" audit fees, consents, and any other fees associated with amendments and/or revisions required to support Licensee's or its Affiliates' Securities and Exchange Commission disclosure obligations.

ARTICLE 10
INTELLECTUAL PROPERTY MATTERS

10.1. **Ownership of Inventions**. Inventorship will be determined in accordance with U.S. patent laws. Each Party will own any Inventions made solely by its own employees, agents, or independent contractors during the Term in the course of conducting any activities under this Agreement, together with all Intellectual Property Rights therein (the "Sole Inventions"). The Parties will jointly own any Inventions that are made jointly by employees, agents, or independent contractors of each Party in the course of performing activities under this Agreement, together with all Intellectual Property Rights therein (the "Joint Inventions").

10.2. **Disclosure of Inventions**.

10.2.1 Sole Inventions and Joint Inventions. Each Party will promptly disclose to the other Party any invention disclosures, or other similar documents, submitted to it by its employees, agents, or independent contractors describing Inventions that are Sole Inventions or Joint Inventions, and all Information relating to such Inventions to the extent necessary for the use of such Invention in the Exploitation of a Licensed Product in the Field in the Licensee Territory (with respect to Takeda's disclosure obligation) or in the Field in the Takeda Territory (with respect to Licensee's disclosure obligation). In addition the inventing Party will disclose to the other Party any such Information related to such Sole Invention or Joint Invention, to the extent patentable, necessary for the preparation, filing, Prosecution, and maintenance of any Patent Right with respect to such Invention in accordance with the terms and conditions of this Article 10 (Intellectual Property Matters).

10.2.2 Filing Decisions. Within [***] days of disclosure of an Invention to the other Party as required in Section 10.2.1 (Sole Inventions and Joint Inventions): (a) the Party that owns a Sole Invention shall determine, in its sole discretion, whether and when to file a provisional or non-provisional patent application on the Sole Invention; and (b) the Parties shall mutually agree whether and when to file a provisional or non-provisional patent application on any Joint Invention and shall cooperate in the preparation and filing of the same (at the Parties' equally shared expense); *provided*, *however*, that in the event that a non-provisional patent application is filed pursuant to

clause (a) or (b), the non-provisional patent application shall include an application filed under the Patent Cooperation Treaty ("PCT"). Unless otherwise agreed by the Parties, any PCT application Covering a Joint Invention shall be prepared, filed, and Prosecuted by Licensee in accordance with Section 10.4.1 (Prosecution in the Licensee Territory). The filing, Prosecution, and maintenance of any national stage filings from any PCT application under clause (a) or (b) shall be governed by Section 10.4.1 (Prosecution in the Licensee Territory) and Section 10.4.2 (Prosecution in the Takeda Territory).

10.3. **Exploitation of Joint Technology**. Subject to the rights and licenses granted to, and the obligations of, each Party in this Agreement, either Party is entitled to practice, license, sublicense, or otherwise transfer rights in and to the Joint Patent Rights and Joint Know-How without the consent of and without a duty of accounting to the other Party. Each Party will grant and hereby does grant to the other Party all permissions, consents, and waivers with respect to, and all licenses under, the Joint Patent Rights and Joint Know-How, throughout the world, necessary to provide the other Party with such rights of use and Exploitation of the Joint Patent Rights and Joint Know-How, and will execute documents as necessary to accomplish the foregoing.

10.4. **Prosecution of Patent Rights**.

10.4.1 Prosecution in the Licensee Territory. Beginning on Effective Date, and except as otherwise provided in this Section 10.4.1 (Prosecution in the Licensee Territory), as between the Parties, Licensee will have the sole right and authority to prepare, file, Prosecute and maintain the Licensee Patent Rights, Joint Patent Rights (subject to Section 10.2.2 (Filing Decisions)) and Takeda Patent Rights in the Licensee Territory (which is worldwide with respect to the TAK-448 Licensed Compound and TAK-448 Licensed Products). Licensee will bear all expenses of preparation, filing, Prosecution, and maintenance of such Patent Rights in the Licensee Territory. Licensee will provide Takeda a reasonable opportunity to review and comment on material communications from any patent authority in the Licensee Territory regarding the Joint Patent Rights and Takeda Patent Rights, as well as drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Licensee will consider Takeda's comments regarding such communications and drafts in good faith but is not required to implement such comments. In addition, Licensee will provide Takeda with copies of all final material filings and responses made to any patent authority with respect to the Licensee Patent Rights in a timely manner following submission thereof. If Licensee determines in its sole discretion to abandon or not to maintain any Joint Patent Right or Takeda Patent Right that is being Prosecuted or maintained by Licensee in the Licensee Territory, then Licensee will provide Takeda with written notice promptly after any such determination to allow Takeda a reasonable period of time to determine, on a country-by-country basis in its sole discretion, its interest in such Patent Right in the Licensee Territory (which notice by Licensee will be given no later than [***] days prior to the final deadline for any pending action or response that may be due with respect to such Patent Right with the applicable patent authority). If Takeda provides written notice to Licensee expressing its interest in maintaining such Patent Right, then, with respect to such Patent Right in such country in the Licensee Territory (a) Licensee will no longer be responsible for such expenses relating to Prosecuting, and maintaining (as applicable) such Patent Right; (b) [***]; (c) Takeda may, in its sole discretion, Prosecute and maintain such Patent Right; and (d) upon Takeda's request, Licensee will promptly provide all files related to filing, Prosecuting, and maintaining such Patent Right to Takeda or counsel designated by Takeda. With respect to the TAK-448 Licensed Compound and TAK-448 Licensed Products, Licensee shall have the sole right and authority to prepare, file, Prosecute, and maintain Licensee Patent Rights, Joint Patent Rights, and Takeda Patent Rights worldwide.

10.4.2 Prosecution in the Takeda Territory. Except as otherwise provided in this Section 10.4.2 (Prosecution in the Takeda Territory), as between the Parties, and solely with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products, Takeda will have the sole right

and authority to prepare, file, Prosecute and maintain the Licensee Patent Rights, Joint Patent Rights, and Takeda Patent Rights in the Takeda Territory. Takeda will bear all expenses of preparation, filing, Prosecution, and maintenance of such Patent Rights in the Takeda Territory. Takeda will provide Licensee a reasonable opportunity to review and comment on material communications from any patent authority in the Takeda Territory regarding such Licensee Patent Rights and Joint Patent Rights, as well as drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Takeda will consider Licensee's comments regarding such communications and drafts in good faith but is not required to implement such comments. In addition, Takeda will provide Licensee with copies of all final material filings and responses made to any patent authority with respect to the Takeda Patent Rights in a timely manner following submission thereof. If Takeda determines in its sole discretion to abandon or not to maintain any Licensee Patent Right or Joint Patent Right that is being Prosecuted or maintained by Takeda in the Takeda Territory, then Takeda will provide Licensee with written notice promptly after any such determination to allow Licensee a reasonable period of time to determine, on a country-by-country basis in its sole discretion, its interest in such Patent Right in the Takeda Territory (which notice by Takeda will be given no later than [***] days prior to the final deadline for any pending action or response that may be due with respect to such Patent Right with the applicable patent authority). If Licensee provides written notice to Takeda expressing its interest in maintaining such Patent Right, then, with respect to such Patent Right in such country in the Takeda Territory (a) Takeda will no longer be responsible for such expenses relating to Prosecuting, and maintaining (as applicable) such Patent Right; (b) [***]; (c) Licensee may, in its sole discretion, Prosecute and maintain such Patent Right; and (d) upon Licensee's request, Takeda will promptly provide all files related to filing, Prosecuting, and maintaining such Patent Right to Licensee or counsel designated by Licensee.

10.4.3 Covenants in Support of Assignment.

(a) In the event that Takeda exercises its right to [***] pursuant to Section 10.4.1 (Prosecution in the Licensee Territory), then upon Takeda's request, Licensee will provide all further cooperation that Takeda reasonably determines is necessary to [***] Patent Rights, including executing and delivering further [***], consents, releases, and other commercially reasonable documentation, and providing good faith testimony by affidavit, declaration, deposition, in person or other proper means, and otherwise assisting Takeda in support of any effort by Takeda to establish, perfect, defend, or enforce its rights in such [***] Patent Rights.

(b) In the event that Licensee exercises its right to [***] pursuant to Section 10.4.2 (Prosecution in the Takeda Territory), then upon Licensee's request, Takeda will provide all further cooperation that Licensee reasonably determines is necessary to [***] Joint Patent Rights, including executing and delivering further assignments, consents, releases, and other commercially reasonable documentation, and providing good faith testimony by affidavit, declaration, deposition, in person or other proper means, and otherwise assisting Licensee in support of any effort by Licensee to establish, perfect, defend, or enforce its rights in such [***] Joint Patent Rights.

10.4.4 Pending PCT Application. The Parties acknowledge as of the Effective Date patent application number [***] has been filed under the PCT (the "Pending PCT Application"). Notwithstanding the allocation of responsibility for Prosecution and maintenance of Patent Rights set forth in Section 10.4.1 (Prosecution in the Licensee Territory) and Section 10.4.2 (Prosecution in the Takeda Territory), [***].

10.4.5 Cooperation in Prosecution. Each Party will provide the other Party reasonable assistance and cooperation in the Prosecution efforts provided above in this Section 10.4 (Prosecution of Patent Rights), including providing any necessary powers of attorney, complying with any applicable

duty of candor or disclosure with a Patent Office and executing any other required documents or instruments for such Prosecution, as well as further actions as set forth below.

(a) *Preparation and Prosecution*. The Parties will respectively prepare, file, maintain and Prosecute the Takeda Patent Rights, Licensee Patent Rights, and Joint Patent Rights as set forth in this Section 10.4 (Prosecution of Patent Rights). Each Party will designate a primary contact for issues related to Prosecution of Patent Rights as set forth under this Agreement. The primary contact for each Party will work with the primary contact for the other Party to ensure a coordinated strategy for Prosecution of such Patent Rights. The Parties shall discuss in good faith appointment of a single outside counsel for Prosecution of both the Takeda Patent Rights and the Licensee Patent Rights that Cover the TAK-385 Licensed Compound or any TAK-385 Licensed Product. Licensee shall have the right to select such outside counsel, subject to Takada's consent, such consent not to be unreasonably withheld, conditioned, or delayed.

(b) *Communication*. All communications between the Parties relating to the preparation, filing, Prosecution, or maintenance of the Takeda Patent Rights, Licensee Patent Rights, and Joint Patent Rights, including copies of any draft or final documents or any communications received from or sent to Patent Offices or patenting authorities with respect to such Patent Rights, except to the extent publicly disclosed by such Patent Offices or patenting authorities, will be considered Confidential Information and subject to the confidentiality provisions of Article 12 (Confidentiality).

(c) *Assignments*. Assignments of Licensee Patent Rights, Joint Patent Rights, and Takeda Patent Rights will be effected as follows: Takeda and Licensee, as applicable, will each cause (i) employees or agents of Licensee that are named as inventors on Licensee Patent Rights to assign their interest in such Patent Rights to Licensee; (ii) employees or agents of Takeda that are named as inventors on Takeda Patent Rights to assign their interest in such Patent Rights to Takeda; and (iii) employees or agents of Takeda or Licensee that are named as inventors on Joint Patent Rights to assign their interest in such Patent Rights to their respective employer.

10.5. **Patent Term Extensions**.

10.5.1 Licensee Territory. Licensee shall have the right to decide for which, if any, of the Patent Rights within the Licensee Patent Rights, Joint Patent Rights, and Takeda Patent Rights, the Parties should seek patent term extensions in the Licensee Territory. Licensee shall inform Takeda of its decision. Licensee shall be responsible for applying for the patent term extension, unless, with respect to Takeda Patent Rights, the applicable patent authority requires Takeda to file such application; in such event, Takeda shall cooperate with Licensee and shall apply for the patent term extension, at Licensee's expense. Licensee shall be responsible for all expenses associated with any such patent term extension, including any Third Party expenses incurred by Takeda in furtherance of such filing. Licensee shall have the right to decide for which, if any, of the Patent Rights relating to the TAK-448 Licensed Compound or TAK-385 Licensed Products within the Licensee Patent Rights, Joint Patent Rights, and Takeda Patent Rights, the Parties should seek patent term extensions worldwide.

10.5.2 Takeda Territory. Takeda shall have the right to decide for which, if any, of the Patent Rights relating to the TAK-385 Licensed Compound or TAK-385 Licensed Products within Licensee Patent Rights, Joint Patent Rights, and Takeda Patent Rights, the Parties should seek patent term extensions in the Takeda Territory. Takeda shall inform Licensee of its decision. Takeda shall be responsible for applying for such patent term extension, unless, with respect to Licensee Patent Rights, the applicable patent authority requires Licensee to file such application; in such event, Licensee shall cooperate with Takeda and shall apply for the patent term extension, at Takeda's

expense. Takeda shall be responsible for all expenses associated with any such patent term extension, including any Third Party expenses incurred by Licensee in furtherance of such filing.

10.5.3 Cooperation. The Party that does not apply for an extension under this Section 10.5 (Patent Term Extensions) shall cooperate fully with the other Party in making such filings or actions, for example making available all required regulatory data and information and executing any required authorizations to apply for such patent term extension.

10.6. **Infringement of Patent Rights by Third Parties**.

10.6.1 Notification. Each Party will promptly notify the other Party in writing of any existing, alleged, or threatened infringement, misappropriation, or other violation of the Takeda Patent Rights, Licensee Patent Rights, or Joint Patent Rights in the Field in the Licensee Territory or in the Takeda Territory of which it becomes aware, and will provide all Information in such Party's possession or Control demonstrating such infringement.

10.6.2 Infringement Actions in the Licensee Territory.

(a) *Licensee's Right*. Licensee will have the first right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged, or threatened infringement or other violation of a Licensee Patent Right, Takeda Patent Right, or Joint Patent Right related to a compound or product that competes with a Licensed Compound or a Licensed Product in the Field in the Licensee Territory (a "Licensed Product Infringement").

(b) *Takeda's Right*. Licensee will notify Takeda of its decision as to whether to take any action in accordance with Section 10.6.2(a) (Infringement Action in the Licensee Territory; Licensee's Right) at least [***] days before any time limit set forth in an Applicable Law or regulation, including the time limits set forth under the Hatch-Waxman Act (21 U.S.C. § 355) or within [***] days after being notified of such Licensed Product Infringement, whichever is shorter. If Licensee decides not to take such action, then Licensee will so notify Takeda in writing, and Takeda will have the second right, but not the obligation, to commence a suit or take action to enforce the applicable Patent Right against such Third Party perpetrating such Licensed Product Infringement in the Licensee Territory at its own expense. If one Party elects to bring suit or take action against the Licensed Product Infringement, then the other Party will have the right, prior to commencement of the trial, suit, or action, to join any such suit or action.

(c) *Cooperation*. Each Party will provide to the Party enforcing any such rights under this Section 10.6.2 (Infringement of Patent Rights by Third Parties) reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action or providing the enforcing Party any reasonably requested documentation or other materials. The enforcing Party will keep the other Party regularly informed of the status and progress of such enforcement efforts, including providing the other Party a reasonably opportunity to comment on the enforcing Party's determination of litigation strategy and the filing of important papers to the competent court and the enforcing Party will consider such comments in good faith.

(d) *Expenses*. Subject to Section 10.6.2(f) (Allocation of Proceeds), the enforcing Party will be solely responsible for all expenses arising from a suit or action against a Licensed Product Infringement. For the avoidance of doubt, the enforcing Party will not be responsible for the other Party's internal expenses (e.g., FTEs) incurred as a result of the other Party's cooperation with the enforcement action as provided in Section 10.6.2(c)

(Infringement of Patent Rights by Third Parties; Cooperation). The Party not bringing an action with respect to Licensed Product Infringement in the Licensee Territory under this Section 10.6.2 (Infringement of Patent Rights by Third Parties) will be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party will at all times cooperate fully with the Party bringing such action.

(e) *Settlement*. Neither Party will settle any claim, suit, or action that it brought under this Section 10.6.2 (Infringement of Patent Rights by Third Parties) that could reasonably be expected to affect the other Party's rights or interests without the prior written consent of the other Party, which consent will not be unreasonably withheld, conditioned, or delayed.

(f) *Allocation of Proceeds*. If either Party recovers monetary damages from any Third Party in a suit or action brought under Section 10.6.2 (Infringement Actions in the Licensee Territory), Section 10.6.2(e) (Infringement of Patent Rights by Third Parties; Settlement), or Section 10.7.2(d) (Defense in the Licensee Territory; Settlement) or any royalties from a license agreement with a Third Party related to any alleged Licensed Product Infringement, whether such damages or royalties result from the infringement of Takeda Patent Rights, Licensee Patent Rights, or Joint Patent Rights, such recovery will be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, action, or license, and any remaining amounts will be split as follows: (i) [***] will be paid to the Party initiating or defending such suit or action and (ii) [***] will be paid to the non-initiating or defending Party.

10.6.3 Infringement Actions in the Takeda Territory. Takeda will have the sole right, but not the obligation, to bring an appropriate suit or other action against any Third Party engaged in any existing, alleged, or threatened infringement, or other violation of a Licensee Patent Right, Takeda Patent Right, or Joint Patent Right related to a compound or product that competes with the TAK-385 Licensed Compound or a TAK-385 Licensed Product in the Field in the Takeda Territory (a "Takeda Licensed Product Infringement"). Licensee will provide to Takeda reasonable assistance in such enforcement, at Takeda's request and expense, including joining such action as a party plaintiff if required by Applicable Law to pursue such action. If Takeda recovers monetary damages from any Third Party in such a suit or action or any royalties from a license agreement with a Third Party related to any alleged Takeda Licensed Product Infringement in [***], whether such damages or royalties result from the infringement of Takeda Patent Rights, Licensee Patent Rights, or Joint Patent Rights, such recovery will be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation, action, or license, and any remaining amounts will be split as follows: (a) [***] will be paid to Takeda and (b) [***] will be paid to Licensee. If Takeda recovers monetary damages from any Third Party in such a suit or action or any royalties from a license agreement with a Third Party related to any alleged Takeda Licensed Product Infringement in [***], then [***] of any such monetary damages.

10.7. **Infringement of Third Party Rights**.

10.7.1 Notice. If any Licensed Product used or sold by Licensee or Takeda, their respective Affiliates or Sublicensees, becomes the subject of a Third Party's (a) claim or assertion of infringement, misappropriation, or other violation of such Third Party's Patent Rights or other Intellectual Property Right as a result of the Exploitation of the Licensed Compounds or a Licensed Product or (b) challenge to the validity, scope, or enforceability of a Takeda Patent Right, Licensee Patent Right, or Joint Patent Right exclusively licensed to Licensee or Takeda, as applicable, under this Agreement, the Party first having notice of the claim or assertion will promptly notify the other Party (a "Third Party IP Claim").

10.7.2 Defense in the Licensee Territory.

(a) *Licensee's Right*. Licensee will have the first right, but not the obligation, to defend against any such Third Party IP Claim in the Licensee Territory, at Licensee's expense.

(b) *Takeda's Right*. If Licensee does not defend against any such Third Party IP Claim in the Licensee Territory within [***] days after it receives notice thereof (or within [***] days after it should have given notice thereof to Takeda as required by Section 10.7.1 (Notice)), then to the extent allowed by Applicable Law, Takeda will have the second right, but not the obligation, to assume the defense against such Third Party IP Claim by counsel of its choice, at Takeda's expense.

(c) *Cooperation*. The non-defending Party will reasonably assist and cooperate with the Party conducting the defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney.

(d) *Settlement*. Neither Party will enter into any settlement of any Third Party IP Claim in the Licensee Territory that could reasonably be expected to affect the other Party's rights or interests without such other Party's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. Each Party will have the right to decline to defend or to tender defense of any such claim to the other Party upon reasonable notice, including if the other Party fails to agree to a settlement that such Party proposes.

10.7.3 Takeda Territory. Takeda will have the sole right, but not the obligation, to defend against any such Third Party IP Claim related to the TAK-385 Licensed Compound or a TAK-385 Licensed Product in the Takeda Territory, at Takeda's expense. Licensee will reasonably assist and cooperate with Takeda's defense of the claim or assertion, including if required to conduct such defense, furnishing a power of attorney.

10.8. **Patent Oppositions and Other Proceedings**.

10.8.1 Third Party Patent Rights. If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination, *inter partes* review, post-grant review or other attack upon the validity, title, or enforceability of a Patent Right Controlled by a Third Party and having one or more claims that Cover a Licensed Compound or Licensed Product, or the use, sale, offer for sale, or importation of a Licensed Compound or Licensed Product (except if such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 10.7 (Infringement of Third Party Rights)), in which case the provisions of Section 10.7 (Infringement of Third Party Rights) will govern, such Party will so notify the other Party and the Parties will promptly confer to determine whether to bring such action or the manner in which to settle such action.

(a) *Licensee's Rights*. Licensee will have the first right, but not the obligation, to bring at its own expense and in its sole control such action in the Licensee Territory.

(b) *Takeda's Rights*. If Licensee does not bring such an action in the Licensee Territory within [***] days of notification thereof pursuant to this Section 10.8.1 (Third Party Patent Rights) (or earlier, if required by the nature of the proceeding), then Takeda will have the second right, but not the obligation, to bring, at Takeda's sole expense, such action in the Licensee Territory. Takeda will have the sole right, but not the obligation, to bring at its own expense and in its sole control such action in the Takeda Territory related to the TAK-385 Licensed Compound or a TAK-385 Licensed Product.

(c) *Cooperation*. The Party not bringing an action under this Section 10.8 (Patent Oppositions and Other Proceedings) will be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and will cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action will be first allocated to reimburse the initiating Party's expenses in such action and any remaining amounts will be retained by such Party.

10.8.2 Parties' Patent Rights. If any Takeda Patent Right, Licensee Patent Right, or Joint Patent Right becomes the subject of any proceeding commenced by a Third Party within the Licensee Territory or the Takeda Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference, *inter partes* review, post-grant review or other attack upon the validity, title, or enforceability thereof (except if such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 10.6 (Infringement of Patent Rights by Third Parties), in which case the provisions of Section 10.6 (Infringement of Patent Rights by Third Parties) will govern), then the Party responsible for filing, preparing, Prosecuting and maintaining such Patent Right as set forth in Section 10.4 (Prosecution of Patent Rights), will control such defense at its own expense. The controlling Party will permit the non-controlling Party to participate in the proceeding to the extent permissible under Applicable Law, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If either Party decides that it does not wish to defend against such action, then the other Party will have a backup right to assume defense of such Third Party action at its own expense. Any awards or amounts received in defending any such Third Party action will be allocated between the Parties as provided in Section 10.6.2(f) (Allocation of Proceeds).

10.9. **Trademarks**. Each Party has the right to use any Trademark it Controls for the Commercialization of Licensed Products in its respective Territory at its sole discretion, and each Party and its Affiliates will retain all rights, title, and interest in and to its and their respective corporate names and logos. The JRC will discuss the selection of any Trademarks to be exclusively used in connection with the Commercialization of such TAK-385 Licensed Product (the "Product Trademarks"); *provided that* each Party will have sole discretion over the Product Trademarks to be used by such Party in connection with the Commercialization of a TAK-385 Licensed Product in its respective Territory. Each Party will solely own and be solely responsible for applying for and maintaining registrations of the Product Trademarks, in its respective Territory (including payment of expenses associated therewith), and all goodwill associated therewith will inure to the benefit of such Party. Each Party will be responsible for all expenses incurred by such Party to apply for and maintain such Product Trademarks and assume full responsibility, at its sole expense, for any infringement of its Product Trademarks by a Third Party. If either Party determines to use any Product Trademark developed or used by the other Party, in the case of Takeda, with respect to the Commercialization of TAK-385 Licensed Products in the Licensee Territory (the "Licensee Product Trademarks") to Commercialize any TAK-385 Licensed Product in the Takeda Territory, and in the case of Licensee, with respect to the Commercialization of TAK-385 Licensed Products in the Takeda Territory (the "Takeda Product Trademarks") to Commercialize TAK-385 Licensed Products in the Licensee Territory, then Licensee and Takeda will enter into a separate trademark license agreement containing commercially reasonable and customary terms pursuant to which Licensee or Takeda, as applicable, will grant the other Party an exclusive, royalty-free license to use the applicable Licensee Product Trademarks or Takeda Product Trademarks to Commercialize TAK-385 Licensed Products in the Takeda Territory or Licensee Territory, as applicable. In the event either Party becomes aware of any infringement by a Third Party of any Product Trademark owned by the other Party, such Party will promptly notify the other Party and the Parties will consult with each other and jointly determine the best way to prevent such infringement, including by the institution of legal proceedings against such Third Party. For clarity, Licensee shall have sole discretion over and responsibility for Trademarks to be used in connection with the Commercialization of any TAK-448 Licensed Product, and the JRC will not have authority to discuss any such Trademarks.

10.10. **Common Interest**. All information exchanged between the Parties representatives pursuant to this Article 10 (Intellectual Property Matters) regarding the preparation, filing, Prosecution, maintenance, or enforcement of Patent Rights will be the disclosing Party's Confidential Information. [***].

ARTICLE 11
REPRESENTATIONS AND WARRANTIES

11.1. **Mutual Representations, Warranties and Covenants**. Each of the Parties hereby represents and warrants to the other Party as of the Effective Date and covenants that:

11.1.1 Organization. It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

11.1.2 Binding Agreement. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

11.1.3 Authorization. The execution, delivery, and performance of this Agreement by such Party have been duly authorized by all necessary corporate action and do not conflict with any agreement, instrument, or understanding, oral or written, to which it is a party or by which it is bound, nor violate any Applicable Law or any order, writ, judgment, injunction, decree, determination, or award of any court or governmental body, or administrative or other agency presently in effect applicable to such Party.

11.1.4 No Further Approval. It is not aware of any government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law, currently in effect, necessary for, or in connection with, the transactions contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements (save for Regulatory Approvals and similar authorizations from Regulatory Authorities necessary for the Exploitation of the Licensed Compounds and Licensed Products as contemplated hereunder).

11.1.5 No Inconsistent Obligations. Neither Party is under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

11.1.6 Transparency Reporting. Each Party will be responsible for tracking and reporting transfers of value initiated and controlled by its and its Affiliates' employees, contractors, and agents pursuant to the requirements of the marketing reporting laws of any Government Authority in the Licensee Territory, including Section 6002 of the Patient Protection and Affordable Care Act, commonly referred to as the "Sunshine Act."

11.2. **Additional Representations and Warranties of Takeda**.

Takeda represents and warrants as of the Effective Date to Licensee that:

11.2.1 Sufficient Rights. Takeda has all rights necessary to grant the rights and licenses under the Takeda Intellectual Property Rights and rights of reference to Regulatory Materials, in each case, Controlled by Takeda as of the Effective Date that it grants to Licensee in this Agreement.

11.2.2 Ownership of Takeda Patent Rights. Takeda is the sole and exclusive owner of the entire right, title, and interest in the Takeda Patent Rights set forth on Schedule 1.151 (Takeda Patent Rights) free of any encumbrance, lien, or claim of ownership by any Third Party.

11.2.3 Completeness of Patent Schedule. Schedule 1.151 (Takeda Patent Rights) includes all Patent Rights owned or Controlled by Takeda that are necessary for Licensee to Exploit the Licensed Compounds and Licensed Products in the Licensee Territory and Develop the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Takeda Territory.

11.2.4 Registration and Maintenance. To Takeda's Knowledge, all registrations and applications for the Takeda Patent Rights set forth on Schedule 1.151 (Takeda Patent Rights) are valid, enforceable, and subsisting. Except as stated therein, no registration, or application therefor, for any of the Takeda Patent Rights set forth in Schedule 1.151 (Takeda Patent Rights) has lapsed, expired, been abandoned, or been withdrawn, and no such registrations, or applications therefor, are the subject of any opposition, interference, cancellation, *inter partes* review, post-grant review, or other legal or governmental proceeding pending before any Governmental Authority (other than standard patent prosecution before a Patent Office). To Takeda's Knowledge, each of the Takeda Patent Rights properly identifies each and every inventor of the claims therein as determined in accordance with Applicable Law of the jurisdiction in which such Takeda Patent Right is issued or such application is pending.

11.2.5 Infringement. There is no claim pending by Takeda alleging that a Third Party is or was infringing, misappropriating, or otherwise violating the Takeda Technology in the Field in the Licensee Territory, and, to Takeda's Knowledge, as of the Effective Date, the use, manufacture, or sale of the Licensed Compounds and Licensed Products in the Field does not infringe any Patent Right of any Third Party.

11.2.6 No Government Funding. The Inventions claimed or disclosed by the Takeda Patent Rights set forth on Schedule 1.151 (Takeda Patent Rights) (a) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the U.S. or any agency thereof, (b) are not a "subject invention" as that term is described in 35 U.S.C. § 201(f), and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as well as any regulations promulgated pursuant thereto, including 37 C.F.R. Part 401, and any successor statutes or regulations (also known as the Bayh-Dole Act).

11.2.7 No Debarment. Neither Takeda nor any of its Affiliates has been debarred by the FDA, and are not subject to any similar sanction of other Regulatory Authorities in the Licensee Territory, and neither Takeda nor any of its Affiliates has used, in any capacity, in connection with this Agreement or any other Transaction Agreement, any Person who either has been debarred by such a Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA.

11.2.8 No Claims. No claim or litigation in the Licensee Territory has been brought or, to Takeda's Knowledge, threatened by any Person alleging, and Takeda has no Knowledge of any claim, whether or not asserted: (a) that any of the Takeda Patent Rights is invalid or unenforceable, (b) that the Takeda Regulatory Materials or the Takeda Technology violates, infringes, or otherwise conflicts or interferes with, or would violate, infringe, or otherwise conflict or interfere with, any Intellectual Property Right of any Person, and (c) that the Exploitation of the Licensed Compounds and Licensed Products violates, infringes, or otherwise conflicts or interferes with, any Intellectual Property Right of any Person.

11.2.9 Safety Data. Takeda and its Affiliates have provided or made available to Licensee true, complete, and correct copies (as of the Effective Date) of all material information known to Takeda with respect to the safety of the Licensed Compounds and Licensed Products. For the avoidance of doubt, this representation does not apply to information to the extent it arises from the On-Going Clinical Trials.

11.2.10 Regulatory Materials. Takeda or its Affiliates own all Regulatory Materials to be assigned to Licensee hereunder, and to Takeda's Knowledge, Takeda and its Affiliates have maintained and retained all material Regulatory Materials that are required to be maintained or retained pursuant to and in accordance with Applicable Law, and all such information is true, complete, and correct in all material respects.

11.3. **Additional Covenants of Takeda**. Takeda covenants to Licensee that:

11.3.1 No Conflicting Rights. As from the Effective Date and for the duration of the Term, Takeda will not, and will cause its Affiliates not to, grant to any Third Party rights in the Field in the Licensee Territory that encumber, diminish, or conflict with the rights granted to Licensee hereunder with respect to the Takeda Regulatory Materials or Takeda Technology.

11.3.2 No Debarment. Neither Takeda nor any of its Affiliates will engage, in any capacity, in connection with this Agreement or any other Transaction Agreement, any Person who either has been debarred by such a Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA. Takeda will inform Licensee in writing promptly if it or any Person engaged by Takeda or any of its Affiliates who is performing any activities under or in connection with this Agreement or any other Transaction Agreement (if any) is debarred or is the subject of a conviction described in Section 306 of the FFDCA, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to Takeda's Knowledge, is threatened, relating to the debarment or conviction of Takeda, any of its Affiliates, or any such Person performing activities.

11.3.3 Invention Assignment. To the extent permissible under Applicable Law, Takeda will cause its and its Affiliates' employees performing activities under this Agreement, and will use Diligent Efforts to cause its and its Affiliates' Sublicensees and Subcontractors performing activities under this Agreement, to be under an obligation to assign all rights, title, and interests in and to their Inventions and other Information, whether or not patentable, and Intellectual Property Rights therein, to Takeda or its Affiliates as the sole owner thereof. Licensee will have no obligation to contribute to any remuneration of any inventor employed or previously employed by Takeda or any of its Affiliates in respect of any such Inventions, Information, or Intellectual Property Rights therein that are so assigned to Takeda or its Affiliates. Takeda will pay all such remuneration due to such inventors with respect to such Inventions and other Information and Intellectual Property Rights therein.

11.3.4 Foreign Corruption Compliance. In performing its obligations under this Agreement, or any other Transaction Agreement (if any), Takeda will, and will cause its Affiliates to, comply with all Applicable Law, including any applicable anti-corruption or anti-bribery laws or regulations, of any Governmental Authority with jurisdiction over the activities performed by Takeda or its Affiliates in furtherance of such obligations.

11.4. **Additional Representations and Warranties of Licensee**. Licensee represents and warrants as of the Effective Date that:

11.4.1 No Debarment. Neither Licensee nor any of its Affiliates has been debarred by the FDA, and are not subject to any similar sanction of other Regulatory Authorities in the Licensee Territory, and neither Licensee nor any of its Affiliates has used, in any capacity, in connection with this

Agreement or any other Transaction Agreement, any Person who either has been debarred by such a Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA.

11.4.2 Cash-on-Hand. Licensee or RSL has at least [***] in immediately available funds as of the Effective Date (the "Cash-on-Hand"). The bank statements of RSL attached hereto as Schedule 11.4.2 (Financial Statements) accurately reflect RSL's immediately available funds as of March 31, 2016.

11.5. **Additional Covenants of Licensee**. Licensee covenants to Takeda that:

11.5.1 No Debarment. Neither Licensee nor any of its Affiliates will engage, in any capacity, in connection with this Agreement or any other Transaction Agreement, any Person who either has been debarred by such a Regulatory Authority, or is the subject of a conviction described in Section 306 of the FFDCA. Licensee will inform Takeda in writing promptly if it or any Person engaged by Licensee or any of its Affiliates who is performing any activities under or in connection with this Agreement or any other Transaction Agreement (if any) is debarred or is the subject of a conviction described in Section 306 of the FFDCA, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to Licensee's knowledge, is threatened, relating to the debarment or conviction of Licensee, any of its Affiliates, or any such Person performing activities.

11.5.2 Specific Notifications Regarding Licensed Products. Prior to Regulatory Approval of any Licensed Product in the Field in the Territory, Licensee will, and will cause its Affiliates and Sublicensee to, promptly advise Takeda if such party is aware of any suspension, clinical hold, or other regulatory action by any Regulatory Authority relating to any Licensed Product where such action has had or would reasonably be expected to have a material adverse impact on the further Exploitation of such Licensed Product in the Field in the Territory.

11.5.3 [***]

11.5.4 Invention Assignment. To the extent permissible under Applicable Law, Licensee will cause its and its Affiliates' employees performing activities under this Agreement, and will use Commercially Reasonable Efforts to cause its and its Affiliates' Sublicensees and Subcontractors performing activities under this Agreement, to be under an obligation to assign all rights, title and interests in and to their Inventions and other Information, whether or not patentable, and Intellectual Property Rights therein, to Licensee or its Affiliates as the sole owner thereof. Takeda will have no obligation to contribute to any remuneration of any inventor employed or previously employed by Licensee or any of its Affiliates in respect of any such Inventions, Information, and discoveries and Intellectual Property Rights therein that are so assigned to Licensee or its Affiliates. Licensee will pay all such remuneration due to such inventors with respect to such Inventions and other Information and Intellectual Property Rights therein.

11.5.5 Foreign Corruption Compliance. In performing its obligations under this Agreement, or other Transaction Agreement (if any), Licensee will, and will cause its Affiliates to, comply with all Applicable Law, including any applicable anti-corruption or anti-bribery laws or regulations, of any Governmental Authority with jurisdiction over the activities performed by Licensee or its Affiliates in furtherance of such obligations.

11.5.6 Non-Solicit. Licensee, without the prior written consent of Takeda[***] will not solicit, induce, encourage, or participate in soliciting, inducing, or encouraging any employee of Takeda, or any of its Affiliates[***] to terminate his or her relationship with Takeda or Takeda's Affiliate and accept employment with Licensee. An offer of employment to an employee of Takeda by Licensee which results directly from unsolicited responses to general advertisements for employment or from an unsolicited inquiry by such employee will not be deemed to be in violation of this provision.

11.6. **[***]**.

11.7. **No Other Representations or Warranties**. EXCEPT AS EXPRESSLY STATED IN THIS Article 11 (REPRESENTATIONS, WARRANTIES, AND COVENANTS), NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE LICENSED COMPOUND, LICENSED PRODUCTS, OR THE SUBJECT MATTER OF THIS AGREEMENT. ANY INFORMATION PROVIDED BY TAKEDA OR ITS AFFILIATES IS MADE AVAILABLE ON AN "AS IS" BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

ARTICLE 12
CONFIDENTIALITY

12.1. **Nondisclosure and Non-Use**. Each Party agrees that, during the Term and for a period of [***] years thereafter, a Party (the "Receiving Party") receiving Confidential Information of the other Party (the "Disclosing Party") will (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential or proprietary information of similar kind and value, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose, except to exercise its right and perform its obligations under this Agreement (it being understood that this Section 12.1 (Nondisclosure) will not create or imply any rights or licenses not expressly granted under this Agreement). Notwithstanding anything to the contrary in the foregoing, the obligations of confidentiality and non-use with respect to any trade secret within such Confidential Information will survive for so long as such Confidential Information remains protected as a trade secret under Applicable Law.

12.2. **Exceptions**. The obligations in Section 12.1 (Nondisclosure) will not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent evidence:

12.2.1 is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party hereunder;

12.2.2 is known to the Receiving Party or any of its Affiliates at the time of its receipt, and not through a prior disclosure by the Disclosing Party, without any obligation to keep it confidential or any restriction on its use, prior to such disclosure by the Disclosing Party;

12.2.3 is subsequently disclosed to the Receiving Party or any of its Affiliates on a non-confidential basis by a Third Party that, to the Receiving Party's knowledge, is not bound by a similar duty of confidentiality or restriction on its use;

12.2.4 is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party or any of its Affiliates, generally known or available, either before or after it is disclosed to the Receiving Party;

12.2.5 is independently discovered or developed by or on behalf of the Receiving Party or any of its Affiliates without the aid, use of, access to, or application of any of the Confidential Information belonging to the Disclosing Party; or

12.2.6 is the subject of written permission to disclose provided by the Disclosing Party.

12.3. **Authorized Disclosure**.

12.3.1 Permitted Disclosure. Notwithstanding the provisions of Section 12.1 (Nondisclosure and Non-Use), the Receiving Party may disclose Confidential Information belonging to the Disclosing Party only to the extent such disclosure is reasonably necessary in the following instances: (a) filing or Prosecution of Patent Rights as permitted by this Agreement; (b) filing of Regulatory Materials in order to obtain or maintain Regulatory Approvals; (c) prosecuting or defending litigation as contemplated by this Agreement; (d) complying with Applicable Law or regulation or order of any or court or Government Authority, including responding to a subpoena in a Third Party litigation; or (e) to its Affiliates, Sublicensees or prospective Sublicensees, Subcontractors or prospective Subcontractors, payors, consultants, agents, and advisors on a "need-to-know" basis in order for the Receiving Party to exercise its rights or fulfill its obligations under this Agreement, each of whom prior to disclosure must be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are substantially similar to those set forth in this Article 12 (Confidentiality) (but which obligations may be of shorter duration for Third Parties, but at least [***] years); *provided*, *however*, that, in each of the above situations, the Receiving Party will remain responsible for any failure by any Person who receives Confidential Information pursuant to Section 12.3.2 (Notice; Confidential Treatment) to treat such Confidential Information as required under this Article 12 (Confidentiality). Notwithstanding the foregoing, (i) [***], and (ii) Licensee may disclose the Confidential Information of Takeda to its Parent Affiliates and its Parent Affiliates' direct and indirect subsidiaries solely in connection with and for the purpose of the performance of administrative services for Licensee and for internal reporting and compliance purposes.

12.3.2 Notice; Confidential Treatment. If and whenever any Confidential Information is disclosed in accordance with this Section 12.3 (Authorized Disclosure), such disclosure will not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (other than by breach of this Agreement). Notwithstanding the foregoing, if a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 12.3. 1 (a), (b), (c), or (d) (Permitted Uses), then it will, except where illegal, (a) give reasonable advance notice to the other Party of such disclosure and use not less than the same efforts to secure confidential treatment of or a protective (or similar) order for such Information as it would to protect its own Confidential Information from disclosure and (b) only disclose the minimum amount of Confidential Information reasonably required for the purpose of such disclosure.

12.4. **Terms of this Agreement**. The Parties acknowledge that this Agreement and all of the respective terms of this Agreement will be treated as Confidential Information of both Parties. Neither Party nor its Affiliates shall disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other Party, except to a Third Party or Related Party in connection with (a) a financing (or proposed financing) or an equity investment (or proposed investment) in such Party or its Affiliates, including to its shareholders and prospective shareholders, (b) the entry into any agreement with respect to the Development, Manufacture, or Commercialization of a Licensed Product, (c) a merger, consolidation, or similar transaction by such Party or its Affiliates, (d) the sale of all or substantially all of the assets of such Party or its Affiliates to which this Agreement relates, or (e) in connection with a securitization, *provided that* (i) all such disclosures are made in accordance with this Article 12 (Confidentiality) and (ii) such Third Party executes a non-use and non-disclosure agreement with confidentiality and non-use obligations similar to those contained in this Agreement. In addition, upon advance written notice to the other Party, either Party may provide a copy of this Agreement to the United States Internal Revenue Service or other tax authorities, if requested by such authority.

12.5. **Publicity**. The Parties will make a joint public announcement regarding the execution of this Agreement, which will be issued following the Effective Date at a time to be agreed by the Parties. The Parties will agree on a form of joint public announcement within two (2) weeks of the Effective Date. Each Party

agrees not to issue any other press release or other public statement disclosing other information relating to this Agreement or the transactions contemplated hereby that contains information not previously publicly disclosed without the prior written consent of the other Party, not to be unreasonably withheld, conditioned, or delayed. Each Party shall have the right to use the other Party's name and logo in presentations, such Party's website, collateral materials, corporate overviews, and other public disclosures describing the licensing relationship.

12.6. **Securities Filings**. Notwithstanding anything to the contrary in this Article 12 (Confidentiality), if either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction (including the NASDAQ and the NYSE) a registration statement or any other disclosure document that describes or refers to the terms and conditions of this Agreement or any related agreements between the Parties and constitutes Confidential Information, then such Party will notify the other Party of such intention and will provide the other Party with a copy of relevant portions of the proposed filing at least [***] Business Days prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto that refer to the other Party or the terms and conditions of this Agreement or any related agreements between the Parties. The Party making such filing will only disclose Confidential Information that its counsel advises is legally required to be disclosed and, if this Agreement or any related agreements between the Parties are proposed to be filed as exhibits, will cooperate in good faith with the other Party to obtain confidential treatment of the terms and conditions of this Agreement or such related agreements that the other Party reasonably requests to be kept confidential. No such notice will be required if the description of or reference to this Agreement or a related agreement between the Parties contained in the proposed filing has been included in any previous filing made by the either Party in accordance with this Section 12.6 (Securities Filings) or otherwise approved by the other Party.

12.7. **Publications**.

12.7.1 Publication Plan. Subject to the terms of Section 12.7.2 (Publication Guidelines), each Party shall have the right to publish summaries of results of all Clinical Trials conducted by or on behalf of such Party during the Term with respect to a TAK-385 Licensed Product; provided, however, that the other Party shall have the right to review all such proposed publications prior to submission of such publication, and the proposing Party shall deliver to the other Party a copy of the proposed written publication at least [***] days prior to submission for publication, in order to review the Clinical Trial results and any and all such data which are the subject of such proposed publication in order to prepare any necessary Patent Office filings. The Parties shall discuss and reasonably cooperate in order to facilitate and ensure publication under this Section 12.7.1 (Publication Plan) of any such summaries of Clinical Trial data and results as required under Applicable Law on the Clinical Trial registry of each respective Party.

12.7.2 Publication Guidelines. All publications relating to the TAK-385 Licensed Compound or TAK-385 Licensed Products shall be prepared, presented, and published in accordance with pharmaceutical industry accepted guidelines including: (a) International Committee of Medical Journal Editors (ICMJE) guidelines, (b) Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, (c) Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, and (d) Principles on Conduct of Clinical Trials.

12.8. **Equitable Relief**. Given the nature of the Confidential Information and the competitive damage that could result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 12 (Confidentiality). In addition to all other remedies, a Party will be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 12 (Confidentiality).

ARTICLE 13
TERM AND TERMINATION

13.1. **Term**. This Agreement will become effective as of the Effective Date and will continue in full force and effect until the expiration of this Agreement as described in this Section 13.1 (Term), unless earlier terminated pursuant to this Article 13 (the "Term"). This Agreement will expire as follows:

13.1.1 on a country-by-country and Licensed Product-by-Licensed Product basis, upon the expiration of the Royalty Term with respect to each Licensed Product in each country in the Licensee Territory or Takeda Territory, as applicable; or

13.1.2 in its entirety, upon the expiration of the Royalty Term with respect to the last Licensed Product Commercialized in the last country in the Licensee Territory or Takeda Territory.

13.2. **Termination at Will**. Licensee may terminate this Agreement at will, in its sole discretion, in its entirety, or with respect to the Men's Health Field or the Women's Health Field for the TAK-385 Licensed Compound, or on a Licensed Compound-by-Licensed Compound basis for all fields, (a) on not less than [***] months' prior written notice to Takeda, if such termination is for a TAK-448 Licensed Product, (b) on not less than [***] months' prior written notice to Takeda if such notice is provided for the TAK-385 Licensed Compound prior to Licensee's receipt of the first Regulatory Approval for the first TAK-385 Licensed Product for the Terminated Field in the Licensee Territory, and (c) on not less than [***] months' prior written notice to Takeda if such notice is provided for a Licensed Compound following Licensee's receipt of the first Regulatory Approval for a Licensed Product for the Terminated Field in the Licensee Territory.

13.3. **Termination for Material Breach**.

13.3.1 Cure Periods. Either Party (the "Non-Breaching Party") may terminate this Agreement in its entirety, with respect to the Men's Health Field or the Women's Health Field for the TAK-385 Licensed Compound, or on a Licensed Compound-by-Licensed Compound basis for all fields in the event the other Party (the "Breaching Party") has materially breached this Agreement in its entirety or with respect to the Men's Health Field or the Women's Health Field for the TAK-385 Licensed Compound or with respect to a particular Licensed Compound, and such material breach has not been cured (a) within [***] Business days of receiving notice thereof with respect to any breach of any undisputed payment obligation under this Agreement and (b) within [***] days of receiving notice thereof with respect to any other breach (as applicable, the "Cure Period"). The written notice describing the alleged material breach will provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement pursuant to this Section 13.3.1 (Cure Periods) will become effective at the end of the Cure Period, unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period. The right of either Party to terminate this Agreement with respect to the Men's Health Field, Women's Health Field for the TAK-385 Licensed Compound, or the TAK-385 Licensed Compound or TAK-448 Licensed Compound in all fields, as provided in this Section 13.3.1(a) (Cure Periods) will not be affected in any way by such Party's waiver of or failure to take action with respect to any previous breach under this Agreement.

13.3.2 Tolling of Cure Period. If the Parties reasonably and in good faith disagree as to whether there has been a material breach, including whether such breach was material, the Party that disputes whether there has been a material breach may contest the allegation in accordance with Article 14 (Dispute Resolution). Notwithstanding anything to the contrary contained in Section 13.3.1 (Cure Periods), the Cure Period for any Dispute will run from the date that written notice was first provided to the Breaching Party by the Non-Breaching Party through the resolution of such Dispute pursuant to Article 14 (Dispute Resolution), and it is understood and acknowledged that, during the pendency of a Dispute pursuant this Section 13.3.2 (Tolling of Cure Period), all of the

terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement.

13.4. **Termination by Licensee for Safety Reasons**.

13.4.1 Termination by Licensee. At any time after the Effective Date, Licensee may terminate this Agreement with respect to the TAK-385 Licensed Compound or the TAK-448 Licensed Compound on not less than [***] months' prior written notice to Takeda if Licensee reasonably determines based upon its review of the clinical data or upon a determination by an applicable drug safety monitoring board or Governmental Authority that the TAK-385 Licensed Compound or TAK-385 Licensed Products [***], based upon then-available data, to preclude continued Development or Commercialization of a Licensed Product (such termination, a "Safety Termination"). Upon delivery of any such notice of a Safety Termination, Licensee may wind-down its then on-going activities related to the Licensed Products, including any on-going Clinical Trials (to the extent consistent with Applicable Law), in accordance with Section 13.9.2(b)(ii) (Clinical Trial Wind-Down).

13.4.2 Termination by Consensus. The Parties may terminate this Agreement with respect to the TAK-385 Licensed Compound or the TAK-448 Licensed Compound, or the Men's Health Field or the Women's Health Field prior to expiration of the [***] month notice period provided in Section 13.4.1 (Termination by Licensee) upon written agreement if the Parties: (a) reach consensus that Licensee is unable to continue Developing or Commercializing a Licensed Product in the Field in the Licensee Territory; and (b) have completed all applicable wind-down and other transition activities, including those set forth in Section 13.9 (Effects of Termination).

13.5. **Termination for Commercial Viability**.

13.5.1 Commercial Viability Termination. At any time after the Effective Date, Licensee may terminate this Agreement with respect to the TAK-385 Licensed Compound for all fields or with respect to the Men's Health Field or the Women's Health Field, on not less than [***] months' prior written notice to Takeda if Licensee reasonably and in good faith determines, and provides written documentation to Takeda to support such determination, that it is not viable to Commercialize the TAK-385 Licensed Products (whether or not Regulatory Approval is achieved) due to (a) [***] or (b) [***] (such termination, a "Commercial Viability Termination").

13.5.2 Determination as to Commercial Viability. If, following Takeda's receipt of notice of a Commercial Viability Termination, Takeda reasonably and in good faith disputes Licensee's determination with respect to the applicable Licensed Products' lack of commercial viability (which notice shall contain the factual basis upon which Takeda disputes such determination), then Takeda will notify Licensee in writing within [***] days. In such event, the matter shall be referred for resolution in accordance with Article 14 (Dispute Resolution). During the pendency of such a dispute resolution proceeding, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement.

13.6. **Termination for Cessation of Activities**. Without prejudice to any other remedies available to it at law or in equity (including for any breach of the terms hereof), if Licensee does not initiate or conduct, or cause to be initiated or conducted, [***] Development or Commercialization activities with respect to any Licensed Compound (which Development or Commercialization activities must be consistent with the TAK-385 Development Plan or the Commercialization Plan with respect to TAK-385 Licensed Products) during any consecutive [***] month period, and such suspension of activity is not: (a) by written agreement of the Parties or (b) a result of Licensee's reasonable response to guidance from or action by a Regulatory Authority or other Governmental Authority (such as a clinical hold, a Recall or withdrawal), then Takeda may terminate this Agreement with respect to the applicable Licensed Compound with [***] days' written

notice to Licensee, unless within such [***] day period Licensee provides to Takeda suitable documentation evidencing Licensee's conduct of such [***] Development or Commercialization activities during the applicable [***] month period.

13.7. **Termination for Patent Challenge**. If either Party, or any of such Party's Affiliates, directly, or indirectly through assistance granted to a Third Party, commences any interference or opposition proceeding, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to any Takeda Patent Right or Licensee Patent Right, as applicable, or any other Patent Right Controlled by the other Party that claims or discloses the composition of matter or the method of making or using a Licensed Compound Licensed Product, then such other Party may, in its sole discretion, upon written notice to the Party commencing such action, either (a) terminate this Agreement with respect to the applicable Licensed Compound by providing written notice of termination to the commencing Party or (b) leave the Agreement in effect, but increase the applicable Royalties payable to such other Party with respect to the applicable Licensed Products pursuant to Section 9.2.1 (Royalty Rates) by [***] and, in any case, if such other Party so chooses, sue the commencing Party for infringement in any forum of competent jurisdiction of such other Party's choosing; *provided that* the Party commencing such action shall have a period of [***] days from written notice of such election in which to withdraw or terminate such action with prejudice.

13.8. **Termination for Insolvency**.

Either Party may terminate this Agreement in its entirety upon providing written notice to the other Party on or after the time that such other Party makes a general assignment for the benefit of creditors, files an insolvency petition in bankruptcy, petitions for or acquiesces in the appointment of any receiver, trustee, or similar officer to liquidate or conserve its business or any substantial part of its assets, commences under the laws of any jurisdiction any proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation, or any other similar proceeding for the release of financially distressed debtors, or becomes a party to any proceeding or action of the type described above, and such proceeding or action remains un-dismissed or un-stayed for a period of more than [***] days.

13.9. **Effects of Termination**. All of the following effects of termination (but not expiration) are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and will not be construed to limit any such rights or remedies.

13.9.1 All Termination Events. In the event of any termination of this Agreement for any reason with respect to any TAK-385 Licensed Compound or TAK-448 Licensed Compound (the applicable Licensed Compound and category of Licensed Products, the "Terminated Compounds" and "Terminated Products", respectively), or the Men's Health Field or the Women's Health Field for the TAK-385 Licensed Compound (the "Terminated Field"):

(a) the Terminated Compound and Terminated Products and all rights under the Takeda Patent Rights and Takeda's interest in the Joint Patent Rights licensed to Licensee in this Agreement (or, where such termination relates to a specific Terminated Field for the TAK-385 Licensed Compound, solely to the extent relating to the Terminated Field) will revert to Takeda solely with respect to the Terminated Compound and Terminated Products;

(b) all other rights and licenses granted by Takeda under this Agreement solely with respect to the Terminated Compounds and Terminated Products (or, where such termination relates to a specific Terminated Field for the TAK-385 Licensed Compound, solely to the extent relating to the Terminated Field) will immediately terminate, including any sublicense granted by Licensee pursuant to Section 3.3.3 (Performance by Licensee Sublicensees);

(c) subject to 13.9.2 (Certain Termination Events), all rights granted to Takeda under the Licensee Patent Rights and Licensee's interest in the Joint Patent Rights licensed by Licensee to Takeda in this Agreement solely with respect to the Terminated Compound and Terminated Products (or, where such termination relates to a specific Terminated Field for the TAK-385 Licensed Compound, solely to the extent relating to the Terminated Field) will revert to Licensee, and all sublicenses granted by Takeda thereunder to any Sublicensee pursuant to Section 3.3.3 (Performance by Licensee Sublicensees) will terminate; and

(d) subject to this Section 13.9 (Effects of Termination) and Section 13.13 (Survival), all other rights and obligations of the Parties under this Agreement (or, where such termination relates to a specific Terminated Field for the TAK-385 Licensed Compound, solely to the extent relating to the Terminated Field) will terminate with respect to the Terminated Compounds and Terminated Products.

13.9.2 Certain Termination Events. In the event of termination of this Agreement with respect to a Terminated Compound, or with respect to a particular Terminated Field for the TAK-385 Licensed Compound, by Licensee pursuant to Section 13.2 (Termination at Will), Section 13.4 (Termination for Safety Reasons), or Section 13.5 (Termination for Commercial Viability), by Takeda pursuant to Section 13.3 (Termination for Material Breach), Section 13.5 (Termination for Cessation of Activities), or by Takeda pursuant to Section 13.7 (Termination for Patent Challenge), or by either Party pursuant to Section 13.8 (Termination for Insolvency), then:

(a) *Transition Plan*. During the applicable notice period prior to the effective date of termination, Licensee will continue to meet its obligations to Exploit the Terminated Compound and Terminated Products in accordance with the terms and conditions of this Agreement and bear its expenses with respect thereto as set forth hereunder. Within [***] days after the date of the notice of such termination, Takeda will prepare and the Parties will negotiate in good faith and establish a transition and wind-down plan that will include, at a minimum, a plan for accomplishing the activities described in this Section 13.9.2 (Certain Termination Events). In accordance with such plan, Licensee will undertake Commercially Reasonable Efforts to effect a smooth and orderly transition to Takeda of all Exploitation activities and responsibilities under this Agreement with respect to the Terminated Compound and Terminated Products (or, where such termination relates to a particular Terminated Field for the TAK-385 Licensed Compound, solely to the extent relating to the Terminated Field), so as to enable Takeda to continue the Exploitation of the Terminated Compound and Terminated Products in the Territory or to continue to Exploit the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field in the Terminated Territory.

(b) *Clinical Trials*.

(i) Clinical Trial Completion. Upon termination of the Agreement in its entirety or with respect to a TAK-385 Licensed Compound in the Men's Health Field for any reason listed in this Section 13.9.2 (Certain Termination Events) other than pursuant to Section 13.4 (Termination for Safety Reasons), if such termination occurs prior to receipt of the first Regulatory Approval of a TAK-385 Licensed Compound in the Men's Health Field in Japan, then Licensee must either (A) reimburse Takeda for Takeda's out of pocket costs and expenses directly incurred in connection with Takeda's completion of the TAK-385 Development Plan in the Men's Health Field, up to a maximum total reimbursement of seventy million dollars ($70,000,000) (such amount, the "Reimbursed Expenses"); *provided that* if Licensee validly terminates this Agreement pursuant to Section 13.5 (Termination for Commercial Viability), then Takeda

will pay to Licensee an [***] royalty on Net Sales of the applicable Terminated Product, up to a maximum total amount equal to the Reimbursed Expenses or (B) complete the conduct of any Clinical Trials of the TAK-385 Licensed Products in the Men's Health Field that are ongoing as of the effective date of such termination as set forth in the then-current TAK-385 Development Plan, at its cost and expense. If Takeda undertakes to complete the TAK-385 Development Plan pursuant to clause (A) above, then Takeda will invoice Licensee following the end of each Calendar Quarter for the costs and expenses incurred by Takeda during such Calendar Quarter, and will provide supporting documentation as reasonably requested by Licensee. Licensee will have the right to audit Takeda's records relating to such costs and expenses in accordance with Section 9.6 (Audit).

(ii) Clinical Trial Wind-Down. Upon Takeda's receipt of the notice of termination of the Agreement by Licensee pursuant to Section 13.4 (Termination for Safety Reasons), Licensee will responsibly wind-down, in accordance with accepted pharmaceutical industry norms and ethical practices, any on-going Clinical Trials of Terminated Products for which it has responsibility hereunder in which patient dosing has commenced. Licensee will be responsible for any Development expenses associated with such wind-down.

(iii) Clinical Trial Information and Documents. Upon completion pursuant to Section 13.9.2(b)(i) (Clinical Trial Completion) or wind-down pursuant to Section 13.9.2(b)(ii) (Clinical Trial Wind-Down), as applicable, of the Clinical Trials ongoing as of the effective date of such termination, as soon as reasonably practical after the effective date of such termination Licensee will provide to Takeda, as applicable and to the extent permitted under any applicable Third Party contract (A) any Information, including copies of all Clinical Trial data and results, developed by or for the benefit of Licensee relating to the Terminated Products and (B) other documents to the extent relating to the Terminated Products that are necessary in the continued Exploitation of a Terminated Product (including material documents and agreements relating to the sourcing and Manufacture of a Terminated Product for sale, promotion, distribution, or use of such Terminated Product) throughout the Licensee Territory; *provided that* if such termination relates to a particular Terminated Field for the TAK-385 Licensed Compound, then the foregoing obligations shall apply with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field.

(c) *Assignment of Regulatory Materials*. Licensee will and hereby does, and will cause its Affiliates and its Sublicensees to, (i) effective as of the effective date of termination, assign to Takeda all of its rights, title, and interests in and to all Regulatory Materials and Regulatory Approvals, to the extent allowed under Applicable Law, pertaining to the Terminated Compound or Terminated Products then Controlled by Licensee or any of its Affiliates or its Sublicensees (subject to the provisions of Section 3.3.2 (Sublicense Requirements)) and (ii) to the extent assignment pursuant to clause (i) is delayed or not permitted by the applicable Regulatory Authority, permit Takeda to cross-reference and rely upon any Regulatory Materials and Regulatory Approvals filed by Licensee with respect to any Terminated Product. As soon as practicable after such transfer, Licensee will take all steps necessary to transfer ownership of all such assigned Regulatory Materials and Regulatory Approvals to Licensee, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Licensee) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory Approval. Notwithstanding the foregoing, if such termination relates to a particular

Terminated Field for the TAK-385 Licensed Compound, then the foregoing obligations shall apply with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field.

(d) *License Grant to Takeda*. Licensee will and hereby does, and will cause its Affiliates and its Sublicensees to, effective as of the effective date of termination, grant to Takeda a non-exclusive, fully paid-up, royalty-free, worldwide, transferable, perpetual, and irrevocable license and right of reference, with the right to sublicense, in and to any and all (i) Regulatory Materials and Regulatory Approvals pertaining to any Terminated Compound or Terminated Products Controlled by Licensee, its Affiliates, or its Sublicensees (subject to the provisions of Section 3.3.2 (Sublicense Requirements)) as of the effective date of termination that are not assigned to Takeda pursuant to Section 13.9.2(c) (Assignment of Regulatory Filings), and (ii) Patent Rights and Information Controlled by Licensee as of the effective date of termination that are necessary or are used as of the effective date of such termination to Exploit any Terminated Compound or Terminated Products, in each case ((i) and (ii)), to Exploit the Terminated Compound and Terminated Products; *provided that* if such termination relates to a particular Terminated Field for the TAK-385 Licensed Compound, then the foregoing license and right of reference shall only apply with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field. In addition, in the event of a termination of this Agreement in its entirety, all sublicenses granted by Takeda under this Agreement pursuant to Section 3.3.3 (Performance by Licensee Sublicensees) will survive such termination and become non-exclusive. Licensee shall assume no liability for the use of any such Regulatory Materials or Regulatory Approvals, or the practice of any such Patent Rights or Information, thereafter by Takeda or its Affiliates and Sublicensees.

(e) *Prosecution Responsibilities*. Takeda will have the right to assume all Prosecution, maintenance, and enforcement activities under Article 10 (Intellectual Property Matters) with respect to all Takeda Patent Rights and Joint Patent Rights that pertain to the Terminated Compound and Terminated Products (but no other Licensed Compound or Licensed Products); *provided that* if such termination relates to a particular Terminated Field for the TAK-385 Licensed Compound, then the foregoing obligations shall apply with respect to any such Patent Rights that have Valid Claims Covering the Exploitation of the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field; *provided*, *further*, that in the event a Patent Right has Valid Claims Covering the Exploitation of the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field and a non-Terminated Field, the Parties will agree on whether the Prosecution, maintenance, and enforcement activities related to such Patent Right should be transferred to Takeda, retained by Licensee or if such Patent Right should be Prosecuted as two (2) separate Patent Rights (e.g., divisional patent applications). Licensee will cooperate with Takeda and provide Takeda with reasonable assistance and cooperation with the Prosecution, maintenance, and enforcement activities with respect to such Takeda Patent Rights and Joint Patent Rights.

(f) *Patent Information*. For each Patent Right for which Takeda assumes the Prosecution, maintenance, and enforcement activities pursuant to Section 13.9.2(e) (Prosecution Responsibilities), Licensee, if requested in writing by Takeda, will provide, at Takeda's expense, any and all (i) material correspondence with the relevant Patent Offices pertaining to Licensee's prosecution of the Takeda Patent Rights, and Licensee's interest in the Joint Patent Rights, in each case to the extent pertaining to the Terminated Products and not previously provided to Takeda during the course of the Agreement and (ii) a report detailing the status of all Licensee Patent Rights, Takeda Patent Rights, and Joint Patent Rights at the time of termination or expiration; *provided that* if such termination

relates to a particular Terminated Field for the TAK-385 Licensed Compound, then the foregoing obligations shall apply with respect to any such Patent Rights that have Valid Claims Covering the Exploitation of the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field.

(g) *Trademark Assignment*. Effective as of the date of termination, Licensee will and hereby does assign to Takeda all of its rights, title, and interests in and to all Licensee Product Trademarks that pertain to the Terminated Products, including all associated goodwill. Licensee will provide all cooperation reasonably requested by Takeda in any effort of Takeda to establish, perfect, or defend its rights in such Licensee Product Trademarks, including the execution of assignments, releases, or other documentation, and the provision of good faith testimony by declaration, by affidavit or in-person; *provided that* if such termination relates to a specific Terminated Field for the TAK-385 Licensed Compound, then the foregoing obligations shall apply with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field.

(h) *Selected Third Party Agreements*. In the event Licensee has assumed responsibility for Manufacturing any Terminated Compound or Terminated Product, at Takeda's written request, Licensee will, and cause its Affiliates and its Sublicensees to, assign to Takeda any Selected Third Party Agreement requested by Takeda, unless, with respect to any such Selected Third Party Agreement, such Selected Third Party Agreement expressly prohibits such assignment, in which case Licensee (or such Affiliate or Sublicensee, as applicable) will cooperate with Takeda in all reasonable respects to secure the consent of the applicable Third Party to such assignment and if any such consent cannot be obtained with respect to a Selected Third Party Agreement, Licensee will, and cause its Affiliates and its Sublicensees to, obtain for Takeda substantially all of the practical benefit and burden under such Selected Third Party Agreement, including by (i) entering into appropriate and reasonable alternative arrangements on terms mutually agreeable to Takeda and Licensee (or such Affiliate or Sublicensee, as applicable) and (ii) subject to the consent and control of Takeda, enforcing, at Takeda's expense and for the account of Takeda, any and all rights of Licensee (or such Affiliate or Sublicensee, as applicable) against the other party thereto arising out of the breach or cancellation thereof by such other party or otherwise. Notwithstanding the foregoing, if such termination relates to a particular Terminated Field for the TAK-385 Licensed Compound, then the foregoing obligations shall apply with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field.

(i) *Supply of Licensed Product*. At Takeda's written request, Licensee will make available for Takeda to purchase any quantities of the Terminated Compound and Terminated Products or the TAK-385 Licensed Compound and TAK-385 Licensed Products in the event of termination with respect to a Terminated Field (in bulk drug substance, bulk drug product, or finished drug product form, as requested by Takeda) then in Licensee's possession or control as Takeda indicates in written orders therefor from time to time at a price equal to Licensee's [***] (where Licensee Manufactured such quantities), or at the same cost as Licensee paid to Takeda for such quantities (where Takeda Manufactured such quantities) in its most recent invoice. If requested, Licensee will Manufacture or have Manufactured such Terminated Compound and Terminated Products (or the TAK-385 Licensed Compound and TAK-385 Licensed Products) for supply to Takeda until the later of (i) such time as Takeda has established an alternate, validated source of supply for the Terminated Compound and Terminated Products (or the TAK-385 Licensed Compound and TAK-385 Licensed Products) and Takeda is receiving supply from such alternative source and (ii) the [***] month anniversary of the effective date of termination of this Agreement with respect to the applicable Terminated Compound or

Terminated Products (or the TAK-385 Licensed Compound and TAK-385 Licensed Products).

(j) *Further Assistance*. Licensee will provide any other assistance or take any other actions, in each case, reasonably requested by Takeda as necessary to transfer to Takeda the Exploitation of the Terminated Compound and Terminated Products, and will execute all documents as may be reasonably requested by Takeda in order to give effect to this Section 13.9.2 (Certain Termination Events). Notwithstanding the foregoing, if such termination relates to a particular Terminated Field for the TAK-385 Licensed Compound, then the foregoing obligations shall apply with respect to the TAK-385 Licensed Compound and TAK-385 Licensed Products in the Terminated Field.

13.9.3 Responsibility for Costs and Expenses of Certain Effects of Termination. Except as provided in Section 13.9.2(b)(i) (Clinical Trial Completion), in the event of termination by Licensee pursuant to Section 13.4 (Termination for Safety Reasons) or by either Party pursuant to Section 13.8 (Termination for Insolvency), Takeda will bear the costs and expenses associated with the conduct of all activities set forth under Section 13.9.2 (Certain Termination Effects). In the event of termination by Licensee pursuant to Section 13.2 (Termination at Will), Section 13.5 (Termination for Commercial Viability) or by Takeda pursuant to Section 13.3 (Termination for Material Breach), or by Takeda pursuant to Section 13.5 (Termination for Cessation of Activities), or by Takeda pursuant to Section 13.7 (Termination for Patent Challenge) Licensee will bear the costs and expenses associated with the conduct of all activities set forth under Section 13.9.2 (Certain Termination Effects), except as set forth in Section 13.9.2(i) (Supply of Licensed Product).

13.10. **Effects of Expiration**.

13.10.1 Licenses to Licensee. Following the expiration of the Royalty Term for Licensee Royalties in a country in the Licensee Territory (but not termination of this Agreement), subject to the terms and conditions of this Agreement, the licenses granted to Licensee in Section 3.1.1 (Exclusive License Grant) and Section 3.1.2 (Non-Exclusive License Grant) will become perpetual, irrevocable, fully paid-up, and royalty-free.

13.10.2 Licenses to Takeda. Following the expiration of the Royalty Term for Takeda Royalties in a country in the Takeda Territory (but not termination of this Agreement), subject to the terms and conditions of this Agreement, the licenses granted to Takeda in Section 3.2.1 (Exclusive License Grant) and Section 3.2.2 (Non-Exclusive License Grant) will become perpetual, irrevocable, fully paid-up, and royalty-free.

13.10.3 Expiration of Term in Entirety. Upon expiration of the Term in its entirety, all provisions of this Agreement shall expire and cease to have effect, other than those provisions that survive termination or expiration of this Agreement pursuant to Section 13.13 (Survival) or as otherwise provided in this Agreement.

13.11. **Accrued Rights**. Expiration or termination of this Agreement will not relieve the Parties of any obligation or liability that accrued hereunder prior to the effective date of such expiration or termination, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, and any such termination will be without prejudice to the rights of either Party against the other. The remedies provided in this Article 13 (Term and Termination) are not exclusive of any other remedies a Party may have in law or equity. Without limiting the generality of the foregoing, upon expiration or termination of this Agreement each Party will pay to the other Party all Royalties and other amounts due to such other Party as of the effective date of termination or expiration within [***] days following such effective date of termination or expiration. All payments made pursuant to this Section 13.10 (Accrued Rights) will be non-creditable and non-refundable.

13.12. **No Waiver**. The right of a Party to terminate this Agreement, as provided in this Article 13 (Term and Termination), will not be affected in any way by its waiver or failure to take action with respect to any prior default.

13.13. **Survival**. The following provisions will survive any expiration or termination of this Agreement for the period of time specified therein (or, if no such period is specified, indefinitely): Article 12 (Confidentiality), Article 14 (Dispute Resolution) Article 15 (Indemnification; Insurance), Article 16 (Miscellaneous) and Section 5.7 (Records; Disclosure of Data and Results), Section 9.3 (Royalty Reports; Royalty Payments), Section 9.4 (Exchange Rate), Section 9.5 (Taxes), Section 9.6 (Audits), Section 9.7 (Manner of Payment; Late Payment), Section 10.1 (Ownership of Inventions), 10.3 (Exploitation of Joint Technology), Section 10.4.5(c)(iii) (solely as it relates to Joint Patents), 11.6 ([*******]), Section 11.7 (No Other Representations or Warranties), Section 13.9 (Effects of Termination), Section 13.10 (Effects of Expiration), Section 13.11 (Accrued Rights), Section 13.13 (Survival), and Section 13.14 (Rights in Bankruptcy).

13.14. **Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement are, and will otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar laws in any other jurisdiction outside of the Licensee Territory (collectively, the "Bankruptcy Laws"), licenses of rights to "intellectual property" as defined under the Bankruptcy Laws. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws then, unless and until this Agreement is rejected as provided pursuant to such Bankruptcy Laws, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee) will perform all of the obligations in this Agreement intended to be performed by such Party. If a case is commenced during the Term by or against a Party under the Bankruptcy Laws and this Agreement is rejected as provided for under the Bankruptcy Laws, and the non-bankrupt Party elects to retain its rights hereunder as provided for under the Bankruptcy Laws, then the Party subject to such case under the Bankruptcy Laws (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), will provide to the non-bankrupt Party copies of all Patent Rights and Information necessary for the non-bankrupt Party to Prosecute, maintain and enjoy its rights under the terms of this Agreement. All rights, powers, and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Laws) in the event of the commencement of a case by or against a Party under the Bankruptcy Laws. In particular, it is the intention and understanding of the Parties to this Agreement that the rights granted to the Parties under this Section 13.8 (Termination for Insolvency) are essential to the Parties' respective businesses and the Parties acknowledge that damages are not an adequate remedy.

ARTICLE 14
DISPUTE RESOLUTION

14.1. **Exclusive Dispute Resolution Mechanism**. The Parties agree that the procedures set forth in this Article 14 (Dispute Resolution) will be the exclusive mechanism for resolving disputes, actions, claims, controversies, suits, or proceedings arising in whole or in part out of, related to, based upon or in connection with this Agreement or the subject matter hereof between the Parties (each, a "Dispute", and collectively, the "Disputes").

14.2. **Resolution by Executive Officers**. Except as otherwise provided in this Section 14.2 (Resolution by Executive Officers) or in Section 13.5 (Termination for Commercial Viability), in the event of any Dispute that is not resolved (a) pursuant to a Party's final decision making authority as set forth in Section 2.2.2 (JRC Decisions), or (b) through good faith negotiation between the Parties pursuant to Section 2.2.2 (JRC Decisions), the Parties will first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves on an informal basis for a period of [***] Business Days after receipt of written notice of such Dispute by a Party. If such Dispute is not resolved within such [***] Business Day period, either Party may, by written notice to the other Party, refer the Dispute to the senior executive officer (or his or her delegate) (each, an "Executive Officer") of the other Party for attempted resolution by

good faith negotiation within [***] days after such notice is received. Each Party may, in its sole discretion, seek resolution of any and all Disputes that are not resolved under this Section 14.2 (Resolution by Executive Officers) in accordance with Section 14.3 (Litigation).

14.3. **Litigation**. Any unresolved Dispute which was subject to Section 14.2 (Resolution by Executive Officers) must be brought exclusively in a court of competent jurisdiction, federal or state, located in New York, New York, and in no other jurisdiction. Each Party hereby consents to personal jurisdiction and venue in, and agrees to service of process issued or authorized by, such court.

14.4. **Jurisdiction**. Each Party to this Agreement, by its execution hereof, (a) hereby irrevocably submits to the exclusive jurisdiction of the United States District Court and state courts located in New York, New York for the purpose of any and all unresolved Disputes which were subject to Section 14.2 (Resolution by Execution Officers), (b) hereby waives to the extent not prohibited by Applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such action brought in one of the above-named courts in such jurisdiction should be dismissed on grounds of *forum non conveniens*, should be transferred to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (c) hereby agrees not to commence any such action other than before one of the above-named courts nor to make any motion or take any other action seeking or intending to cause the transfer or removal of any such action to any court other than one of the above-named courts whether on the grounds of inconvenient forum or otherwise. Notwithstanding the foregoing, application may be made to any court of competent jurisdiction with respect to the enforcement of any judgment or award.

14.5. **Injunctive Relief**. Notwithstanding the foregoing, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 14.2 (Resolution by Executive Officers).

14.6. **Waiver of Right to Jury Trial**. IN CONNECTION WITH THE PARTIES' RIGHTS UNDER SECTION 14.3 (LITIGATION), EACH PARTY, TO THE EXTENT PERMITTED BY APPLICABLE LAWS, KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION OR OTHER LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT AND THE TRANSACTIONS IT CONTEMPLATES. THIS WAIVER APPLIES TO ANY ACTION OR LEGAL PROCEEDING, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE

14.7. **Confidentiality**. Any and all activities conducted under this Article 14 (Dispute Resolution), including any and all proceedings and decisions under Section 14.3 (Litigation), shall be deemed Confidential Information of each of the Parties, and shall be subject to the terms of Article 12 (Confidentiality).

ARTICLE 15
INDEMNIFICATION; INSURANCE

15.1. **Indemnification by Licensee**. Licensee hereby agrees to defend, indemnify, and hold harmless Takeda and its Affiliates, and each of their respective directors, officers, employees, agents and representatives (each, a "Takeda Indemnitee") from and against any and all claims, suits, actions, demands or other proceedings brought by any Third Party (each, a "Claim") and all liabilities, expenses, damages, or losses, including reasonable legal expense and attorneys' fees (collectively, "Losses"), to which any Takeda Indemnitee may become subject as a result of any such Claim to the extent such Claim arise or result from: (a) the practice by Licensee or its Affiliate of any license granted to it under Article 3 (License Grants); (b) the Exploitation

of the Licensed Compounds or Licensed Products in the Field in the Licensee Territory, or the Development of the Licensed Compounds or Licensed Products in the Men's Health Field in the Takeda Territory, in each case, by or on behalf of Licensee, its Affiliate, or its Sublicensee; (c) the breach by Licensee of any warranty, representation, covenant, or agreement made by Licensee in this Agreement; (d) the negligence, gross negligence or willful misconduct of Licensee, its Affiliate, or its Sublicensee, or any officer, director, employee, agent, or representative thereof; and (e) the failure to comply with Applicable Law by or on behalf of Licensee in connection with the Licensed Compound, Licensed Products, or this Agreement; except, with respect to each of subsections (a) through (e) above, to the extent such Losses arise directly or indirectly from the negligence, gross negligence, or willful misconduct of any Takeda Indemnitee or the breach by Takeda of any warranty, representation, covenant, or agreement made by Takeda in this Agreement.

15.2. **Indemnification by Takeda**. Takeda hereby agrees to defend, indemnify, and hold harmless Licensee and its Affiliates and each of their respective directors, officers, employees, agents and representatives (each, an "Licensee Indemnitee") from and against any and all Losses to which any Licensee Indemnitee may incur, suffer, or be required to pay as a result of, or arising in connection with, any Claim to the extent such Claims arise or result from: (a) the Exploitation of the Licensed Compounds or Licensed Products by Takeda or its Affiliate or its licensee prior to the Effective Date; (b) the Exploitation of the Licensed Compounds or Licensed Products in the Women's Health Field in the Takeda Territory, or the Commercialization of the Licensed Compounds or Licensed Products in the Men's Health Field in the Takeda Territory, in each case, by or on behalf of Takeda, its Affiliate, or its licensee (other than Licensee or its Affiliate); (c) the breach by Takeda of any warranty, representation, covenant, or agreement made by Takeda in this Agreement; (d) the negligence, gross negligence, or willful misconduct of Takeda or its Affiliate or its licensee (other than Licensee or its Affiliate), or any officer, director, employee, agent or representative thereof; and (e) the failure to comply with Applicable Law by or on behalf of Takeda in connection with the Licensed Compound, Licensed Products, or this Agreement; except, with respect to each of subsections (a) through (e) above, to the extent such Losses result from the negligence, gross negligence, or willful misconduct of any Licensee Indemnitee, or the breach by Licensee of any warranty, representation, covenant, or agreement made by Licensee in this Agreement.

15.3. **Indemnification Procedures**.

15.3.1 Notice. Promptly after a Takeda Indemnitee or a Licensee Indemnitee (each, an "Indemnitee") receives notice of a pending or threatened Claim, such Indemnitee will give written notice of the Claim to the Party from whom the Indemnitee is entitled to receive indemnification pursuant to Section 15.1 (Indemnification by Licensee) or Section 15.2 (Indemnification by Takeda), as applicable (the "Indemnifying Party"). However, an Indemnitee's delay in providing or failure to provide such notice will not relieve the Indemnifying Party of its indemnification obligations, except to the extent it can demonstrate prejudice due to the delay or lack of notice.

15.3.2 Defense. Upon receipt of notice under Section 15.3.1 (Notice) from the Indemnitee, the Indemnifying Party will have the duty to either compromise or defend, at its own expense and by counsel (reasonably satisfactory to Indemnitee), such Claim. The Indemnifying Party will promptly (and in any event not more than [***] days after receipt of the Indemnitee's original notice) notify the Indemnitee in writing that it acknowledges its obligation to indemnify the Indemnitee with respect to the Claim pursuant to this Article 15 (Indemnification; Insurance) and of its intention either to compromise or defend such Claim. Once the Indemnifying Party gives such notice to the Indemnitee, (a) the Indemnifying Party will have the right to control the defense and settlement of such Claim, subject to this Section 15.3 (Indemnification Procedures) and (b) the Indemnifying Party is not liable to the Indemnitee for the fees of other counsel or any other expenses subsequently incurred by the Indemnitee in connection with such defense, other than the Indemnitee's reasonable expenses of investigation and cooperation. However, the Indemnitee will have the right to employ separate counsel and to control the defense of a Claim at its own expense.

15.3.3 Cooperation. The Indemnitee will cooperate fully with the Indemnifying Party and its legal representatives in the investigation and defense of any Claim. The Indemnifying Party will keep the Indemnitee informed on a reasonable and timely basis as to the status of such Claim (to the extent the Indemnitee is not participating in the defense of such Claim) and conduct the defense of such Claim in a prudent manner.

15.3.4 Settlement. If an Indemnifying Party assumes the defense of a Claim, no compromise or settlement of such Claim may be effected by the Indemnifying Party without the Indemnitee's written consent (which consent will not be unreasonably withheld, conditioned, or delayed), unless: (a) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the Indemnitee; (b) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party; and (c) the Indemnitee's rights under this Agreement are not adversely affected. If the Indemnifying Party fails to assume defense of a Claim within a reasonable time, the Indemnitee may settle such Claim on such terms as it deems appropriate with the consent of the Indemnifying Party (which consent will not be unreasonably withheld, conditioned, or delayed), and the Indemnifying Party will be obligated to indemnify the Indemnitee for such settlement as provided in this Article 15 (Indemnification; Insurance).

15.4. **Insurance**. Each Party, at its own expense, shall maintain liability insurance in an amount consistent with industry standards during the Term, but in no event shall such insurance be in an amount less than [***] per occurrence/annual aggregate during the Term. In addition, during the term of Commercialization of any Licensed Product and for a period of at least [***] years thereafter, each Party shall maintain product liability insurance in an amount not less than [***] per occurrence and annual aggregate. A Party responsible for the conduct any Clinical Trials hereunder shall maintain clinical trial insurance in compliance with all Applicable Law pertaining to the jurisdictions in which such Clinical Trials are conducted. Each Party shall provide a certificate of insurance evidencing such coverage to the other Party upon its written request. Each Party shall notify the other [***] days in advance of cancelation of any such insurance. Takeda shall be permitted to satisfy its obligations hereunder through a program of self-insurance.

ARTICLE 16
MISCELLANEOUS

16.1. **Notice**. Any notice, request, or other communication permitted or required under this Agreement will be in writing, will refer specifically to this Agreement and will be hand delivered or sent by a recognized overnight delivery service, expenses prepaid, or by facsimile (with transmission confirmed), to the following addresses or to such other addresses as a Party may designate by written notice in accordance with this Section 16.1 (Notice):

If to Takeda:

Takeda Pharmaceuticals International AG
Thurgauerstrasse 130, 8152
Glattpark-Opfikon Zurich, Switzerland
Attention: Legal Department
Facsimile: +41-44-555-10-01

Copy to:

Takeda Pharmaceuticals U.S.A., Inc.
One Takeda Parkway
Deerfield, IL 60015

Attention: General Counsel, Legal Department
Facsimile: 224-554-7831

Copy to (which will not constitute notice):

Ropes & Gray LLP
800 Boylston Street; Prudential Tower
Boston, MA 02199
Attention: David M. McIntosh
Facsimile: 617-235-0507

If to Licensee:

Roivant Endocrinology Ltd.
Clarendon House
2 Church Street
Hamilton HM 11
Bermuda
Attention: Corporate Secretary

Copy to:

Roivant Endocrinology, Inc.
320 West 37th Street
5th Floor
New York, NY 10018
Attention: SVP, Finance & Operations

16.2. **Designation of Affiliates**. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

16.3. **Assignment**. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other except that: (a) each Party may assign its rights and obligations under this Agreement in whole or in part to one or more of its Affiliates without the consent of the other Party; and (b) each Party may assign this Agreement in connection with the sale or other transfer of all or substantially all of the assets of the business to which this Agreement relates (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction), but, with respect to assignment by Licensee, only if such potential assignee is not then developing or commercializing a Competing Product or [***] in a manner that would constitute a breach of Section 5.5.1 (Exclusivity Covenants). Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.3 (Assignment) will be null, void and of no legal effect.

16.4. **Limitation of Liability**. EXCEPT WITH RESPECT TO (a) A BREACH OF THE OBLIGATIONS OF A PARTY UNDER SECTION 5.5 (EXCLUSIVITY), OR Article 12 (CONFIDENTIALITY), OR, (b) A CLAIM FOR FRAUD, OR WILLFUL MISCONDUCT OR (c) A CLAIM BY EITHER PARTY THAT THE OTHER PARTY IS INFRINGING ANY INTELLECTUAL PROPERTY RIGHTS OF THE CLAIMING PARTY THAT ARE LICENSED TO SUCH OTHER PARTY UNDER THIS AGREEMENT

AS A RESULT OF SUCH OTHER PARTY'S OR ANY OF ITS AFFILIATES EXPLOITING SUCH INTELLECTUAL PROPERTY RIGHTS OUTSIDE THE SCOPE OF THE LICENSE GRANTED IN THIS AGREEMENT, or (d) A CLAIM FOR INDEMNIFICATION PURSUANT TO Article 15 (INDEMNIFICATION; INSURANCE), NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY, OR OTHER LEGAL OR EQUITABLE THEORY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS ARISING OUT OF OR IN CONNECTION WITH ANY TRANSACTION AGREEMENT OR THEIR RESPECTIVE SUBJECT MATTER.

16.5. **Severability**. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

16.6. **Waiver and Non-Exclusion of Remedies**. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

16.7. **Further Assurances**. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

16.8. **[***]**.

16.9. **Relationship of the Parties**. It is expressly agreed that Takeda, on the one hand, and Licensee, on the other hand, will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Takeda nor Licensee will have the authority to make any statements, representations or commitments of any kind, or to take any action which will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party will be employees of that Party and not of the other Party and all expenses and obligations incurred by reason of such employment will be for the account and expense of such Party.

16.10. **Construction; Rules of Construction**. Interpretation of this Agreement will be governed by the following rules of construction: (a) words in the singular will be held to include the plural and vice versa, and words of one gender will be held to include the other gender as the context requires; (b) references to the terms "Section", "Exhibit", or "Schedule" are to a Section, Exhibit, or Schedule of this Agreement unless otherwise specified; (c) the terms "hereof", "hereby", "hereto", and derivative or similar words refer to this entire Agreement; (d) references to "$" or "Dollars" will mean the currency of the United States and all references to "€" or "Euros" will mean the currency of the European Union; (e) the word "including" and words of similar import when used in this Agreement will mean "including without limitation," unless otherwise specified; (f) the word "or" will not be exclusive; (g) references to "written" or "in writing" include in electronic form; (h) the titles and headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement; (i) each of the Parties has participated in the negotiation and drafting of this Agreement and if an ambiguity or question of

interpretation should arise, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or burdening either Party by virtue of the authorship of any of the provisions in this Agreement or any interim drafts of this Agreement; (j) the word "shall" will be construed to have the same meaning and effect as the word "will"; (k) references to "days" will mean calendar days, unless otherwise specified; and (l) a reference to any Person includes such Person's successors and permitted assigns.

16.11. **Governing Law**. This Agreement was prepared in the English language, which language will govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof will be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

16.12. **Entire Agreement**. This Agreement, including the Exhibits and Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between the body of this Agreement and the Exhibits or Schedules to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibitor subsequent ancillary agreement, the terms contained in this Agreement will control.

16.13. **Counterparts**. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures will be deemed to bind each Party hereto as if they were the original signatures.

[Signature Page Follows]

IN WITNESS WHEREOF, each of Takeda Pharmaceuticals International AG, Roivant Endocrinology Ltd., and Roivant Sciences Ltd. have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

TAKEDA PHARMACEUTICAL INTERNATIONAL AG

By: /s/ Marcello Agosti

Name: Marcello Agosti

Title: Head of Global Business Development

Date: April 26, 2016

ROIVANT ENDOCRINOLOGY LTD.

By: _____

Name: _____

Title: _____

Date: _____

ROIVANT SCIENCES LTD. (Solely for purposes of Section 5.5 (Exclusivity), Section 5.6 (Competing Product Acquisitions), Section 11.5.3 ([***]), and Section 16.8 ([***]).)

By: _____

Name: _____

Title: _____

Date: _____

IN WITNESS WHEREOF, each of Takeda Pharmaceuticals International AG, Roivant Endocrinology Ltd., and Roivant Sciences Ltd. have caused this Agreement to be executed by their respective duly authorized officers as of the Effective Date, each copy of which will for all purposes be deemed to be an original.

TAKEDA PHARMACEUTICAL INTERNATIONAL AG

By: _____

Name: _____

Title: _____

Date: _____

ROIVANT ENDOCRINOLOGY LTD.

By: /s/ Marianne L. Romeo

Name: Marianne L. Romeo

Title: Head, Global Transactions & Risk Management

Date: April 29, 2016

ROIVANT SCIENCES LTD. (Solely for purposes of Section 5.5 (Exclusivity), Section 5.6 (Competing Product Acquisitions), Section 11.5.3 ([***]), and Section 16.8 ([***]).)

By: /s/ Marianne L. Romeo

Name: Marianne L. Romeo

Title: Head, Global Transactions & Risk Management

Date: April 29, 2016

Schedule 1.151

Takeda Patent Rights

Part (a) - TAK-385 Patent Rights

[***]

Schedule 1.78(a)

TAK-385 Licensed Product INDs

IND Nos. [***]

Schedule 1.78(b)

TAK-448 Licensed Product INDs

IND [***]

Schedule 1.138

TAK-385 Licensed Compound

[***]

Schedule 1.141

TAK-448 Licensed Compound

[***]

Schedule 5.3

TAK-385 Development Plan

[***]

Schedule 9.1(a)

Subscription Agreement

EXECUTION VERSION

Dated this April 29, 2016

B E T W E E N :

ROIVANT ENDOCRINOLOGY LTD.

and

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

SUBSCRIPTION AGREEMENT

Conyers Dill & Pearman Limited
Hamilton, Bermuda

THIS SUBSCRIPTION AGREEMENT (the "**Agreement**") is made the 29th day of April 2016.

BETWEEN:

Roivant Endocrinology Ltd. an exempted limited company incorporated in Bermuda with its registered office at Clarendon House, 2 Church Street, Hamilton HM1 1, Bermuda (the "**Company**"); and

Takeda Pharmaceuticals International AG, a company incorporated in Switzerland with a registered office at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland (the "**Subscriber**").

WHEREAS:

(A) The Company wishes to sell 9,000,000 shares of the Company to the Subscriber; and

(B) The Subscriber wishes to acquire those shares of the Company.

(C) The Company and the Subscriber are parties to that certain License Agreement dated as of the date hereof (the "**License Agreement**").

THE PARTIES AGREE as follows:

1. INTERPRETATION

1.1. In this Agreement, unless the context otherwise requires, the following words and expressions shall have the following meanings:

"**Affiliate**"	means, with respect to any specified person, any other person who directly or indirectly controls, is controlled by, or is under common control with such person, including without limitation any parent or direct or indirect subsidiary
"**Effective Date**"	means the Effective Date (as defined in the License Agreement).
"**Liabilities**"	means any damages, debts, obligations and other liabilities, losses, claims, Taxes, interest obligations, deficiencies, judgments, assessments, fines, fees, penalties, expenses (including amounts paid in settlement, interest, court costs, costs of investigators, reasonable fees and expenses of attorneys, accountants, financial advisors, consultants and other experts, and other expenses of litigation), whether direct or indirect, fixed or unfixed, contingent or absolute, matured or unmatured, liquidated or unliquidated, accrued or not accrued, asserted or unasserted, known or unknown, disputed or undisputed, joint or several, secured or unsecured, determined, determinable or otherwise, whenever or however arising.

"**Material Adverse Effect**"	means a material adverse effect on the business, assets (including intangible assets), liabilities, financial condition, property, prospects or results of operations of the Company.
"**Share**"	means a common share in the capital of the Company of US$0.00001 par value having the rights provided for under the memorandum of association and bye-laws of the Company;
"**Shareholders Agreements**"	means that certain Investor Rights Agreement in the form attached hereto as Exhibit A (the "**Investor Rights Agreement**") and that certain Right of First Refusal and Co-Sale Agreement in the form attached hereto as Exhibit B (the "**Right of First Refusal and Co-Sale Agreement**"), in each case, of even date herewith and by and among the Company, the Subscriber and the other parties thereto.
"**Taxes**"	(i) any and all taxes and governmental impositions of any kind in the nature of (or similar to) taxes payable to any federal, state, local or foreign tax authority or other governmental authority, including, but not limited to, those on or measured by or referred to as income, franchise, profits, gross receipts, capital, ad valorem, customs duties, alternative or add-on minimum taxes, estimated, environmental, disability, registration, value added, sales, use, service, real property, personal property, capital stock, license, payroll, withholding, employment, social security (or similar including FICA), workers' compensation, unemployment compensation, escheat or unclaimed property obligation, gift, estate, utility, severance, production, excise, stamp, occupation, premiums, windfall profits, transfer and gains taxes, and interest, penalties and additions to tax imposed with respect thereto, whether disputed or not and (ii) any liability for the payment of any amounts of the type described in clause (i) of this definition as a result of being a member of an affiliated, consolidated, combined or unitary group for any period, as a result of any tax sharing or tax allocation agreement, arrangement or understanding, or as a result of being liable for another person's taxes as a transferee or successor, by contract or otherwise.

2. In this Agreement:

2.1. the clause headings are included for convenience only and shall not affect the interpretation of this Agreement;

2.2. words denoting the singular number include the plural and vice versa;

2.3. words denoting one gender include the other genders.

3. SUBSCRIPTION FOR SHARES BY SUBSCRIBER

3.1. The Subscriber hereby subscribes for and requests that the Company allot to it 9,000,000 Shares for entering into the License Agreement.

3.2. Upon the Effective Date, the Company shall issue to the Subscriber the 9,000,000 Shares subscribed for by the Subscriber.

3.3. Each Share subscribed for pursuant to the foregoing clause shall be credited as fully paid and on issue shall rank *pari passu* in all respects with other shares in issue.

3.4. The Subscriber agrees to take the Shares subject to the memorandum of association and the bye-laws of the Company and the Shareholders Agreements, and authorises the Company to enter its name and address as set forth in Schedule 1 in the register of members of the Company.

4. REPRESENTATIONS AND WARRANTIES

4.1. The Company makes the following representations and warranties as of the Effective Date:

(a) The Company is an exempted limited company duly organized, validly existing and is in good standing under the laws of Bermuda (meaning solely that it has not failed to make any filing with any Bermuda governmental authority, or to pay any Bermuda government fee or tax, which would make it liable to be struck off the Register of Companies and thereby cease to exist under the laws of Bermuda) and has all requisite corporate power and authority to carry on its business as presently conducted and as proposed to be conducted. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a Material Adverse Effect.

(b) (i) It has an authorized share capital of US$10,000 consisting of 1,000,000,000 Shares having a par value of US$0.00001 of which 66,000,000 are issued and outstanding and (ii) that immediately following the issuance to the Subscriber of 9,000,000 Shares in accordance with Section 3.2, Subscriber will beneficially own 12.0% of the Company. All of the outstanding Shares have been duly authorized, are fully paid and nonassessable (which term when used herein means that no further sums are required to be paid by the holders thereof in connection with the issue thereof) and were issued in compliance with all applicable federal and state securities laws. No Shares have been reserved for issuance for any purpose, including, but not limited to, issuance to officers, directors, employees and consultants of the Company pursuant to any equity incentive plan. Other than the Warrant (as defined in the License Agreement), there are no outstanding options, warrants, rights (including conversion or preemptive rights and rights of first refusal or similar rights), or agreements, orally or in writing, to purchase or acquire from the Company any Shares, or any securities convertible into or exchangeable for any Shares.

(c) The Shares, when issued, sold and delivered in accordance with the terms and for the consideration set forth in this Agreement, will be validly issued, fully paid and nonassessable and free of restrictions on transfer other than restrictions on transfer under the Shareholder Agreements, applicable state and federal securities laws and liens or encumbrances created by or imposed by the Subscriber. Assuming the accuracy of the representations of the Subscriber in Section 4.3 of this Agreement, the Shares will be issued in compliance with all applicable federal and state securities laws.

(d) No "bad actor" disqualifying event described in Rule 506(d)(1)(i)-(viii) of the Securities Act (a "**Disqualification Event**") is applicable to the Company or, to the Company's knowledge, any Company Covered Person, except for a Disqualification Event as to which Rule 506(d)(2)(ii- iv) or (d)(3), is applicable. For the purposes of this Agreement, "**Company Covered Person**" means, with respect to the Company as an "issuer" for purposes of Rule 506 promulgated under the Securities Act, any person listed in the first paragraph of Rule 506(d)(1).

(e) The Company does not currently own or control, directly or indirectly, any interest in any other corporation, partnership, trust, joint venture, limited liability company, association, or other business entity. The Company is not a participant in any joint venture, partnership or similar arrangement.

(f) The memorandum of association and the bye-laws of the Company are in the form provided to the Subscriber. The copy of the minute books of the Company provided to the Subscriber contains minutes of all meetings of directors and shareholders and all actions by written consent without a meeting by the directors and shareholders since the date of incorporation of the Company and accurately reflects in all material respects all actions by the directors (and any committee of directors) and shareholders with respect to all transactions referred to in such minutes.

(g) Assuming the accuracy of the representations made by the Subscriber in Section 4.3 of this Agreement, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority is required on the part of the Company in connection with the consummation of the transactions contemplated by this Agreement, except for filings pursuant to Regulation D of the Securities Act, and applicable state securities laws, which have been made or will be made in a timely manner.

(h) The Company was formed solely to further purposes contemplated in the License Agreement and this Agreement. Except as contemplated by the License Agreement and this Agreement, the Company does not hold, nor has it held, any material assets and has not incurred, directly or indirectly, through any Affiliate, any obligations or Liabilities or engaged in any business activities of any type or kind whatsoever or entered into any agreements or arrangements with any person.

4.2. Each party to this Agreement makes the following representations and warranties as of the Effective Date:

(a) All corporate authorisations and all other applicable governmental, statutory, regulatory or other consents, licences, authorisations, waivers or exemptions required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained and are valid and subsisting.

(b) This Agreement constitutes legal, valid and binding obligations of the party.

(c) The execution, delivery and performance by the party of this Agreement does not and will not violate, breach or result in a contravention of:

(i) any law;

(ii) any authorisation, ruling, consent, judgment, order or decree of any governmental, statutory or regulatory agency; or

(iii) the memorandum of association and articles of association or bye-laws or any other similar constitutional document of the party.

(d) All information provided by the party to the other parties under or in connection with this Agreement and/or the Shareholders Agreements is true in all material respect and is not, by omission or otherwise, misleading in any material respect.

4.3. The Subscriber makes the following representations and warranties as of the Effective Date:

(a) The Shares to be acquired by the Subscriber will be acquired for investment for the Subscriber’s and its Affiliates’ own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Subscriber has no present intention of selling, granting any participation in, or otherwise distributing the same; and the Subscriber does not presently have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person, with respect to any of the Shares.

(b) It understands that (i) the Shares have not been, and will not be, registered under the Securities Act of 1933, as amended (the "**Securities Act**"), by reason of a specific exemption from the registration provisions of the Securities Act which depends upon, among other things, the bona fide nature of the investment intent and the accuracy of the Subscriber's representations as expressed herein; (ii) the Shares are "restricted securities" under applicable U.S. federal and state securities laws and that, pursuant to these laws, the Subscriber must hold the Shares indefinitely unless they are registered with the Securities and Exchange Commission and qualified by state authorities, or an exemption from such registration and qualification requirements is available; (iii) the Company has no obligation to register or qualify the Shares for resale except as set forth in the Shareholders Agreements; and (iv) if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Shares, and on requirements relating to the Company which are outside of the Subscriber's control, and which the Company is under no obligation and may not be able to satisfy.

(c) It understands that no public market now exists for the Shares, and that the Company has made no assurances that a public market will ever exist for the Shares.

(d) It understands that the Shares and any securities issued in respect of or exchange for the Shares, may bear the following legend:

"THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF, AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"). SUCH SHARES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR AN EXEMPTION THEREFROM UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

THE SALE, PLEDGE, HYPOTHECATION OR TRANSFER OF THE SHARES REPRESENTED BY THIS CERTIFICATE IS SUBJECT TO, AND IN CERTAIN CASES PROHIBITED BY, THE ISSUER'S BYLAWS, A CERTAIN INVESTOR RIGHTS AGREEMENT BETWEEN THE ISSUER AND THE HOLDER, AND A CERTAIN RIGHT OF FIRST REFUSAL AND CO-SALE AGREEMENT AMONG THE HOLDER, THE ISSUER AND CERTAIN OTHER HOLDERS OF EQUITY OF THE ISSUER. COPIES OF SUCH AGREEMENTS MAY BE OBTAINED UPON WRITTEN REQUEST TO THE SECRETARY OF THE ISSUER.";

(e) It is an accredited investor as defined in Rule 501(a) of Regulation D promulgated under the Securities Act.

(f) It has satisfied itself as to the full observance of the laws of its jurisdiction in connection with any invitation to subscribe for the Shares or any use of this Agreement, including any foreign exchange restrictions applicable to such purchase and the income tax and other tax consequences, if any, that may be relevant to the purchase, holding, redemption, sale, or transfer of the Shares.

(g) Neither the Subscriber, nor any of its officers, directors, employees, agents, stockholders or partners has either directly or indirectly, including through a broker or finder (i) engaged in any general solicitation, or (ii) published any advertisement in connection with the offer and sale of the Shares.

5. CLOSING DELIVERABLES

5.1. Upon the Effective Date, or as soon as practicable thereafter, the Company shall deliver the following to the Subscriber:

(a) a certificate from the sole Director of the Company certifying that (a) the representations and warranties of the Company set forth in Sections 4.1 and 4.2 are true and correct in all respects as of the Effective Date and (b) the Company has performed and complied with all covenants, agreements, obligations and conditions contained in this Agreement that were required to be performed or complied with by the Company on or before the Effective Date;

(b) an opinion, from Conyers Dill & Pearman Limited, counsel for the Company, dated as of the Effective Date, in substantially the form of Exhibit C attached to this Agreement;

(c) the Investor Rights Agreement executed by the Company each "Investor" named therein;

(d) the Right of First Refusal and Co-Sale Agreement executed by the Company, each "Investor" named therein and each "Key Holder" named therein;

(e) a certificate by the Secretary of the Company certifying (i) the bye-laws of the Company, (ii) the memorandum of association of the Company, (iii) and resolutions of the Board of Directors of the Company approving this Agreement and the Shareholder Agreements; and

(f) good standing certificates (or equivalent) from each jurisdiction in which the Company is either organized or qualified to do business.

5.2. All corporate and other proceedings in connection with the transactions contemplated under this Agreement upon the Effective Date and all documents incident thereto shall be reasonably satisfactory in form and substance to the Subscriber, and the Subscriber (or its counsel) shall have received all such counterpart original and certified or other copies of such documents as reasonably requested.

6. SURVIVAL OF REPRESENTATIONS AND WARRANTIES

Unless otherwise set forth in this Agreement, the representations and warranties of the Company and the Subscriber contained in or made pursuant to this Agreement shall survive the execution and delivery of this Agreement and the issuance of Shares hereunder and shall in no way be affected by any investigation or knowledge of the subject matter thereof made by or on behalf of the Subscriber or the Company.

7. SEVERABILITY

The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision.

8. SUCCESSORS AND ASSIGNS

The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

9. COSTS

Each party shall pay its own costs relating to the negotiation, preparation, execution and implementation by it of this Agreement and of each document referred to in it.

10. ENTIRE AGREEMENT

10.1. Save as set forth in the Shareholders Agreement, this Agreement constitutes the entire agreement and understanding of the parties and supersedes any previous agreement between the parties relating to the subject matter of this Agreement.

10.2. Each of the parties acknowledges and agrees that in entering into this Agreement it does not rely on, and shall have no remedy in respect of, any statement, representation, warranty or understanding (whether negligently or innocently made) of any person (where party to this Agreement or not) other than as expressly set out in this Agreement as a representation or warranty. The only remedy available to it for breach of the representations or warranties shall be for breach of contract under the terms of this Agreement. Nothing in this clause shall, however, operate to limit or exclude any liability for fraud.

11. COUNTERPARTS

This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed an original but all such counterparts shall constitute one and the same instrument. Delivery of a counterpart signature page by facsimile transmission or by e-mail transmission of an Adobe Portable Document Format file (or similar electronic record) shall be effective as delivery of an executed counterpart signature page.

12. VARIATION

No variation of or amendment to this Agreement shall be valid unless it is in writing and signed by or on behalf of each of the parties.

13. GOVERNING LAW AND JURISDICTION

The terms and conditions of this Agreement and the rights of the parties hereunder shall be governed by and construed in all respects in accordance with the laws of the State of Delaware, without giving effect to conflict of law principles thereof. The parties to this Agreement hereby irrevocably agree that the state and federal courts located in the State of Delaware shall have exclusive jurisdiction in respect of any dispute, suit, action, arbitration or proceedings (the "**Proceedings**") which may arise out of or in connection with this Agreement and waive any objection to Proceedings in the courts of Bermuda on the grounds of venue or on the basis that the Proceedings have been brought in an inconvenient forum.

AGREED by the Parties through their authorised signatories on the date first written above:

For, and on behalf of

ROIVANT ENDOCRINOLOGY LTD.

By: _____

Name: _____

Title: _____

AGREED by the Parties through their authorised signatories on the date first written above:

For, and on behalf of

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

By: _____

Name: _____

Title: _____

[Signature Page to REL Subscription Agreement]

SCHEDULE 1

Subscriber name and address:

Takeda Pharmaceuticals International AG

Thurgauerstrasse 130, 8152
Glattpark-Opfikon, Zurich, Switzerland
Facsimile: +41-44-555-10-01

EXHIBIT A

INVESTOR RIGHTS AGREEMENT

EXHIBIT B

RIGHT OF FIRST REFUSAL AND CO-SALE AGREEMENT

EXECUTION VERSION

RIGHT OF FIRST REFUSAL AND CO-SALE AGREEMENT

THIS RIGHT OF FIRST REFUSAL AND CO-SALE AGREEMENT (this "**Agreement**") is made as of April 29, 2016 by and among Roivant Endocrinology Ltd., an exempted limited company incorporated under the laws of Bermuda (the "**Company**"), the Investors set forth on Schedule A hereto and the Key Holders set forth on Schedule B hereto.

RECITALS

WHEREAS, each Key Holder is the beneficial owner of Common Shares, or options or warrants to purchase Common Shares;

WHEREAS, the Company and Takeda Pharmaceuticals International AG ("**Takeda**") are parties to that certain Subscription Agreement of even date herewith (the "**Subscription Agreement**"); and

WHEREAS, in order to induce the Company to enter into the Subscription Agreement and to induce Takeda to enter into that certain License Agreement of even date herewith between the Company and Takeda and to perform the transactions contemplated thereby, the parties hereto hereby agree that this Agreement shall govern the matters set forth herein.

The parties hereto hereby agree as follows:

1. Definitions.

1.1 "**Affiliate**" means, with respect to any specified Person, any other Person who directly or indirectly controls, is controlled by, or is under common control with such Person, including without limitation any parent or direct or indirect subsidiary.

1.2 "**Board**" means the Board of Directors of the Company.

1.3 "**Capital Stock**" means all shares of the Company whether now or hereafter authorized, including, without limitation, the Common Shares.

1.4 "**Change of Control**" means (i) any consolidation, amalgamation or merger of the Company with or into any other corporation or other Person, or any other corporate reorganization or similar transaction, in which the holders of outstanding voting securities of the Company immediately prior to such consolidation, merger, reorganization or similar transaction hold, directly or indirectly, less than fifty percent (50%) of the outstanding voting securities of the Company or of the surviving or resulting entity (or the power to direct or cause the direction of the management and policies of the surviving or resulting entity) immediately after such consolidation, merger, reorganization or similar transaction; or (ii) any transaction or series of related transactions as a result of which the holders of outstanding voting securities of the Company immediately prior to such transaction or transactions hold, directly or indirectly, less than fifty percent (50%) of the outstanding voting securities of the Company (or the power to direct or cause the direction of the management and policies of the Company) immediately after such transaction or transactions.

1.5 "**Common Shares**" means the common shares, US$0.00001 par value per share, of the Company as consolidated or subdivided from time to time.

1.6 "**Company Notice**" means written notice from the Company notifying the selling Key Holder that the Company intends to exercise its Right of First Refusal as to some or all of the Transfer Securities with respect to any Proposed Key Holder Transfer.

1.7 "**Investor Notice**" means written notice from an Investor notifying the Company and the selling Key Holder that it intends to exercise its Secondary Refusal Right as to a portion of the Transfer Securities with respect to any Proposed Key Holder Transfer.

1.8 "**Investors**" means the Persons named on Schedule A hereto and each Person to whom the rights of such parties are assigned pursuant to Subsection 6.8, each Person who hereafter becomes a signatory to this Agreement pursuant to Subsection 6.15 and any one of them, as the context may require.

1.9 "**IPO**" means the Company's first firm commitment underwritten public offering of its Common Shares under the Securities Act.

1.10 "**Key Holders**" means the Persons named on Schedule B hereto, each Person to whom the rights of a Key Holder are assigned pursuant to Subsection 3.1, each Person who hereafter becomes a signatory to this Agreement pursuant to Subsection 6.8 or 6.16 and any one of them, as the context may require.

1.11 "**Person**" means any individual, corporation, partnership, trust, limited liability company, association or other entity.

1.12 "**Proposed Key Holder Transfer**" means any assignment, sale, offer to sell, pledge, mortgage, hypothecation, encumbrance, disposition of or any other like transfer or encumbering of any Transfer Securities (or any interest therein) proposed by any of the Key Holders.

1.13 "**Proposed Transfer Notice**" means written notice from a Key Holder setting forth the terms and conditions of a Proposed Key Holder Transfer.

1.14 "**Prospective Transferee**" means any Person to whom a Key Holder proposes to make a Proposed Key Holder Transfer.

1.15 "**Right of Co-Sale**" means the right, but not an obligation, of an Investor to participate in a Proposed Key Holder Transfer on the terms and conditions specified in the Proposed Transfer Notice.

1.16 "**Right of First Refusal**" means the right, but not an obligation, of the Company, or its permitted transferees or assigns, to purchase some or all of the Transfer Securities with respect to a Proposed Key Holder Transfer, on the terms and conditions specified in the Proposed Transfer Notice.

1.17 "**Secondary Notice**" means written notice from the Company notifying the Investors and the selling Key Holder that the Company does not intend to exercise its Right of First Refusal as to all Transfer Securities with respect to any Proposed Key Holder Transfer.

1.18 "**Secondary Refusal Right**" means the right, but not an obligation, of each Investor to purchase up to its pro rata portion (based upon the total number of shares of Capital Stock held by all Investors on a fully-diluted basis) of any Transfer Securities not purchased pursuant to the Right of First Refusal, on the terms and conditions specified in the Proposed Transfer Notice.

1.19 "**Securities Act**" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

1.20 "**Transfer Securities**" means (i) all shares of Capital Stock owned by a Key Holder or issued to a Key Holder on or after the date hereof; (ii) any shares of Capital Stock issued or issuable (directly or indirectly) in exchange for and/or exercise of any other securities of the Company acquired by the Key Holders after the date hereof; and (iii) all shares of Capital Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares of Capital Stock referenced in clauses (i) and (ii) above.

1.21 "**Undersubscription Notice**" means written notice from an Investor notifying the Company and the selling Key Holder that such Investor intends to exercise its option to purchase all or any portion of the Transfer Securities not purchased pursuant to the Right of First Refusal or the Secondary Refusal Right.

2. Agreement Among the Company, the Investors and the Key Holders.

2.1 Right of First Refusal.

(a) Grant. Subject to the terms of Section 3 below, each Key Holder hereby unconditionally and irrevocably grants to the Company a Right of First Refusal to purchase all or any portion of Transfer Securities that such Key Holder may propose to transfer in a Proposed Key Holder Transfer, at the same price and on the same terms and conditions as those offered to the Prospective Transferee.

(b) Notice. Each Key Holder proposing to make a Proposed Key Holder Transfer must deliver a Proposed Transfer Notice to the Company and each Investor no later than 45 days prior to the consummation of such Proposed Key Holder Transfer. Such Proposed Transfer Notice shall contain the material terms and conditions (including price and form of consideration) of the Proposed Key Holder Transfer, the identity of the Prospective Transferee and the intended date of the Proposed Key Holder Transfer. To exercise its Right of First Refusal under this Section 2, the Company must deliver a Company Notice to the selling Key Holder within 15 days after delivery of the Proposed Transfer Notice. In the event of a conflict between this Agreement and any other agreement that may have been entered into by a Key Holder with the Company that contains a preexisting right of first refusal (including, without limitation, the Company's Bylaws), the Company and the Key Holder acknowledge and agree that the terms of this Agreement shall control and the preexisting right of first refusal shall be deemed satisfied by compliance with Subsection 2.1(a) and this Subsection 2.1(b).

(c) Grant of Secondary Refusal Right to the Investors. Subject to the terms of Section 3 below, each Key Holder hereby unconditionally and irrevocably grants to the Investors (other than itself as a Key Holder) a Secondary Refusal Right to purchase all or any portion of the Transfer Securities not purchased by the Company pursuant to the Right of First Refusal, as provided in this Subsection 2.1(c). If the Company does not intend to exercise its Right of First Refusal with respect to all Transfer Securities subject to a Proposed Key Holder Transfer, the Company must deliver a Secondary Notice to the selling Key Holder and to each Investor to that effect no later than 15 days after the selling Key Holder delivers the Proposed Transfer Notice to the Company. To exercise its Secondary Refusal Right, an Investor must deliver an Investor Notice to the selling Key Holder and the Company within 10 days after the Company's deadline for its delivery of the Secondary Notice as provided in the preceding sentence.

(d) Undersubscription of Transfer Securities. If options to purchase have been exercised by the Company and the Investors with respect to some but not all of the Transfer Securities by the end of the 10-day period specified in the last sentence of Subsection 2.1(c) (the "**Investor Notice Period**"), then the Company shall, immediately after the expiration of the Investor Notice Period, send written notice (the "**Company Undersubscription Notice**") to those Investors who fully exercised their Secondary Refusal Right within the Investor Notice Period (the "**Exercising Investors**"). Each Exercising Investor shall, subject to the provisions of this Subsection 2.1(d), have an additional option to purchase all or any part of the balance of any such remaining unsubscribed shares of Transfer Securities on the terms and conditions set forth in the Proposed Transfer Notice. To exercise such option, an Exercising Investor must deliver an Undersubscription Notice to the selling Key Holder and the Company within 10 days after the expiration of the Investor Notice Period. In the event there are two or more such Exercising Investors that choose to exercise the last-mentioned option for a total number of remaining shares in excess of the number available, the remaining shares available for purchase under this Subsection 2.1(d) shall be allocated to such Exercising Investors pro rata based on the number of shares of Transfer Securities such Exercising Investors have elected to purchase pursuant to the Secondary Refusal Right (without giving effect to any shares of Transfer Securities that any such Exercising Investor has elected to purchase pursuant to the Company Undersubscription Notice). If the options to purchase the remaining shares are exercised in full by the Exercising Investors, the Company shall immediately notify all of the Exercising Investors and the selling Key Holder of that fact.

(e) Consideration; Closing. If the consideration proposed to be paid for the Transfer Securities is in property, services or other non-cash consideration, the fair market value of the consideration shall be as determined in good faith by the Board and as set forth in the Company Notice. If the Company or any Investor cannot for any reason pay for the Transfer Securities in the same form of non-cash consideration, the Company or such Investor may pay the cash value equivalent thereof, as determined in good faith by the Board and as set forth in the Company Notice. The closing of the purchase of Transfer Securities by the Company and the Investors shall take place, and all payments from the Company and the Investors shall have been delivered to the selling Key Holder, by the later of (i) the date specified in the Proposed Transfer Notice as the intended date of the Proposed Key Holder Transfer and (ii) 45 days after delivery of the Proposed Transfer Notice.

2.2 Right of Co-Sale.

(a) Exercise of Right. If any Transfer Securities subject to a Proposed Key Holder Transfer are not purchased pursuant to Subsection 2.1 above and thereafter are to be sold to a Prospective Transferee, each respective Investor (unless the Investor is the transferring Key Holder) may elect to exercise its Right of Co-Sale and participate on a pro rata basis in the Proposed Key Holder Transfer as set forth in Subsection 2.2(b) below and, subject to Subsection 2.2(d), otherwise on the same terms and conditions specified in the Proposed Transfer Notice. Each Investor that desires to exercise its Right of Co-Sale (each, a "**Participating Investor**") must give the selling Key Holder written notice to that effect within 15 days after the deadline for delivery of the Secondary Notice described above, and upon giving such notice such Participating Investor shall be deemed to have effectively exercised the Right of Co-Sale.

(b) Shares Includable. Each Participating Investor may include in the Proposed Key Holder Transfer all or any part of such Participating Investor's shares of Capital Stock equal to the product obtained by multiplying (i) the aggregate number of Transfer Securities subject to the Proposed Key Holder Transfer (excluding Common Shares purchased by the Company or the Participating Investors pursuant to the Right of First Refusal or the Secondary Refusal Right) by (ii) a fraction, the numerator of which is the number of shares of Capital Stock owned by such Participating Investor, on a fully-diluted and as-converted to Common Shares basis, immediately before consummation of the Proposed Key Holder Transfer and the denominator of which is the total number of shares of Capital Stock owned, in the aggregate and on a fully-diluted and as-converted to Common Shares basis, by all Participating Investors immediately prior to the consummation of the Proposed Key Holder Transfer, plus the number of shares of Transfer Securities held by the Key Holders (excluding any Participating Investor). To the extent one or more of the Participating Investors exercise such right of participation in accordance with the terms and conditions set forth herein, the number of shares of Transfer Securities that the selling Key Holder may sell in the Proposed Key Holder Transfer shall be correspondingly reduced.

(c) Purchase and Sale Agreement. The Participating Investors and the selling Key Holder agree that the terms and conditions of any Proposed Key Holder Transfer in accordance with Subsection 2.2 will be memorialized in, and governed by, a written purchase and sale agreement with the Prospective Transferee (the "**Purchase and Sale Agreement**") with customary terms and provisions for such a transaction, and the Participating Investors and the selling Key Holder further covenant and agree to enter into such Purchase and Sale Agreement as a condition precedent to any sale or other transfer in accordance with this Subsection 2.2.

(d) Allocation of Consideration. Subject to Subsection 2.2(d)(ii), the aggregate consideration payable to the Participating Investors and the selling Key Holder shall be allocated based on the number of shares of Capital Stock sold to the Prospective Transferee by each Participating Investor and the selling Key Holder as provided in Subsection 2.2(b), provided that if a Participating Investor wishes to sell shares of Capital Stock other than the series of Capital Stock subject to the Proposed Key Holder Transfer, the price set forth in the Proposed Transfer Notice shall be appropriately adjusted based on the conversion ratio of such Capital Stock into Common Shares.

(e) Purchase by Selling Key Holder; Deliveries. Notwithstanding Subsection 2.2(c) above, if any Prospective Transferee or Transferees refuse(s) to purchase securities subject to the Right of Co-Sale from any Participating Investor or Investors or upon the failure to negotiate in good faith a Purchase and Sale

Agreement reasonably satisfactory to the Participating Investor or Investors, no Key Holder may sell any Transfer Securities to such Prospective Transferee or Transferees unless and until, simultaneously with such sale, such Key Holder purchases all securities subject to the Right of Co-Sale from such Participating Investor or Investors on the same terms and conditions (including the proposed purchase price) as set forth in the Proposed Transfer Notice and as provided in Subsection 2.2(d)(i). In connection with such purchase by the selling Key Holder, the Participating Investor or Investors shall deliver to the selling Key Holder a certificate or certificates, properly endorsed for transfer, representing the Capital Stock being purchased by the selling Key Holder (or request that the Company effect such transfer in the name of the selling Key Holder). Each such certificate delivered to the selling Key Holder will be transferred to the Prospective Transferee against payment therefor in consummation of the sale of the Transfer Securities pursuant to the terms and conditions specified in the Proposed Transfer Notice, and the selling Key Holder shall concurrently therewith remit or direct payment to the Participating Investor or Investors the portion of the aggregate consideration to which each such Participating Investor is entitled by reason of its participation in such sale as provided in this Subsection 2.2(e).

(f) Additional Compliance. If any Proposed Key Holder Transfer is not consummated within 45 days after receipt of the Proposed Transfer Notice by the Company, the Key Holders proposing the Proposed Key Holder Transfer may not sell any Transfer Securities unless they first comply in full with each provision of this Section 2. The exercise or election not to exercise any right by any Investor hereunder shall not adversely affect its right to participate in any other sales of Transfer Securities subject to this Subsection 2.2.

2.3 Effect of Failure to Comply.

(a) Transfer Void; Equitable Relief. Any Proposed Key Holder Transfer not made in compliance with the requirements of this Agreement shall be null and void ab initio, shall not be recorded on the books of the Company or its transfer agent and shall not be recognized by the Company. Each party hereto acknowledges and agrees that any breach of this Agreement would result in substantial harm to the other parties hereto for which monetary damages alone could not adequately compensate. Therefore, the parties hereto unconditionally and irrevocably agree that any non-breaching party hereto shall be entitled to seek protective orders, injunctive relief and other remedies available at law or in equity (including, without limitation, seeking specific performance or the rescission of purchases, sales and other transfers of Transfer Securities not made in strict compliance with this Agreement).

(b) Violation of First Refusal Right. If any Key Holder becomes obligated to sell any Transfer Securities to the Company or any Investor under this Agreement and fails to deliver such Transfer Securities in accordance with the terms of this Agreement, the Company and/or such Investor may, at its option, in addition to all other remedies it may have, send to such Key Holder the purchase price for such Transfer Securities as is herein specified and transfer to the name of the Company or such Investor (or request that the Company effect such transfer in the name of an Investor) on the Company's books the certificate or certificates representing the Transfer Securities to be sold.

(c) Violation of Co-Sale Right. If any Key Holder purports to sell any Transfer Securities in contravention of the Right of Co-Sale (a "**Prohibited Transfer**"), each Investor, if it desires to exercise its Right of Co-Sale under Subsection 2.2, may, in addition to such remedies as may be available by law, in equity or hereunder, require such Key Holder to purchase from such Investor the Common Shares that such Investor would have been entitled to sell to the Prospective Transferee had the Prohibited Transfer been effected in compliance with the terms of Subsection 2.2. The sale will be made on the same terms, including, without limitation, as provided in Subsection 2.2(d)(i) and the first sentence of Subsection 2.2(d)(ii), as applicable, and subject to the same conditions as would have applied had the Key Holder not made the Prohibited Transfer, except that the sale (including, without limitation, the delivery of the purchase price) must be made within 90 days after the Investor learns of the Prohibited Transfer, as opposed to the timeframe proscribed in Subsection 2.2. Such Key Holder shall also reimburse each Investor for any and all reasonable and documented out-of-pocket fees and expenses, including reasonable legal fees and expenses, incurred pursuant to the exercise or the attempted exercise of the Investor's rights under Subsection 2.2.

3. Exempt Transfers.

3.1 Exempted Transfers. Subject to the terms of Section 3.3, but notwithstanding the foregoing or any other provision to the contrary herein, the provisions of Subsections 2.1 and 2.2 shall not apply: (a) in the case of a Key Holder that is an entity, upon transfer by such Key Holder to its Affiliates, (b) to a repurchase of Transfer Securities from a Key Holder by the Company at a price no greater than that originally paid by such Key Holder for such Transfer Securities and pursuant to an agreement containing vesting and/or repurchase provisions approved by a majority of the Board, or (c) in the case of a Key Holder that is a natural person, upon a transfer of Transfer Securities by such Key Holder made for bona fide estate planning purposes, either during his or her lifetime, or on death by will or intestacy to his or her spouse, child (natural or adopted) , any other direct lineal descendant, father, mother or brother or sister (or his or her spouse) of such Key Holder (all of the foregoing collectively referred to as "family members"), or any custodian or trustee of any trust, partnership or limited liability company for the benefit of, or the ownership interests of which are owned wholly by, such Key Holder or any such family member, provided that in the case of clause(s) (a) or (c), (x) the Key Holder shall deliver prior written notice to the Investor of such gift, sale or transfer and (y) such Transfer Securities shall at all times remain subject to the terms and restrictions set forth in this Agreement and such transferee shall, as a condition to such issuance, deliver a counterpart signature page to this Agreement as confirmation that such transferee shall be bound by all the terms and conditions of this Agreement as a Key Holder (but only with respect to the securities so transferred to the transferee), including the obligations of a Key Holder with respect to Proposed Key Holder Transfers of such Transfer Securities pursuant to Section 2.

3.2 Exempted Offerings. Notwithstanding the foregoing or anything to the contrary herein, the provisions of Section 2.1 shall not apply to the sale of any Transfer Securities (a) to the public in an offering pursuant to an effective registration statement under the Securities Act, or (b) pursuant to a Change of Control. Notwithstanding the foregoing or anything to the contrary herein, the provisions of Section 2.2 shall not apply to the sale of any Transfer Securities to the public in an offering pursuant to an effective registration statement under the Securities Act.

3.3 Prohibited Transferees. Notwithstanding the foregoing, no Key Holder shall transfer any Transfer Securities to (a) any entity other than an Affiliate which, in the good faith determination of the Board, directly or indirectly competes with the Company or (b) any customer, distributor or supplier of the Company, if the Board should determine in good faith that such transfer would result in such customer, distributor or supplier receiving information that would place the Company at a competitive disadvantage with respect to such customer, distributor or supplier.

4. Legend. Each certificate representing Transfer Securities held by the Key Holders or Transfer Securities issued to any permitted transferee in connection with a transfer permitted by Subsection 3.1 hereof shall be endorsed with the following legend:

THE SHARES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF, AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "**ACT**"). SUCH SHARES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR AN EXEMPTION THEREFROM UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

THE SALE, PLEDGE, HYPOTHECATION OR TRANSFER OF THE SHARES REPRESENTED BY THIS CERTIFICATE IS SUBJECT TO, AND IN CERTAIN CASES PROHIBITED BY, THE ISSUER'S BYLAWS, A CERTAIN INVESTOR RIGHTS AGREEMENT BETWEEN THE ISSUER AND THE HOLDER, AND A CERTAIN RIGHT OF FIRST REFUSAL AND CO-SALE AGREEMENT AMONG THE HOLDER, THE ISSUER AND CERTAIN OTHER HOLDERS OF EQUITY OF THE ISSUER. COPIES OF SUCH AGREEMENTS MAY BE OBTAINED UPON WRITTEN REQUEST TO THE SECRETARY OF THE ISSUER.

Each Key Holder agrees that the Company may instruct its transfer agent to impose transfer restrictions on the shares represented by certificates bearing the legend referred to in this Section 4 above to enforce the provisions of this Agreement, and the Company agrees to promptly do so. The legend shall be removed upon termination of this Agreement at the request of the holder.

5. "Market Stand-off" Agreement. Each Key Holder agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company or any successor corporation of the Company of its equity securities under the Securities Act on a registration statement for the IPO, and ending on the date specified by the Company and the managing underwriter (such period not to exceed 180 days), (a) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any Common Shares or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Shares or (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (a) or (b) above is to be settled by delivery of Common Shares or other securities, in cash, or otherwise. The foregoing provisions of this Section 5 shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement or the transfer of any shares to any Affiliate of the Key Holder; provided that such Affiliate shall agree to be bound by the provisions of this Section 5 with respect to future transfers; provided further that this Section 5 shall be applicable to each Key Holder and transferee only if all officers and directors of the Company are subject to the same restrictions and the Company obtains a similar agreement from all shareholders individually owning more than one percent (1%) of the Company's outstanding equity interests. The underwriters in connection with such registration are intended third party beneficiaries of this Section 5 and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Each Key Holder further agrees to execute such agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Section 5 or that are necessary to give further effect thereto. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to the Common Shares (or other securities) held by each Key Holder (and the securities of every other Person subject to the foregoing restriction) until the end of such period.

6. Miscellaneous.

6.1 Term. This Agreement shall automatically terminate upon the earlier of (a) immediately prior to the consummation of the Company's IPO, (b) the closing of a transaction described in clause (i) of the definition of Change of Control, and (c) the liquidation or other dissolution of the Company.

6.2 Ownership. Each Key Holder represents and warrants that such Key Holder is the sole legal and beneficial owner of the Transfer Securities subject to this Agreement and that no other Person or entity has any interest in such shares (other than a community property interest as to which the holder thereof has acknowledged and agreed in writing to the restrictions and obligations hereunder).

6.3 WAIVER OF JURY TRIAL. EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE OTHER TRANSACTION DOCUMENTS, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER WARRANTS AND REPRESENTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

6.4 Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (a) personal delivery to the party to be notified; (b) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next business day; (c) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) one business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the Investors and Key Holders at their respective addresses set forth on Schedule A and Schedule B, respectively, and to Company at the address set forth below in the signature page, or at such other address as the Key Holders, Company or Investors may designate by 10 days advance written notice to the other parties hereto.

6.5 Entire Agreement. This Agreement (including any Schedules and Exhibits hereto) constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

6.6 Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power or remedy of such non-breaching or non-defaulting party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring; nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies, either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

6.7 Amendment; Waiver and Termination. This Agreement may be amended, modified or terminated (other than pursuant to Section 6.1 above) and the observance of any term hereof may be waived (either generally or in a particular instance and either retroactively or prospectively) only by a written instrument executed by (a) the Company, (b) the Key Holders holding a majority of the Transfer Securities then held by all of the Key Holders who are then providing services to the Company as officers, employees or consultants and (c) the Investors. Any amendment, modification, termination or waiver so effected shall be binding upon the Company, the Investors, the Key Holders and all of their respective successors and permitted assigns whether or not such party, assignee or other shareholder entered into or approved such amendment, modification, termination or waiver. Notwithstanding the foregoing, (i) this Agreement may not be amended, modified or terminated and the observance of any term hereunder may not be waived with respect to any Investor or Key Holder without the written consent of such Investor or Key Holder unless such amendment, modification, termination or waiver applies to all Investors and Key Holders, respectively, in the same fashion and (ii) the consent of the Key Holders shall not be required for any amendment, modification, termination or waiver if such amendment, modification, termination or waiver does not apply to the Key Holders. The Company shall give prompt written notice of any amendment, modification or termination hereof or waiver hereunder to any party hereto that did not consent in writing to such amendment, modification, termination or waiver. No waivers of or exceptions to any term, condition or provision of this Agreement, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such term, condition or provision.

6.8 Assignment of Rights.

(a) The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the respective successors and permitted assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

(b) Any successor or permitted assignee of any Key Holder, including any Prospective Transferee who purchases Transfer Securities in accordance with the terms hereof, shall deliver to the Company and the Investors, as a condition to any transfer or assignment, a counterpart signature page hereto pursuant to which such successor or permitted assignee shall confirm their agreement to be subject to and bound by all of the provisions set forth in this Agreement that were applicable to the predecessor or assignor of such successor or permitted assignee.

(c) The rights of the Investors hereunder are not assignable without the Company's written consent (which shall not be unreasonably withheld, delayed or conditioned), except by each Investor to its Affiliates or to a third party in connection with a transfer of all of the shares of Capital Stock held by such Investor to such third party, it being acknowledged and agreed that any such assignment shall be subject to and conditioned upon any such assignee's delivery to the Company and the other Investors of a counterpart signature page hereto pursuant to which such assignee shall confirm their agreement to be subject to and bound by all of the provisions set forth in this Agreement that were applicable to the assignor of such assignee.

(d) Except in connection with an assignment by the Company by operation of law to the acquirer of the Company, the rights and obligations of the Company hereunder may not be assigned under any circumstances.

6.9 Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.10 Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the internal law of the State of Delaware in all respects as such laws are applied to agreements among Delaware residents entered into and performed entirely within Delaware, without giving effect to conflict of law principles thereof. With respect to any controversy arising out of or related to this Agreement, the parties hereto consent to the exclusive jurisdiction of, and venue in, the state or federal courts located in Delaware.

6.11 Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

6.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

6.13 Aggregation of Securities. All securities of the Company held or acquired by Affiliated entities or Persons shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated Persons may apportion such rights as among themselves in any manner they deem appropriate.

6.14 Specific Performance. In addition to any and all other remedies that may be available at law in the event of any breach of this Agreement, each Investor shall be entitled to specific performance of the agreements and obligations of the Company and the Key Holders hereunder and to such other injunction or other equitable relief as may be granted by a court of competent jurisdiction.

6.15 Additional Investors. Notwithstanding anything to the contrary contained herein, if the Company issues additional securities after the date hereof, any purchaser of such securities may become a party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement and thereafter shall be deemed an "Investor" for all purposes hereunder.

6.16 Additional Key Holders. In the event that after the date of this Agreement, the Company issues Common Shares, or options to purchase Common Shares, to any employee or consultant, which Common Shares or options would collectively constitute with respect to such employee or consultant (taking into account all Common Shares, options and other purchase rights held by such employee or consultant) 1% or more of the Company's then outstanding equity interests, the Company shall, as a condition to such issuance, cause such employee or consultant to execute a counterpart signature page hereto as a Key Holder, and such Person shall thereby be bound by, and subject to, all the terms and provisions of this Agreement applicable to a Key Holder.

[*Signatures Follow*]

IN WITNESS WHEREOF, the parties have executed this Right of First Refusal and Co-Sale Agreement as of the date first set forth above.

COMPANY:

ROIVANT ENDOCRINOLOGY LTD.

By: _____

Name: _____

Title: _____

Address:

Clarendon House
2 Church Street
Hamilton HM 11
Bermuda

IN WITNESS WHEREOF, the parties have executed this Right of First Refusal and Co-Sale Agreement as of the date first set forth above.

INVESTORS:

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

By: _____

Name: _____

Title: _____

[*Signature page to REL Right of First Refusal and Co-Sale Agreement*]

IN WITNESS WHEREOF, the parties have executed this Right of First Refusal and Co-Sale Agreement as of the date first set forth above.

INVESTORS:

ROIVANT SCIENCES LTD.

By: _____

Name: _____

Title: _____

[*Signature page to REL Right of First Refusal and Co-Sale Agreement*]

IN WITNESS WHEREOF, the parties have executed this Right of First Refusal and Co-Sale Agreement as of the date first set forth above.

KEY HOLDERS:

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

By: _____

Name: _____

Title: _____

[*Signature page to REL Right of First Refusal and Co-Sale Agreement*]

IN WITNESS WHEREOF, the parties have executed this Right of First Refusal and Co-Sale Agreement as of the date first set forth above.

KEY HOLDERS:

ROIVANT SCIENCES LTD.

By: _____

Name: _____

Title: _____

[*Signature page to REL Right of First Refusal and Co-Sale Agreement*]

Schedule A

Investors

Takeda Pharmaceuticals International AG
Thurgauerstrasse 130, 8152
Glattpark-Opfikon, Zurich, Switzerland
Facsimile: +41-44-555-10-01

Roivant Sciences Ltd. Clarendon House
2 Church Street
Hamilton HM 11
Bermuda

Schedule B

Key Holders

Takeda Pharmaceuticals International AG
Thurgauerstrasse 130, 8152
Glattpark-Opfikon, Zurich, Switzerland
Facsimile: +41-44-555-10-01

Roivant Sciences Ltd.
Clarendon House
2 Church Street
Hamilton HM 11
Bermuda

EXHIBIT C

FORM OF LEGAL OPINION

29 April 2016

Matter No.:353983
Doc Ref: 11087427.3

1-441-298-7846
neil.henderson@conyersdill.com

Takeda Pharmaceuticals International AG
Thurgauerstrasse 130
8152 Glattpark-Opfikon
Zurich
Switzerland

Dear Sirs,

Roivant Endocrinology Ltd. (the "Company")

We have acted as special Bermuda legal counsel to the Company in connection with the license by the Company of the chemical compound coded by Takeda Pharmaceuticals International AG ("**Takeda**") as TAK-385 and TAK-448 (together, the "**Licensed Compounds**") and the Licensed Products in the Licensee Territory (each as defined in the License Agreement (as defined below)).

For the purposes of giving this opinion, we have examined electronic copies of the following documents:

(i) a license agreement dated 29 April 2016 (the "**License Agreement**") between the Company and Takeda in respect of the license by the Company of the Licensed Compound and the Licensed Products in the Licensee Territory (each as defined therein);

(ii) a subscription agreement dated 29 April 2016 (the "**Subscription Agreement**") between the Company and Takeda in respect of the issuance by the Company to Takeda of 9,000,000 common shares (the "**Shares**");

(iii) an investor rights agreement dated 29 April 2016 between the Company, Roivant Sciences Ltd. ("**RSL**") and Takeda;

(iv) a right of first refusal and co-sale agreement dated 29 April 2016 between the Company, the Investors set forth on Schedule A thereto and the Key Holders set forth on Schedule B thereto; and

(v) a warrant to purchase shares of the Company dated 29 April 2016 (the "**Warrant**") by the Company in favour of Takeda.

The documents listed in items (i) through (v) above are herein sometimes collectively referred to as the "**Documents**" (which term does not include any other instrument or agreement whether or not specifically referred to therein or attached as an exhibit or schedule thereto).

We have also reviewed the memorandum of association and the bye-laws of the Company, each certified by the Secretary of the Company on 29 April 2016, written resolutions of its sole director passed on 27 April 2016 and written resolutions of its shareholder dated 27 April 2016 (together, the "**Resolutions**"), and such other documents and made such enquiries as to questions of law as we have deemed necessary in order to render the opinion set forth below.

We have assumed (a) the genuineness and authenticity of all signatures and the conformity to the originals of all copies (whether or not certified) examined by us and the authenticity and completeness of the originals from which such copies were taken; (b) that where a document has been examined by us in draft form, it will be or has been executed in the form of that draft, and where a number of drafts of a document have been examined by us all changes thereto have been marked or otherwise drawn to our attention; (c) the capacity, power and authority of each of the parties to the Documents, other than the Company, to enter into and perform its respective obligations under the Documents; (d) the due execution and delivery of the Documents by each of the parties thereto, other than the Company, and the physical delivery thereof by the Company with an intention to be bound thereby; (e) the accuracy and completeness of all factual representations made in the Documents and other documents reviewed by us; (f) that the Resolutions were passed at one or more duly convened, constituted and quorate meetings or by unanimous written resolutions, remain in full force and effect and have not been rescinded or amended; (g) that the Company is entering into the Documents pursuant to its business of lawful business; (h) that there is no provision of the law of any jurisdiction, other than Bermuda, which would have any implication in relation to the opinions expressed herein; (i) the validity and binding effect under the laws of New York (the "**New York Laws**") of the License Agreement which is expressed to be governed by such New York Laws in accordance with its terms; (j) the validity and binding effect under the laws of Delaware (the "**Delaware Laws**" and, together with the New York Laws, the "**Foreign Laws**") of the Documents other than the License Agreement which are expressed to be governed by such Delaware Laws in accordance with their respective terms; (k) the validity and binding effect under the New York Laws of the submission by the Company pursuant to the License Agreement to the jurisdiction of the courts of New York (the "**New York Courts**"); (l) the validity and binding effect under the Delaware Laws of the submission by the Company pursuant to the Documents other than the License Agreement to the jurisdiction of the courts of Delaware (the "**Delaware Courts**" and, together with the New York Courts, the "**Foreign Courts**"); (m) that none of the parties to the Documents carries on business from premises in Bermuda at which it employs staff and pays salaries and other expenses; and (n) that on the date of entering into the Documents the Company is and after entering into the Documents will be able to pay its liabilities as they become due.

The obligations of the Company under the Documents (a) will be subject to the laws from time to time in effect relating to bankruptcy, insolvency, liquidation, possessory liens, rights of set off, reorganisation, amalgamation, merger, moratorium or any other laws or legal procedures, whether of a similar nature or otherwise, generally affecting the rights of creditors as well as applicable international sanctions; (b) will be subject to statutory limitation of the time within which proceedings may be brought; (c) will be subject to general principles of equity and, as such, specific performance and injunctive relief, being equitable remedies, may not be available; (d) may not be given effect to by a Bermuda court, whether or not it was applying the Foreign Laws, if and to the extent they constitute the payment of an amount which is in the nature of a penalty; and (e) may not be given effect by a Bermuda court to the extent that they are to be performed in a jurisdiction outside Bermuda and such performance would be illegal under the laws of that jurisdiction. Notwithstanding any contractual submission to the jurisdiction of specific courts, a Bermuda court has inherent discretion to stay or allow proceedings in the Bermuda courts.

We express no opinion as to the enforceability of any provision of the Documents which provides for the payment of a specified rate of interest on the amount of a judgment after the date of judgment, which purports to fetter the statutory powers of the Company, or which purports to grant exclusive jurisdiction to any courts.

We have made no investigation of and express no opinion in relation to the laws of any jurisdiction other than Bermuda. This opinion is to be governed by and construed in accordance with the laws of Bermuda and is limited to and is given on the basis of the current law and practice in Bermuda. This opinion is issued solely for your benefit and use in connection with the matter described herein and is not to be relied upon by any other person, firm or entity or in respect of any other matter.

On the basis of and subject to the foregoing, we are of the opinion that:

1. The Company is duly incorporated and existing under the laws of Bermuda.

2. The Company has the necessary corporate power and authority to enter into and perform its obligations under the Documents. The execution and delivery of the Documents by the Company and the performance by the Company of its obligations thereunder will not violate the memorandum of association or bye-laws of the Company nor any applicable law, regulation, order or decree in Bermuda.

3. The Company has taken all corporate action required to authorise its execution, delivery and performance of the Documents. The Documents have been duly executed and delivered by or on behalf of the Company, and constitute the valid and binding obligations of the Company in accordance with the terms thereof.

4. No order, consent, approval, licence, authorisation or validation of or exemption by any government or public body or authority of Bermuda or any sub-division thereof is required to authorise or is required in connection with the execution, delivery, performance and enforcement of the Documents, except such as have been duly obtained in accordance with Bermuda law.

5. It is not necessary or desirable to ensure the enforceability in Bermuda of the Documents that they be registered in any register kept by, or filed with, any governmental authority or regulatory body in Bermuda. However, to the extent that any of the Documents creates a charge over assets of the Company, it may be desirable to ensure the priority in Bermuda of the charge that it be registered in the Register of Charges in accordance with Section 55 of the Companies Act 1981. On registration, to the extent that Bermuda law governs the priority of a charge, such charge will have priority in Bermuda over any unregistered charges created after 11 July 1984, and over any subsequently registered charges, in respect of the assets which are the subject of the charge. A registration fee of US$630 will be payable in respect of the registration.

   While there is no exhaustive definition of a charge under Bermuda law, a charge includes any interest created in property by way of security (including any mortgage, assignment, pledge, lien or hypothecation). As the Documents are governed by the Foreign Laws, the question of whether they create such an interest in property would be determined under the relevant Foreign Laws.

6. The Documents will not be subject to *ad valorem* stamp duty in Bermuda.

7. The choice of the Foreign Laws as the governing law of the Documents is a valid choice of law and would be recognised and given effect to in any action brought before a court of competent jurisdiction in Bermuda, except for those laws (i) which such court considers to be procedural in nature; (ii) which are revenue or penal laws or (iii) the application of which would be inconsistent with public policy, as such term is interpreted under the laws of Bermuda. The submission in the Documents to the jurisdiction of the relevant Foreign Courts is valid and binding upon the Company.

8. The courts of Bermuda would recognise as a valid judgment, a final and conclusive judgment *in personam* obtained in the Foreign Courts against the Company based upon the Documents under 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) and would give a judgment based thereon provided that (a) such courts had proper jurisdiction over the parties subject to such judgment; (b) such courts did not contravene the rules of natural justice of Bermuda; (c) such judgment was not obtained by fraud; (d) the enforcement of the judgment would not be contrary to the public policy of Bermuda; (e) no new admissible evidence relevant to the action is submitted prior to the rendering of the judgment by the courts of Bermuda; and (f) there is due compliance with the correct procedures under the laws of Bermuda.

9. When issued and paid up in accordance with the Subscription Agreement, the Shares will be validly issued, fully paid and non-assessable (which term when used herein means that no further sums are required to be paid by the holders thereof in connection with the issue thereof).

10. When issued and paid for in accordance with the Warrant, any Shares (as defined in the Warrant) issued pursuant to the Warrant will be validly issued, fully paid and non-assessable (which term when used herein means that no further sums are required to be paid by the holders thereof in connection with the issue thereof).

11. Based solely on a review of the Register of Members of the Company dated the date hereof, the authorized share capital of the Company consists of 1,000,000,000 common shares of par value US $0.00001, of which 66,000,000 shares are registered in the name of Roivant Sciences Ltd. All such issued and outstanding shares have been duly authorized and validly issued and are fully paid and non-assessable (which term when used herein means that no further sums are required to be paid by the holders thereof in connection with the issue thereof).

Yours faithfully,

Conyers Dill & Pearman Limited

Schedule 9.1(b)

Takeda Warrant

Schedule 11.4.2

Financial Statements

[***]

AMENDMENT TO LICENSE AGREEMENT

This Amendment to the License Agreement (this "Amendment"), effective as of August 30, 2016 (the "Amendment Effective Date"), modifies and amends the License Agreement, with the effective date of April 29, 2016 (the "License Agreement"), by and between Roivant Endocrinology Ltd. (n/k/a Myovant Sciences Ltd., Clarendon House, 2 Church Street, Hamilton, Bermuda ("Myovant") and Takeda Pharmaceuticals International AG, Thurgauerstrasse 130, 8152, Glattpark-Opfikon Zurich, Switzerland ("Takeda").

WHEREAS, the parties to the License Agreement now desire amend Schedule 1.151 of the License Agreement as provided herein.

NOW, THEREFORE, for the mutual promises and consideration as set forth herein, the parties agree to amend and modify the License Agreement as follows:

1. Schedule 1.151 of the License Agreement shall be amended to include the Patents listed on Exhibit A attached hereto.

2. Except as herein amended, all terms, covenants and provisions of the License Agreement are and shall remain in full force and effect. Capitalized terms used herein and not otherwise defined shall have the meaning given to them in the License Agreement. This Amendment shall be deemed incorporated into, and a part of, the License Agreement.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the Amendment Effective Date.

ROIVANT ENDOCRINOLOGY LTD.
(n/k/a MYOVANT SCIENCES LTD.)

By:	/s/ Marianne L. Romeo
Name:	Marianne L. Romeo
Title:	Head, Global Transactions & Risk Management

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

By:	/s/ Marcello Agosti
Name:	Marcello Agosti
Title:	Head of Global Commercial

Exhibit A

Part (a) - TAK-385 Patent Rights

[***]

Part (b) - TAK-448 Patent Rights

[***]

Exhibit 10.5

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

Amendment to License Agreement

This Amendment (this "**Amendment**") to the License Agreement, dated April 29, 2016, (the "**License Agreement**") by and between Takeda Pharmaceuticals International AG, a company incorporated under the laws of Switzerland having its principal place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon Zurich, Switzerland ("**Takeda**") and Myovant Sciences Ltd. (formally with the name "Roivant Endocrinology Ltd."), an exempted limited company incorporated under the laws of Bermuda, and having its Granted office at 2 Church Street, Hamilton, Bermuda (the "**Former Licensee**") is being entered into as of November 19, 2019 (the "**Amendment Effective Date**"), by and among Takeda, Myovant Sciences GmbH, a Switzerland limited liability company with an address of Viaduktstrasse 8, 4051 Basel, Switzerland (the "**Licensee**") and Roivant Sciences Ltd. ("**RSL**") (with respect to RSL, solely for purposes of Section 5.5, Section 5.6, Section 11.5.3, and Section 16.8 of the License Agreement) in accordance with Section 16.12 of the License Agreement.

For clarification purpose, the Former Licensee assigned all of its rights and obligations under the License Agreement to the Licensee pursuant to that certain Asset and Contribution Agreement, dated as of November 11, 2016, by and between the Former Licensee and the Licensee, in accordance with Section 16.3 of the License Agreement.

All capitalized terms used but not otherwise defined in this Amendment have the meanings given to them in the License Agreement. The License Agreement is hereby amended as follows:

1. As partial consideration for rights granted with respect to the Added Patents (as defined below), Licensee shall, within ten (10) Business Days of the Amendment Effective Date, wire to Takeda, in immediately available funds, the amount of [***] U.S. dollars [($[***])], which payment shall be non-refundable and non-creditable.

2. Section 1.141 of the License Agreement is deleted in its entirety and replaced with the following:

   "TAK-448 Licensed Compound" means: (a) the oligopeptide coded by Takeda as TAK-448 and the structure of which is set forth on Schedule 1.141 (TAK-448 Licensed Compound); (b) any oligopeptide other than TAK-448 that is Covered by any Takeda Patent Right set forth on Schedule 1.151 (Takeda Patent Rights); and (c) [***] of any compound described in clause (a).

3. Section 1.174 is added to the Agreement:

   "[***]" means collectively those certain letter agreements between Takeda Pharmaceutical Company Limited and [***], each dated as of December 1, 2003, including any amendments thereto.

4. Section 10.8.1(a) of the License Agreement is deleted and replaced in its entirety with the following:

   10.8.1(a) *Licensee's Rights*. Licensee will have the first right, but not the obligation, to bring at its own expense and in its sole control such action in the Licensee Territory. For clarity, Licensee shall be responsible for negotiating any agreement required pursuant to the [***] related to the Commercialization of any Licensed Products Covered by the Added Patents and shall be solely responsible for any compensation paid pursuant to the [***] related thereto. For the avoidance of doubt, Section 9.2.3(a) shall not apply to such compensation and such compensation shall not be credited against Royalties.

5. The Schedule 1.151 of the License Agreement is deleted and replaced in its entirety with the Schedule 1.151 attached hereto as Exhibit A. Specifically, those certain Patents set forth in Schedule 1.151 Part (b)(ii) have

been added to Schedule 1.151 pursuant to this Amendment (the "**Added Patents**"). Except as expressly set forth in this Amendment, the Schedule 1.151 (or Schedule 1.151 Part (a) or Schedule 1.151 Part (b), as applicable) referenced anywhere in the License Agreement refers to the Schedule 1.151 (or Schedule 1.151 Part (a) or Schedule 1.151 Part (b), as applicable) attached hereto as Exhibit A.

6. Except as set forth in Section 7 of this Amendment, the representations and warranties set forth in Section 11.2 of the License Agreement do not apply to the Added Patents nor to any TAK-448 Licensed Compound Covered by an Added Patent.

7. Section 11.2 of the License Agreement is amended to include the following.:

11.2.11 Added Patents. Takeda represents and warrants as of the Amendment Effective Date that:

(a) *Sufficient Rights*. Except for the obligations under the [***], Takeda has all rights necessary to grant the rights and licenses under the Takeda Intellectual Property Rights Controlled by Takeda as of the Amendment Effective Date that it grants to Licensee pursuant to this Amendment.

(b) *Ownership of Takeda Patent Rights*. Except for the obligations under the [***], Takeda is the sole and exclusive owner of the entire right, title, and interest in the Added Patents set forth on Schedule 1.151 free of any encumbrance, lien, or claim of ownership by any Third Party.

(c) *Completeness of Patent Schedule*. Schedule 1.151 includes all Patent Rights owned or Controlled by Takeda that are necessary for Licensee to Exploit the Licensed Compounds and Licensed Products in the Licensee Territory.

(d) *Registration and Maintenance*. To Takeda's Knowledge, all registrations and applications for the Added Patents set forth on Schedule 1.151 are valid, enforceable, and subsisting. Except as stated therein, no registration, or application therefor, for any of the Added Patents set forth in Schedule 1.151 has lapsed, expired, been abandoned, or been withdrawn, and no such registrations, or applications therefor, are the subject of any opposition, interference, cancellation, *inter partes* review, post-grant review, or other legal or governmental proceeding pending before any Governmental Authority (other than standard patent prosecution before a Patent Office). To Takeda's Knowledge, each of the Added Patents properly identifies each and every inventor of the claims therein as determined in accordance with Applicable Law of the jurisdiction in which such Added Patent is issued or such application is pending.

(e) *Infringement*. There is no claim pending by Takeda alleging that a Third Party is or was infringing, misappropriating, or otherwise violating the Added Patents in the Field in the Licensee Territory.

(f) *No Government Funding*. The Inventions claimed or disclosed by the Added Patent set forth on Schedule 1.151(a) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the U.S. or any agency thereof, (b) are not a "subject invention" as that term is described in 35 U.S.C. §201(f), and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§200-212, as well as any regulations promulgated pursuant thereto, including 37 C.F.R. Part 401, and any successor statutes or regulations (also known as the Bayh-Dole Act).

(g) *No Claims*. No claim or litigation in the Licensee Territory has been brought or, to Takeda's Knowledge, threatened by any Person alleging, and Takeda has no Knowledge of any claim, whether or not asserted: (a) that any of the Added Patents set forth on Schedule 1.151 is invalid or unenforceable, and (b) that the Exploitation of the Licensed Compounds and Licensed Products covered by the Added Patents set forth in Schedule 1.151 violates, infringes, or otherwise conflicts or interferes with, any Intellectual Property Right of any Person.

8. Section 12.7.3 is added to the agreement:
TAK-448 Publications: Takeda shall deliver to Licensee a copy of any proposed written publication or oral presentation on a TAK-448 Licensed Compound at least [***] days prior to the submission for publication or the oral presentation. Such publications and presentations shall not be published or given without the prior written consent of Licensee.

9. All other provisions of the License Agreement shall continue in full force and effect. The provisions in Article 16 (Miscellaneous) of the License Agreement shall apply to this Amendment as if included in this Amendment.

[Remainder of this page intentionally left blank]

IN WITNESS WHEREOF, each of Takeda Pharmaceuticals International AG, Myovant Sciences GmbH, and Roivant Sciences Ltd. have caused this Amendment to be executed by their respective duly authorized officers as of the date first above written, each copy of which will for all purposes be deemed to be an original.

TAKEDA PHARMACEUTICAL INTERNATIONAL AG

By:	/s/ Charles Alexander	By:	/s/ Andrea Ferrari
Name:	Charles Alexander	Name:	Andrea Ferrari
Title:	Head International BD	Title:	Regional General Counsel Eucan

MYOVANT SCIENCES GMBH

By:	/s/ Sascha Bucher
Name:	Sascha Bucher
Title:	VP, Head of Global Transactions
Date:	March 3, 2020

ROIVANT SCIENCES LTD. (Solely for purposes of Section 5.5, Section 5.6, Section 11.5.3 and Section 16.8)

By:	/s/ Marianne L. Romero
Name:	Marianne L. Romero
Title:	Head, Global Transactions & Risk Management
Date:	2/7/2020

Exhibit 10.6

CERTAIN Information Identified by "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.

Execution Version

AGREEMENT FOR THE MANUFACTURE &

SUPPLY OF CLINICAL TRIAL MATERIAL BY AND BETWEEN

TAKEDA PHARMACEUTICAL COMPANY LIMITED,

AND

MYOVANT SCIENCES LTD.

DATE: JUNE 7, 2016

AGREEMENT FOR THE MANUFACTURING & SUPPLY OF CLINICAL TRIAL MATERIAL

This Agreement for the Manufacturing & Supply of Clinical Trial Material (the "**Agreement**") is made effective as of June 7, 2016 (the "**Effective Date**") by and between **Takeda Pharmaceutical Company Limited**, a company having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan ("**Takeda**") and **Myovant Sciences Ltd.** (f/k/a Roivant Endocrinology Ltd.), an exempted limited company incorporated under the laws of Bermuda, a having its registered office at 2 Church Street, Hamilton, Bermuda ("**Myovant**"). Myovant and Takeda are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties.**"

RECITALS

WHEREAS, Takeda's Affiliate, Takeda Pharmaceuticals International AG ("**TPIZ**") and Myovant are parties to that certain License Agreement dated April 29, 2016 ("**License Agreement**") pursuant to which TPIZ granted to Myovant a license in the Licensee Territory and the Takeda Territory under certain patents, patent applications, know-how and other proprietary information for the further Development and Commercialization of the TAK-3 85 Licensed Products in accordance with the terms and conditions set forth in the License Agreement;

WHEREAS, under the License Agreement, Takeda agreed to provide to Myovant the Initial Clinical Supply [***] and to manufacture and supply additional amounts of TAK-385 Licensed Compound or TAK-385 Licensed Product, in each case, as required by Myovant to complete the TAK-385 Development Plan, and Myovant agreed to purchase such additional amounts of TAK-385 Licensed Compound and TAK-385 Licensed Product;

WHEREAS, in accordance with the terms of the License Agreement and on the terms and conditions set out below, Takeda, on behalf of TPIZ, now agrees to provide Drug Substance or Drug Product (as defined below) and Myovant agrees to receive from Takeda, all of Myovant's requirements for such Drug Substance or Drug Product in order to complete all Clinical Trials contemplated under the TAK-385 Development Plan.

NOW, THEREFORE, and in consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

ARTICLE 1
DEFINITIONS

The following capitalized terms used in this Agreement shall have the meanings specified below and all other capitalized terms used but not otherwise defined in this Agreement shall have their respective meanings set forth in the License Agreement:

1.1 "**Batch Documentation**" means the documentation provided to Myovant at the time of delivery of Drug Substance or Drug Product, as agreed upon by the Parties in the Quality Agreement.

1.2 "**Credit Note**" means a credit memo issued by Takeda to Myovant and usable by Myovant as: (i) an offset against amounts payable to Takeda by Myovant or, (ii) if no such amounts are outstanding at the time of termination or expiration of this Agreement, for a refund from Takeda to Myovant which Takeda shall pay to Myovant no later than [***] days after any such termination or expiration.

1.3 "**Direct Expenses**" means those material and services expenses captured in invoices and the like which are specifically attributable to Manufacture of the Drug Substance or Drug Product, including [***].

1.4 "**Drug Product**" means a final, unpackaged pharmaceutical product for use solely for administration to humans in Clinical Trials consisting of: (a) the TAK-385 Licensed Product or (b) a placebo version of each formulation of a pharmaceutical product in sub-Section (a), where, in each case, such Drug Product has been Manufactured in accordance with the Specifications and Applicable Laws. The formulations of Drug Product as of the Effective Date are set forth on Exhibit B.

1.5 "**Drug Substance**" means the active pharmaceutical ingredient for the TAK-385 Licensed Compound that has been Manufactured in accordance with the Specifications and Applicable Laws.

1.6 "**Indirect Expenses**" means labor expenses, including [***], and other indirect production expenses such as [***], and expenses for process development and analytical methods development, but excluding, in each case, any Direct Expenses.

1.7 "**Initial Shipment**" means the Drug Product to be shipped by Takeda promptly after the Effective Date of this Agreement. The number of tablets of Drug Product to be shipped as part of the Initial Shipment is set forth on Exhibit C.

1.8 "**Manufacturing Expenses**" means (a) with respect to Drug Substance or Drug Product that is Manufactured by a Third Party the actual purchase price paid by Takeda or its Affiliate to such Third Party for such Drug Substance or Drug Product, and (b) with respect to Drug Substance or Drug Product that is Manufactured directly by Takeda or its Affiliate the Direct Expenses and Indirect Expenses incurred in connection with the Manufacture of the Drug Substance or Drug Product, [***], such calculation being based upon accepted industry standards and the applicable Accounting Standard. Manufacturing Expenses shall not include any: [***].

1.9 "**Permits**" means any licenses, permits, registrations, certifications or other approvals from a Governmental Authority.

1.10 "**Project Work Order**" shall have the meaning set forth in Section 11.1.

1.11 "**Quality Agreements**" means the Quality Assurance Agreements for Drug Product and Drug Substance between the Parties.

1.12 "**Quality Release**" means certification by Takeda's quality control department that Drug Substance or Drug Product Manufactured by or on behalf of Takeda complies with its quality release specifications as confirmed by release testing.

1.13 "**Specifications**" means the specifications for the design, composition, manufacture, packaging, and/or quality control of the Drug Substance and Drug Product as set forth in Exhibit A, which may be amended from time-to-time.

1.14 "**Technical Support Services**" shall have the meaning set forth in Section 11.1.

ARTICLE 2
PRODUCT SUPPLY

2.1 Purchase and Supply. Subject to the terms and conditions set forth in this Agreement, the License Agreement and the Quality Agreement, Takeda shall supply to Myovant, and Myovant shall obtain from Takeda, all of Myovant's requirements for any Drug Substance, Drug Product for its use contemplated under the TAK-385 Development Plan.

2.2 Takeda Reservation of Rights. Any rights of Takeda not expressly granted to Myovant under the provisions of this Agreement, the License Agreement or the Quality Agreement are retained by Takeda.

2.3 Myovant's Rights Outside the Licensee Territory. Except as otherwise provided in the License Agreement: (a) Myovant shall, and shall ensure that its Affiliates, Sublicensees and Subcontractors, use the Drug Substance or Drug Product only in the Field in the Licensee Territory, and (b) Myovant shall not, and shall not permit its Affiliates, Sublicensees and Subcontractors to, use the Drug Substance or Drug Product directly or indirectly (i) in the Takeda Territory, or (ii) in a manner that is reasonably likely to directly or indirectly enable a Third Party to use the Drug Substance or Drug Product in contravention of subsection (i) above.

ARTICLE 3
MANUFACTURING EXPENSES

3.1 Drug Substance and Drug Product. Takeda shall provide to Myovant the Initial Clinical Supply [***] to Myovant. In the event the Initial Clinical Supply is insufficient to conduct and complete the activities contemplated under the TAK-385 Development Plan, Myovant shall pay [***] of the actual Manufacturing Expenses incurred by Takeda in Manufacturing such additional Drug Substance and Drug Product. For the avoidance of doubt, Myovant shall [***] Takeda for all Manufacturing Expenses incurred by Takeda related to the re-working or re-processing of any Drug Substance or Drug Product that was manufactured by Takeda prior to the Effective Date of this Agreement.

3.2 Invoicing. Takeda shall submit an invoice to Myovant within [***] days after the end of each Calendar Quarter for all such Manufacturing Expenses incurred by Takeda during the preceding Calendar Quarter and Myovant shall pay such invoice in accordance with Article 12. For the avoidance of doubt, the first invoice submitted by Takeda pursuant to this Section 3.2 may include Manufacturing Expenses incurred by Takeda in furtherance of its Manufacture of additional Drug Substance or Drug Product that was not part of the Initial Clinical Supply.

ARTICLE 4
REGULATORY ACTIVITIES AND RESPONSIBILITIES

4.1 General Obligations of Takeda. Takeda shall, or shall cause its Affiliates or Third Parties on its behalf to, (a) perform its obligations under this Agreement in compliance with all Applicable Laws, including all GMPs, and in accordance with the Quality Agreement, (b) undertake all regulatory activity with respect to the Manufacture of the Drug Substance and Drug Product for use by Myovant in accordance with the License Agreement and as otherwise required by Applicable Laws or Regulatory Authorities. Takeda shall be responsible for maintaining all Permits and establishment fees required by any Regulatory Authority with respect to any Takeda Manufacturing facility where any aspect of the Drug Substance or Drug Product is Manufactured.

4.2 General Obligations of Myovant. Other than Takeda's Permits and establishment fees related to Takeda's manufacturing facilities, Myovant shall obtain and maintain at its expense during the Term all Permits as well as all Regulatory Approvals required for Myovant to use the Drug Substance or Drug Product in accordance with the License Agreement and fulfill its obligations under this Agreement, the License Agreement and the Quality Agreement. Myovant shall, and shall ensure that its Affiliates, Sublicensees and Subcontractors: (a) comply with the requirements and restrictions of any Permits and other Applicable Laws applicable to the use of the Drug Substance or Drug Product in accordance with the License Agreement; (b) use the Drug Substance or Drug Product in compliance with Applicable Laws and the TAK-385 Licensed Product INDs; and (c) comply with Myovant's obligations under this Agreement.

4.3 Communication with Regulatory Authorities. All other communications with Regulatory Authorities shall be governed by the License Agreement, including Article 6 of the License Agreement.

ARTICLE 5
FORECASTING AND ORDERING

5.1 Forecasts and Purchase Orders.

5.1.1 Forecast Issuance and Acceptance. Attached hereto at Exhibit C is Myovant's forecast of its desired quantities of the Drug Substance and each formulation of Drug Product contemplated under the TAK-385 Development Plan. Within [***] Business Days of the Effective Date of this Agreement, Myovant shall submit to Takeda, at the contact information provided below, Myovant's forecast for its desired quantities of the Drug Substance and each formulation of Drug Product to be delivered to Myovant on a Calendar Quarter-by-Calendar Quarter basis for the first [***] Calendar Quarters of the Term (the "**Initial Rolling Forecast**"). For clarity, the Initial Rolling Forecast shall not include the Initial Shipment. No later than the [***] Business Day of each Calendar Quarter during the remainder of the Term, Myovant shall provide to Takeda a rolling forecast for the proceeding [***] Calendar Quarters ("**Rolling Forecast**"). Myovant will submit each Rolling Forecast to the addressee listed below, which Takeda may update or change by providing written notice to Myovant in accordance with Section 18.2 of this Agreement. The Rolling Forecast shall set forth the desired quantity of Drug Substance and each formulation of Drug Product in full lot increments. Takeda will accept each forecast or provide an alternative proposal to Myovant within [***] Business Days after receipt of such forecast. Subject to Takeda's express rights under this Agreement, Takeda will not unreasonably reject any portion of Myovant's forecasts.

Takeda Contact: [***]

5.1.2 Binding Quantities. The first [***] Calendar Quarters of each Rolling Forecast submitted by Myovant shall constitute a firm order ("**Firm Order Period**"). The [***] Calendar Quarter of each Rolling Forecast shall be binding upon Myovant within plus or minus [***] of the amount set forth for such Calendar Quarter in full lot increments ("**Binding Order Period**"). The final [***] Calendar Quarters of each Rolling Forecast shall be non-binding upon Myovant.

5.1.3 Purchase Orders.

(a) **Issuance and Acceptance.** With its submission of the Initial Rolling Forecast, Myovant shall submit a separate purchase order (each, a "**Purchase Order**") for each Calendar Quarter of the Firm Order Period as set forth in the Initial Rolling Forecast to Takeda (each a "**Purchase Order**"). Thereafter, with each Rolling Forecast submitted to Takeda pursuant to Section 5.1.1, Myovant shall submit a Purchase Order for the [***] Calendar Quarter of the Rolling Forecast (i.e., the Calendar Quarter for which no Purchase Order was previously submitted). Within [***] Business Days of Takeda's receipt of each Purchase Order, Takeda will accept such Purchase Order by providing a confirmation of receipt of the Purchase Order. To the extent of any conflict between a Purchase Order and this Agreement, this Agreement shall control.

(b) **Deviations from the Firm Order Period.** If the quantity set forth in a Purchase Order exceeds the quantity set forth in the corresponding Calendar Quarter of the Firm Order Period, Takeda shall use reasonable efforts to satisfy the amount contained in a Purchase Order; provided, however, that Takeda shall not be in breach of this Agreement if it does not deliver the quantity set forth in a Purchase Order that exceeds the quantity set forth in corresponding Calendar Quarter of the Firm Order Period. For the avoidance of doubt, such reasonable efforts shall not require Takeda to [***]. In the event Myovant issues a Purchase Order in a given Calendar Quarter for a quantity of Drug Substance or formulation of Drug Product that is less than the quantity set forth in the corresponding Calendar Quarter of the Binding Order Period, Takeda may deliver, at its discretion, either the quantity set forth in the Purchase Order or the quantity set forth in the corresponding Calendar Quarter of the Binding Order Period; provided that, in either circumstance, Myovant shall [***] Takeda for [***] of the actual Manufacturing Expenses incurred by Takeda in accordance with Section 3.1. In the event that any Purchase Order quantity deviates from the quantity set forth in the corresponding Calendar Quarter of the Firm Order Period, Takeda shall inform Myovant within [***] Business Days after receipt of such Purchase Order of its best estimate of the quantity it anticipates delivering under such Purchase Order, which estimate shall not be binding upon Takeda.

5.1.4 Initial Shipment. Within [***] Business Days of the Effective Date of this Agreement, the Initial Shipment will be delivered to Myovant in accordance with Section 7.3.

5.2 Delivery. Subject to Section 18.1, Takeda shall supply the Drug Substance and formulation of Drug Product ordered under a Purchase Order by way of delivery pursuant to Article 7. If Takeda is unable to meet the specified delivery date, Takeda shall promptly notify Myovant and provide to Myovant an alternative delivery date which is as close to the original delivery date as reasonably possible. Delivery by Takeda of up to [***] of the quantity of Drug Substance or Drug Product in the Purchase Order will be accepted by Myovant in full satisfaction of Takeda's obligation to supply such Purchase Order, subject to Myovant's inspection of the Drug Substance or Drug Product in accordance with Section 8.1. Myovant will be invoiced for the actual quantities of the Drug Substance or Drug Product shipped, excluding the Initial Clinical Supply, for which Myovant shall not be charged.

5.2.1 Testing by Takeda. Prior to delivery by Takeda pursuant to Section 7.1, Takeda shall undertake release testing to obtain a Quality Release for each batch of the Drug Substance or Drug Product that is Manufactured pursuant to a Purchase Order accepted by Takeda.

5.2.2 Provision of Records. With each batch of Drug Substance or Drug Product delivered by Takeda pursuant to Section 7.1, Takeda shall provide all Batch Documentation for such batch, including a certificate of analysis and certificate of conformance.

5.3 Notice of Potential Inability to Supply. Takeda shall inform Myovant of any events that may prevent Takeda or its designee from fulfilling its supply obligations with respect to amounts ordered pursuant to any Purchase Order as soon as reasonably practicable after becoming aware of such events. In the event Takeda notifies Myovant of a potential inability to supply a Drug Substance or a formulation of Drug Product, the Parties shall discuss in good faith how to resolve such supply problems. Notwithstanding the foregoing, if Takeda's inability to fulfill its supply obligation is due to the unavailability of adequate raw materials and/or resources or because the manufacturing capacity for the Drug Substance or Drug Product of Takeda and/or its supplier is such that Takeda and/or its supplier is unable to meet the demand for the Drug Substance or Drug Product requested by Myovant, then [***].

ARTICLE 6
MANUFACTURING

6.1 Conformance with cGMP. Takeda shall supply the Drug Substance and Drug Product that conforms to GMPs, Applicable Laws and the TAK-385 Licensed Product INDs. Takeda shall be entitled, at its cost and expense, to modify the Specifications, Manufacturing, and testing processes, in each case, employed with regard to the Manufacture of the Drug

Substance or Drug Product from time to time, subject to approval, solely to the extent required by Applicable Laws or Regulatory Authorities.

6.2 Manufacturing by Affiliates and Third Parties. Takeda shall have the right, from time to time, in its sole discretion and following a critical technical risk assessment to use an alternative site for the Manufacture of the Drug Substance or Drug Product or appoint any Affiliate or Third Party to Manufacture or supply the Drug Substance or Drug Product to Myovant hereunder; provided that such site, Affiliate or Third Party has been approved, solely to the extent required by Applicable Law, for such Manufacture by the applicable Regulatory Authorities. Such Manufacturing and supply changes shall not alter the rights, obligations and liabilities of the Parties as set out under this Agreement. Takeda shall promptly notify Myovant if Myovant is required pursuant to Applicable Law to make any changes to the TAK-385 Licensed Product INDs related to the appointment of a Third Party to Manufacture of the Drug Substance or Drug Product.

6.3 Quality Agreement. Promptly after the Effective Date, the Parties will execute the Quality Agreement.

ARTICLE 7
DELIVERY, TITLE AND RISK OF LOSS

7.1 Shipment Terms; Title; Risk of Loss. Except for the Initial Shipment and as otherwise provided under Article 11 of this Agreement, all Drug Substance and Drug Product will be shipped to Myovant EXW (Incoterms 2010) from Takeda's designated site, freight collect, by a common carrier designated by Myovant in the Purchase Order, at Myovant's expense. Title and risk of loss will transfer to Myovant, and delivery shall be deemed to have occurred, when goods are placed at Myovant's disposal, not cleared for export and not loaded onto any collecting vehicle. Myovant shall procure, at its cost, insurance covering damage or loss to the Drug Substance and Drug Product during shipping.

7.2 Importer of Record. Except for the Initial Shipment and as otherwise provided under Article 11 of this Agreement, Myovant shall be the "Importer of Record" of all Drug Substance and Drug Product supplied by Takeda under this Agreement. As the Importer of Record, Myovant shall be responsible for all aspects of importing such Drug Substance and Drug Product, including: (a) customs and other regulatory clearance of the Drug Substance and Drug Product; (b) payment of all tariffs, duties, customs, fees, expenses and charges payable in connection with the importation and delivery of the Drug Substance and Drug Product; and (c) keeping all records, documents, correspondence and tracking information required by Applicable Laws arising out of or in connection with the importation or delivery of such Drug Substance and Drug Product.

7.3 Initial Shipment. The Initial Shipment will be shipped to Myovant DAP (Incoterms 2010) to Myovant's designated site. Title and risk of loss will transfer to Myovant when the Initial Shipment is available for unloading at Myovant's designated site. Myovant will be responsible for import clearance of the Initial Shipment.

ARTICLE 8
NON-CONFORMING PRODUCT/RETURNS

8.1 Claims for Detectable Defects. Myovant shall notify Takeda within [***] Business Days after receipt of any shipment of the Drug Substance or Drug Product supplied by or on behalf of Takeda of the existence and nature of any defect in or failure of the Drug Substance or Drug Product to comply with Section 4.1 or Section 6.1 at the time of delivery that could have been detected by a reasonable physical inspection of the Drug Substance or Drug Product at the time of delivery ("**Detectable Defects**"). If such notice is not provided within such [***] Business Day period, then such Drug Substance or Drug Product will be deemed to be in compliance with this Agreement, Myovant will be deemed to have accepted the Drug Substance or Drug Product, and Takeda will have no further responsibility for such Detectable Defects. A non-conformity relating to stability of the Drug Substance or Drug Product shall not be considered a Detectable Defect.

8.2 Claims for Non-Detectable Defects. Myovant shall notify Takeda within [***] Business Days upon discovery of any defect in or failure of the Drug Substance or Drug Product to comply with Section 4.1 or Section 6.1 that is not a Detectable Defect. Claims that are submitted by Myovant shall state the nature of the alleged defect, including how such alleged defect was discovered, in detail reasonably sufficient to enable Takeda to identify the nature of the alleged defect or to dispute the same, and to determine that the defect existed at the time of delivery.

8.3 Provision of Samples. Myovant shall, when notifying Takeda of an alleged defect, provide samples of any allegedly defective Drug Substance or Drug Product and copies of written reports or investigations performed by or on behalf of Myovant on such allegedly defective Drug Substance or Drug Product.

8.4 Referral to Independent Laboratory. In the event of a dispute between the Parties as to any defect in a Drug Substance or Drug Product, including whether a defect was a Detectable Defect or whether such defect existed at the time of delivery, that cannot be resolved within [***] days of a claim being made to Takeda pursuant to Section 8.1 or Section 8.2, the matter shall promptly (but in no case later than [***] Business Days after the expiration of such [***] day period) be submitted to an independent laboratory to be mutually agreed between the Parties. The independent laboratory will examine the Drug Substance or Drug Product at issue and determine the existence and, if relevant, the timing of any defect in the Drug Product. The decision of the independent laboratory shall be binding on the Parties, except in the case of fraud. Myovant shall bear the costs of the independent laboratory if the independent laboratory finds that the Drug Product or Drug Substance was not defective or that such defect did not exist at the time of delivery. Takeda shall bear the costs of the independent laboratory if the independent laboratory finds that the Drug Product or Drug Substance was defective at the time of delivery.

8.5 Credit Note; Replacement Product; Defective Product. Following a claim from Myovant pursuant to Section 8.1 or Section 8.2, Takeda's sole obligation in the event that Takeda accepts Myovant's claim as valid or the independent laboratory decides in favor of Myovant's claim, shall be to either, at Takeda's election: (a) provide Myovant with a Credit Note equal to the actual Manufacturing Expenses paid by Myovant for the defective Drug Substance or Drug Product; or (b) replace the defective Drug Substance or Drug Product as soon as commercially practicable. Any Drug Substance or Drug Product that is agreed or determined to be defective shall be, as directed by Takeda, either destroyed by Myovant or returned to Takeda, in both cases at Takeda's expense. Except for Takeda's obligations under Article 10 and Article 16, Takeda shall have no liability for defective Drug Substance or Drug Product other than as provided in this Article 8.

ARTICLE 9
STORAGE, HANDLING AND TRANSPORT

9.1 Takeda's Responsibilities. The Drug Substance and Drug Product shall be Manufactured by or on behalf of Takeda, stored, handled, packaged, and transported in accordance with the requirements of this Agreement, the Quality Agreement and all Applicable Laws. Takeda shall maintain appropriate quality assurance and quality control standards and record-keeping practices, including systems, resources and procedures in order to satisfy these obligations.

9.2 Myovant's Responsibilities. The Drug Substance and Drug Product shall be stored, handled, packaged, and transported in accordance with the requirements of this Agreement, the Quality Agreement and all Applicable Laws. Myovant shall maintain appropriate quality assurance and quality control standards and record-keeping practices, including systems, resources and procedures in order to satisfy these obligations.

9.3 Myovant Storage, Handling and Transport of Product. Myovant shall obtain at its sole expense all equipment, facilities and personnel necessary for Myovant to store, handle and transport the Drug Substance and Drug Product in accordance with the terms hereof and shall pay all other costs and expenses in connection therewith. If Myovant, for any reason (other than as a result of a claim for a defect pursuant to Section 8.1 or Section 8.2), refuses to take delivery or possession of any Drug Substance or Drug Product, Myovant shall, notwithstanding Section 16.2, promptly upon receipt of an invoice from Takeda, reimburse Takeda for any resulting direct, out-of-pocket, storage, warehousing, handling or transportation fees that Takeda may have incurred prior to such refusal by Myovant.

9.4 Notice of Inspections by Regulatory Authorities. The Parties' obligations with respect to any inspections or audits by any Regulatory Authority related to the Drug Substance or Drug Product shall be governed by the Quality Agreement.

ARTICLE 10
PRODUCT RECALL

The Parties' obligations with respect to a recall of the Drug Substance or Drug Product shall be governed, as applicable, by the Quality Agreement and the License Agreement, including Section 6.4 of the License Agreement.

ARTICLE 11
TECHNICAL SUPPORT SERVICES

11.1 Technical Support Services. Beginning on the Effective Date and continuing until the earliest of the [***] anniversary of the Effective Date, the termination of this Agreement or the termination of the License Agreement, upon reasonable request of Myovant, Takeda shall provide Myovant with: (a) reasonable technical assistance to effect the transfer to

Myovant or its designee of the Takeda Manufacturing Know-How, including the then-current process for the Manufacture of the Drug Substance and Drug Product, and facilitate the implementation of Manufacture of the Drug Substance and Drug Product at the facilities of Myovant or its designee, and (b) other reasonable technical, regulatory and CMC related services in support of the Development of the Licensed Compound and Licensed Product ((a) and (b) collectively, the "**Technical Support Services**"). Any Technical Support Services provided by Takeda will be documented in work orders, executed by both Parties and substantially in the form attached as Exhibit D (each a "**Project Work Order**"). Technical Support Services will be provided from Takeda's or its Affiliates' facilities unless otherwise expressly set forth in a Project Work Order. Unless otherwise expressly provided in a Project Work Order, any Inventions or other Information arising out of Takeda's performance of the any Technical Support Services will be governed by Article 13 of this Agreement. In furtherance of the Technical Support Services, the Parties may agree that Takeda will ship small quantities of Drug Substance or Drug Product to Myovant. Unless otherwise agreed by the Parties, any such shipment shall not be subject to Article 7 or Article 8 of this Agreement; rather, the terms of such shipment shall be separately agreed by the Parties and may be stated in the applicable Project Work Order.

11.2 Reimbursement for Technical Support Services. Myovant shall compensate Takeda for those FTEs providing the Technical Support Services at the FTE Rate, and shall reimburse Takeda for all reasonable documented out-of-pocketed expenses incurred by Takeda to perform Technical Support Services, provided that any such out-of-pocket expenditure over $[***] shall be approved in advance by Myovant. Takeda shall invoice Myovant within [***] days after the end of each Calendar Quarter for all FTE expenses and Third Party expenses incurred by Takeda during the preceding Calendar Quarter in furtherance of the Technical Support Services, which shall include a tally of FTE hours by individual and date and a brief description of work performed, and Myovant shall pay such invoice in accordance with Article 12.

ARTICLE 12
PAYMENT TERMS

12.1 Payment Terms. Myovant shall pay any amount invoiced by Takeda pursuant to this Agreement that is not disputed in writing by Myovant within [***] days after receipt of such invoice. Myovant shall make all payments for invoices issued by Takeda in Japanese Yen via an Automatic Clearing House payment to Takeda's account designated below or to such other account as Takeda may specify by written notice to Myovant in accordance with Section 18.2.

Bank Name:	[***]
Branch:	[***]
Address:	[***]
Account #:	[***]
Beneficiary's Name:	[***]
Beneficiary's Address:	[***]

12.2 Taxes. Myovant shall pay any applicable taxes, including [***] as a result of payments it makes to Takeda pursuant to this Agreement ("**Payments**"). All other taxes, including but not limited to [***], applicable to payments Myovant makes to Takeda pursuant to this Agreement shall be the sole responsibility of Takeda. Each Party will provide to the other Party any resale exemption, multiple points of use certificates, treaty certification and other exemption information reasonably requested by the other Party.

12.3 Late Payment. If Myovant does not pay or dispute in writing any invoiced amount within [***] days of receipt of such invoice, simple interest shall thereafter accrue on the sum due to Takeda until the date of payment at the per annum rate of [***] over the then-current prime rate quoted by Citibank in New York City or the maximum rate allowable by Applicable Laws, whichever is lower.

ARTICLE 13
INTELLECTUAL PROPERTY

Any Inventions or other Information arising in furtherance of this Agreement shall be subject to the Parties' obligations set forth in the License Agreement, including those set forth in Article 10 of the License Agreement.

ARTICLE 14
CONFIDENTIALITY

A Party's obligations with respect to any Confidential Information of the other Party received in furtherance of this Agreement shall be governed by the License Agreement, including Article 12 of the License Agreement.

ARTICLE 15
REPRESENTATIONS AND WARRANTIES

15.1 Mutual Representations, Warranties and Covenants. Each Party hereby represents, warrants and covenants to the other Party that:

15.1.1 Corporate Existence. As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated.

15.1.2 Corporate Power, Authority and Binding Agreement. As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

15.1.3 Debarment. Neither it nor any of its Affiliates (a) has been debarred by a Regulatory Authority, (b) is subject to debarment proceedings by a Regulatory Authority or (c) will use, in any capacity, in connection with the activities to be performed under this Agreement, any Person that has been debarred, or who is the subject of debarment proceedings by any Regulatory Authority. If either Party learns that a Person performing on its behalf under this Agreement has been debarred by any Regulatory Authority, or has become the subject of debarment proceedings by any Regulatory Authority, such Party shall promptly notify the other Party and shall prohibit such Person from further performance on its behalf under this Agreement.

15.2 Takeda Representations, Warranties and Covenants. Takeda hereby represents, warrants and covenants to Myovant that all Drug Substance and Drug Product supplied to Myovant pursuant to this Agreement, upon delivery to Myovant in accordance with Section 7.1:

15.2.1 will have been Manufactured, tested, released, stored, supplied and otherwise handled in accordance with all Applicable Laws and GMPs), and the TAK-385 Licensed Product INDs;

15.2.2 will have been Manufactured in facilities that are in compliance with Applicable Laws;

15.2.3 will have been Manufactured in accordance with the Quality Agreement and will conform with the certificates provided pursuant to the Quality Agreement;

15.2.4 shall not be adulterated or misbranded within the meaning of the FFDCA; and

15.2.5 may be introduced into interstate commerce pursuant to the FFDCA.

15.3 Myovant Representation, Warranties and Covenants. Myovant hereby represents, warrants and covenants to Takeda that:

15.3.1 it shall discharge its obligations pursuant to this Agreement in accordance with all Applicable Laws; and

15.3.2 it shall maintain the Drug Substance and Drug Product in a facility that is properly equipped to store the Drug Substance and Drug Product and shall maintain product security measures in accordance with Applicable Law; and

15.3.3 in the event it formulates the Drug Substance into a pharmaceutical product and packages such Drug Product for use in Development, it shall do so, and shall distribute such Drug Product, in accordance with all Applicable Laws and the TAK-385 Licensed Product INDs.

15.4 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, THERE ARE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WRITTEN OR ORAL, MADE BY TAKEDA (OR ANY OF ITS AFFILIATES), WITH RESPECT TO THE PRODUCTS OR OTHERWISE, INCLUDING: (A) ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; (B) ANY IMPLIED WARRANTIES ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE IN THE TRADE; (C) ANY WARRANTY OF DESCRIPTION OR OTHERWISE CREATED BY ANY AFFIRMATION OF FACT OR PROMISE OR SAMPLE OR MODEL; OR (D) NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 16
INDEMNIFICATION; NO CONSEQUENTIAL DAMAGES; INSURANCE

16.1 Indemnification Under the License Agreement. The Parties agree that the indemnification of any Losses resulting from the Claim of a Third Party will be governed by the License Agreement, including Article 15 thereof.

16.2 No Consequential or Punitive Damages. NEITHER PARTY HERETO WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR MULTIPLE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER OR FOR ANY LOSS OR INJURY TO THE OTHER PARTY'S PROFITS OR GOODWILL ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. THIS SECTION 16.2 DOES NOT APPLY TO A BREACH OF A PARTY'S OBLIGATIONS UNDER ARTICLE 14 OR TO A PARTY'S OBLIGATIONS PURSUANT TO SECTION 16.1.

16.3 Insurance. Each Party agrees to procure and maintain in full force and effect during the Term insurance policies in accordance with its obligations under the License Agreement, including Section 15.4 thereof.

ARTICLE 17
TERM AND TERMINATION

17.1 Term. This Agreement shall commence on the Effective Date and shall continue until the termination of the License Agreement (the "**Term**"); provided, however, that either Party may terminate this Agreement pursuant to the notice periods provided for in Article 13 of the License Agreement.

17.2 Consequences of Termination.

17.2.1 Termination of the License Agreement for Takeda Breach. The following provisions shall apply if the License Agreement is terminated by Myovant pursuant to Sections 13.3 (Termination for Material Breach), 13.7 (Termination for Patent Challenge) or 13.8 (Termination for Insolvency) of the License Agreement:

(a) Myovant may cancel any Purchase Order; and

(b) Myovant shall have no liability with respect to raw materials on hand or work in progress at Takeda as of the effective date of such termination.

17.2.2 Other Terminations of the License Agreement. Except for Myovant's termination of the License Agreement pursuant to Sections 13.3, 13.7 or 13.8 of the License Agreement, the following provisions shall apply if the License Agreement is terminated by either Party:

(a) Myovant may cancel any Purchase Order;

(b) Myovant shall promptly, at Myovant's cost and at Takeda's election, destroy its remaining inventory of the Drug Substance or Drug Product or return it to Takeda; and

(c) Myovant shall [***] Takeda within [***] days of the effective date of termination for all [***] Manufacturing Expenses incurred by Takeda on its behalf to meet all Purchase Orders submitted to Takeda on or before the effective date of termination of this Agreement, except to the extent that Takeda, using good faith efforts to do so, is able to incorporate, integrate or otherwise use or sell such components, raw materials or work-in-progress, including any Drug Substance or Drug Product, in the normal course of Takeda's business operations.

17.3 Survival of Obligations. Termination or expiration of this Agreement shall not relieve a Party of any obligation to make a payment that was owed prior to or on the effective date of such termination, including amounts invoiced prior to such termination or expiration, nor prejudice either Party's right to obtain performance of any obligation provided for in this Agreement that expressly survives termination or expiration. All provisions of this Agreement that, in accordance with their terms, are intended to have effect after the expiration or termination of this Agreement shall survive such termination or expiration, including Sections 2.2, 2.3, 3.2, 9.2, 9.3, 11.2, 15.4, 17.3 and 17.4 and Articles 4 (solely to the extent necessary to fulfill any obligation to a Regulatory Authority after termination or expiration), 8, 10, 12, 14, 16 and 18.

17.4 Remedies. Except as otherwise expressly provided herein, exercise by a Party of its rights under this Article 17 shall not limit remedies which may otherwise be available to a Party in law or equity.

ARTICLE 18
GENERAL PROVISIONS

18.1 Force Majeure Event. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of such prevention to the other Party. Such excusal shall be continued so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to mitigate the condition. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder at the time of such Force Majeure because of such Force Majeure. If a Force Majeure persists for more than [***] days, the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such Force Majeure.

18.2 Notices. Any notice, request, or other communication permitted or required under this Agreement will be in writing, will refer specifically to this Agreement and will be hand delivered or sent by a recognized overnight delivery service, expenses prepaid, or by facsimile (with transmission confirmed), to the following addresses or to such other addresses as a Party may designate by written notice in accordance with this Section 18.2:

If to Takeda:

Takeda Pharmaceutical Company Limited
1-1, Doshomachi 4-chome,
Chuo-ku, Osaka 540-8645
Attention: Vice President, Production Control Department
Facsimile: (+81) 6-6204-2943

Copy to:

Takeda Pharmaceuticals U.S.A., Inc.
One Takeda Parkway
Deerfield, IL 60015
Attention: General Counsel, Legal Department
Facsimile: 224-554-7831

If to Myovant:

Myovant Sciences Ltd.
Clarendon House
2 Church Street
Hamilton HM 11
Bermuda
Attention: Corporate Secretary

Copy to:

Myovant Sciences, Inc.
320 West 37th Street
5th Floor
New York, NY 10018

Attention: SVP, Finance & Operations

18.3 Dispute Resolution. Any dispute, controversy, or claim between the Parties that may arise from time to time pursuant to this Agreement relating to either Party's rights or obligations hereunder that is not resolved through good faith negotiation between the Parties shall be resolved in accordance with Article 14 of the License Agreement.

18.4 Audits. Each Party will maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of the calculation of any amounts due under this Agreement. In accordance with Section 9.6 of the License Agreement, each Party shall have the right to have an independent certified public accountant verify the accuracy of the calculation of such amounts due under this Agreement. In addition, in accordance with the Quality Agreement, Myovant shall have the right, upon at least [***] Business Days' notice to Takeda, and such date to be reasonably agreed upon by the Parties, either by itself or through independent outside auditors or consultants, not more than [***] per Fiscal Year during the Term of this Agreement, unless reasonable cause is shown, to inspect and audit, at its sole expense and during normal business hours and in a manner that does not interfere unreasonably with operations, any areas in Takeda's Manufacturing facility or any other facilities of Manufacturer or its Affiliates in which any portion of the Manufacturing, packaging or other activities with respect to any Drug Substance or Drug Product is performed. The information obtained during the course of such audit shall be considered Confidential Information and subject to Section 3.4 (Subcontractors) and the provisions of Article 12 (Confidentiality) of the License Agreement.

18.5 Relationship of the Parties. It is expressly agreed that Takeda, on the one hand, and Myovant, on the other hand, will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither Takeda nor Myovant will have the authority to make any statements, representations or commitments of any kind, or to take any action which will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party will be employees of that Party and not of the other Party and all expenses and obligations incurred by reason of such employment will be for the account and expense of such Party.

18.6 Designation of Affiliates. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement will be a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

18.7 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other except that: (a) each Party may assign its rights and obligations under this Agreement in whole or in part to one or more of its Affiliates without the consent of the other Party; and (b) each Party may assign this Agreement in connection with the sale or other transfer of all or substantially all of the assets of the business to which this Agreement relates (whether such transaction occurs by way of a sale of assets, merger, consolidation or similar transaction), but, with respect to assignment by Myovant, only if such assignment is consistent with Sections 5.5 and 5.6 of the License Agreement. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 18.7 will be null, void and of no legal effect.

18.8 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision will be considered severed from this Agreement and will not serve to invalidate any remaining provisions hereof. The Parties will make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

18.9 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

18.10 Construction; Rules of Construction. Interpretation of this Agreement will be governed by the following rules of construction: (a) words in the singular will be held to include the plural and vice versa, and words of one gender will be held to include the other gender as the context requires; (b) references to the terms "Section", "Exhibit", or "Schedule" are to a Section, Exhibit, or Schedule of this Agreement unless otherwise specified; (c) the terms "hereof", "hereby", "hereto", and derivative or similar words refer to this entire Agreement; (d) references to "$" or "Dollars" will mean the currency of the United States; (e) the word "including" and words of similar import when used in this Agreement will mean "including without limitation," unless otherwise specified; (f) the word "or" will not be exclusive; (g) references to "written" or "in writing" include in electronic form; (h) the titles and headings contained in this Agreement are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement; (i) each of the Parties has participated in the negotiation and drafting of this Agreement and if an ambiguity or question of interpretation should arise, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or burdening either Party by virtue of the authorship of any of the provisions in this Agreement or any interim drafts of this Agreement; (j) the word "shall" will be construed to have the same meaning and effect as the word "will"; (k) references to "days" will mean calendar days, unless otherwise specified; and (l) a reference to any Person includes such Person's successors and permitted assigns.

18.11 Further Assurance. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof.

18.12 Governing Law. This Agreement was prepared in the English language, which language will govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof will be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

18.13 Entire Agreement. This Agreement, including the Exhibits and Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change, or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party. In the event of any inconsistency between this Agreement and the Licensee Agreement, unless expressly stated to the contrary herein, the terms contained in the License Agreement will control. In the event of any inconsistency between the body of this Agreement and the Exhibits or Schedules to this Agreement or any subsequent agreements ancillary to this Agreement, unless otherwise expressly stated to the contrary in such Exhibit, Schedule or subsequent ancillary agreement, the terms contained in this Agreement will control.

18.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures will be deemed to bind each Party hereto as if they were the original signatures.

[Signature Page Follows]

THIS AGREEMENT FOR THE MANUFACTURE & SUPPLY OF CLINICAL TRIAL MATERIAL IS EXECUTED by the authorized representatives of the Parties as of the Effective Date.

MYOVANT SCIENCES LTD.		**TAKEDA PHARMACEUTICAL COMPANY LIMITED**	
Signature:	/s/ Marianne L. Romeo	Signature:	/s/ S. Yanai
Name:	Marianne L. Romeo	Name:	Shigeo Yanai
Title:	Head, Global Transactions & Risk Management	Title:	Head of Pharmaceutical Technology R&D Laboratories, CMC Center
Date:	June 7, 2016	Date:	June 8, 2016

EXHIBIT A

Specifications for Drug Substance and Drug Product

[Appears on following page]

Specifications of TAK-385 Drug Substance

[***]

Specifications of TAK-385 Drug Product, T4-B 40 mg and 120 mg Tablets

[***]

Specifications of TAK-385 PlaceboT4-B 40 mg Tablets

[***]

EXHIBIT B

Formulations of Drug Product

[Appears on following page]

TAK-385 Tablet Formulations

[***]

EXHIBIT C

Initial Rolling Forecast

Myovant Forecast of Desired Quantities of Drug Substance and Formulation of Drug Product

[***]

EXHIBIT C_A

[***]

EXHIBIT D

Project Work Order

This Project Work Order (the "**PWO**"), effective as of [DATE] (the "**PWO Effective Date**"), is incorporated into and shall be governed by the Agreement for the Manufacturing & Supply of Clinical Trial by and between Takeda Pharmaceutical Company Limited and Myovant Sciences Ltd., ("**Myovant**"), dated of June 7, 2016. For the purposes of this PWO, "**Takeda**" shall mean Takeda Pharmaceutical Company Limited or the Takeda Affiliate that signs this PWO. Capitalized but undefined terms shall have the meanings first ascribed to them in the Agreement.

1. Description of Services:

2. Project Start Date:

3. Estimated Completion Date:

4. Description of Services:

5. Company Purchase Order No.:

6. Fees. In consideration for Takeda's performance of the Services under this PWO, Myovant shall compensate Takeda on an hourly basis as invoiced by Takeda using the following rate(s):

   FTE Rate: amount of [***] for an FTE per Calendar Year.

7. Expenses. Myovant shall reimburse Takeda for reasonable out-of-pocket expenses actually incurred by Takeda in connection with the Services. For this PWO, Takeda's reimbursable out-of-pocket expenses for performing the Services shall not exceed $[***] without Myovant's prior written consent.

8. Payment Terms and Schedule. Takeda shall invoice Myovant on a Calendar Quarter basis for fees and expenses incurred in performing the Services. Invoices shall be sent via e-mail in pdf format, to accounting@roivant.com (Attn: Myovant).

Myovant shall pay all undisputed amounts set forth on Takeda's invoices within [***] days after receipt. Any amount invoiced by Takeda that is not disputed in writing by Myovant within [***] days after receipt of Takeda's invoice for such amount will be deemed to be accepted by Myovant.

MYOVANT SCIENCES LTD.

Signature: _____

Name: _____

Title: _____

Date: _____

TAKEDA PHARMACEUTICAL COMPANY LIMITED

Signature: _____

Name: _____

Title: _____

Date: _____

FIRST AMENDMENT
TO THE
AGREEMENT FOR THE MANUFACTURE & SUPPLY OF CLINICAL TRIAL MATERIAL

This First Amendment to the Agreement for the Manufacture and Supply of Clinical Trial Material (the "**Amendment**") is entered into effective August 19, 2016 (the "**Amendment Date**") by and between Myovant Sciences Ltd. ("**Myovant**") and Takeda Pharmaceutical Company Limited ("**Takeda**"). Each of Myovant and Takeda may be referred to individually herein as a "**Party**" and jointly as the "**Parties**".

WHEREAS, Myovant and Takeda are parties to that certain Agreement for the Manufacture and Supply of Clinical Trial Material dated June 7, 2016 (the "**Supply Agreement**"); and

WHEREAS, Myovant and Takeda wish to clarify certain matters relating to the Supply Agreement;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Myovant and Takeda, intending to be legally bound, hereby agree as follows:

1. Capitalized terms used herein and not otherwise defined shall have the meaning ascribed in the Supply Agreement.

2. Section 17.1 of the Supply Agreement is hereby superseded and replaced in its entirety to read as follows:
17.1 Term. This Agreement shall commence on the Effective Date and shall continue until the termination of the License Agreement, unless terminated earlier in accordance with subsection (a) or (b) below (the "**Term**").

(a) Termination for Material Breach.

(i) Either Party (the "**Non-Breaching Party**") may terminate this Agreement in its entirety in the event the other Party (the "**Breaching Party**") has materially breached this Agreement and such material breach has not been cured (A) within [***] Business days of receiving notice thereof with respect to any breach of any undisputed payment obligation under this Agreement and (B) within [***] days of receiving notice thereof with respect to any other breach (as applicable, the "**Cure Period**"). The written notice describing the alleged material breach will provide sufficient detail to put the Breaching Party on notice of such material breach. Any termination of this Agreement pursuant to this Section 17.1 will become effective at the end of the Cure Period, unless the Breaching Party has cured any such material breach prior to the expiration of such Cure Period.

(ii) If the Parties reasonably and in good faith disagree as to whether there has been a material breach, including whether such breach was material and whether such breach has been cured, the Party that disputes whether there has been a material breach may contest the allegation in accordance with Article 14 of the License Agreement. The Parties agree that the failure to deliver at least [***] of any Drug Substance or Drug Product ordered via a Purchase Order issued in accordance with Section 5.1.3 in any [***] month period shall be deemed a material breach of this Agreement; provided that Myovant can establish that such delivery shortfall caused, or is reasonably likely to cause, a material delay in the timelines contemplated in the then-current Development Plan. Notwithstanding anything to the contrary contained in this Section 17.1, the Cure Period for any Dispute will run from the date that written notice was first provided to the Breaching Party by the Non-Breaching Party through the resolution of such Dispute pursuant to Article 14 of the License Agreement, and it is understood and acknowledged that, during the pendency of a Dispute pursuant this Section 17.1, all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement.

(iii) If Myovant terminates this Agreement pursuant to this Section 17.1(a) for Takeda's material breach, then Section 17.2.1 of this Agreement shall apply. If Takeda terminates this Agreement pursuant to this Section 17.1(a) for Myovant's material breach, then Section 17.2.2 of this Agreement shall apply, except that Myovant shall not be permitted to cancel any pending Purchase Orders where Takeda either: (1) has Manufactured the Drug Product or Drug Substance to be delivered pursuant to the Purchase Order prior to the effective date of the termination, or (2) cannot, despite good faith efforts, re-allocate to a different program any Manufacturing slot that was scheduled to be used for a pending Purchase Order.

(b) **Termination for Convenience**. Myovant may terminate this Agreement at will, in its sole discretion, on not less than [***] prior written notice to Takeda. If Myovant terminates this Agreement pursuant to this Section

17.1(b), then Section 17.2.2 of this Agreement shall apply; except that Myovant shall not be permitted to cancel any Purchase Orders where [***].

3. Except as expressly set forth herein, all terms and conditions of the Supply Agreement remain in full force and effect.

4. This Amendment may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Amendment may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures will be deemed to bind each Party hereto as if they were the original signatures.

This Amendment is accepted and agreed by the Parties through their duly authorized representatives below as of the Amendment Date.

TAKEDA PHARMACEUTICALS COMPANY LIMITED		**MYOVANT SCIENCES LTD.**	
By:	/s/ Shigeo Yanai	By:	/s/ Marianne L. Romer
Name:	Shigeo Yanai	Name:	Marianne L. Romer
Title:	Japan Head of Formulation Development, Pharmaceutical Sciences	Title:	Head, Global Transactions & Risk Management

Exhibit 10.24

Non-Executive Director Compensation Policy
of
Myovant Sciences Ltd. (this "Policy")
(effective April 1, 2020)

Non-Executive Directors[1] of Myovant Sciences, Ltd. (the "***Company***") are compensated for service on the Board of Directors of the Company (the ***"Board***") through a combination of cash retainer and equity grants. In addition, the Company reimburses Non-Executive Directors for reasonable expenses incurred in serving as a Non-Executive Director. The Compensation Committee may, in its discretion, determine that a Non-Executive Director shall not receive compensation pursuant to this Policy.

Cash Compensation

As of April 1, 2020, annual retainers are paid in the following amounts to Non-Executive Directors:

Annual Retainer	$	40,000
Additional Annual Retainer for Non-Executive Chairman	$	35,000
Additional Annual Retainer for Lead Independent Director	$	15,000
Additional Annual Retainer for Committee Chairs:		
Audit Committee	$	20,000
Compensation Committee	$	15,000
Nominating and Corporate Governance Committee	$	10,000
Additional Annual Retainer for Committee Members:		
Audit Committee	$	10,000
Compensation Committee	$	7,500
Nominating and Corporate Governance Committee	$	5,000

All annual retainers will be paid in cash quarterly in arrears promptly following the end of the applicable fiscal quarter.

Equity Compensation

Upon initial election to the Board, each Non-Executive Director shall receive an initial option grant to purchase common shares of the Company with an aggregate value of $350,000, on the date on which the Non-Executive Director's service as a director begins. Such option is valued based on the Black-Scholes option value of the volume weighted average closing sales price of common shares of the Company for all of the trading days during the 30 calendar day period ending on (and including) the last trading day immediately preceding the date on which the Non-Executive Director's service as a director begins (or such other methodology the Compensation Committee may determine prior to the grant of an award becoming effective). The initial option grant will be automatically granted, without further action, on the date on which the Non-Executive Director's service as a director begins and will vest as to 1/3 of the shares on the first anniversary of the grant date, with the balance of the shares vesting in eight equal quarterly installments thereafter, subject to the applicable Non-Executive Director's continued service through the vesting date.

Each Non-Executive Director who is elected or appointed as a director at least three calendar months prior to an Annual General Meeting of Shareholders (the "***Annual Meeting***") and whose service as a director will continue after such Annual Meeting shall receive an annual grant of an option to purchase common shares of the Company, with an aggregate value of $266,200, on the date of the Annual Meeting. Such option is valued based on the Black-Scholes option value of the volume weighted average closing sales price of common shares of the Company for all of the trading days during the 30 calendar day period ending on (and including) the last trading day immediately preceding the applicable date of the Annual Meeting (or such other methodology the Compensation Committee may determine prior to the grant of an award becoming effective). The annual option grant will be automatically granted, without further action, on the date of the applicable Annual Meeting and will vest in full on the earlier to occur of (i) the first (1st) anniversary of the date of grant and (ii) the date immediately prior to the date of the Annual Meeting for the year following the year in which the grant is made, subject in each case to continued service through the vesting date.

Option grants: (i) have an exercise price equal to the closing price of common shares of the Company on the New York Stock Exchange on the grant date; (ii) are subject to the applicable Non-Executive Director's continued service through the vesting date; (iii) expire on the ten-year anniversary of the grant date; and (iv) are subject to all applicable terms of the 2016 Equity Incentive Plan of the Company and applicable equity award agreements thereunder.

Effectiveness, Amendment, Modification and Termination

This Policy may be amended, modified or terminated by the Compensation Committee or the Board in the future at its sole discretion.

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[1] For purposes of this Policy, a "Non-Executive Director" shall mean any member of the Board of Directors who is not an executive officer of the Company.

* * * *

Exhibit 21.1

Subsidiaries of
MYOVANT SCIENCES LTD.

Name of Subsidiary	**Jurisdiction of Incorporation or Organization**
Myovant Sciences, Inc.	Delaware
Myovant Holdings Ltd.	England and Wales
Myovant Sciences GmbH	Switzerland
Myovant Sciences Ireland Limited	Ireland
Myovant Treasury, Inc.	Delaware
Myovant Treasury Holdings, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-233059) pertaining to the 2016 Equity Incentive Plan;
(2) Registration Statement (Form S-3ASR No. 333-231764);
(3) Registration Statement (Form S-8 No. 333-228277) pertaining to the 2016 Equity Incentive Plan;
(4) Registration Statement (Form S-3 No. 333-221526); and
(5) Registration Statement (Form S-8 No. 333-218057) pertaining to the 2016 Equity Incentive Plan

of our report dated May 18, 2020, with respect to the consolidated financial statements of Myovant Sciences Ltd. included in this Annual Report (Form 10-K) of Myovant Sciences Ltd. for the year ended March 31, 2020.

/s/ Ernst & Young LLP

Redwood City, California
May 18, 2020

Exhibit 31.1

CERTIFICATION

I, Lynn Seely, certify that:

1. I have reviewed this Form 10-K of Myovant 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: May 18, 2020

By: /s/ Lynn Seely

Lynn Seely

Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Frank Karbe, certify that:

1. I have reviewed this Form 10-K of Myovant 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: May 18, 2020

By: /s/ Frank Karbe

Frank Karbe

Principal Financial and Accounting Officer

Exhibit 32.1

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 Myovant 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, Lynn Seely, 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 her 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 results of operations of the Company.

Date: May 18, 2020

By: /s/ Lynn Seely
Lynn Seely
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.

Exhibit 32.2

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 Myovant 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, Frank Karbe, 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 results of operations of the Company.

Date: May 18, 2020

By: /s/ Frank Karbe
Frank Karbe
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.